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

CONTINUING CHALLENGES

TUESDAY, MAY 23, 2017

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:05 a.m., in Room 2123, Rayburn House Office Building, Hon. Tim Murphy [chairman of the subcommittee] presiding.

Present: Representatives Murphy, Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Clarke, Ruiz, and Pallone (ex officio).

Staff Present: Jennifer Barblan, Chief Counsel, O&I; Ray Baum,

Staff Director; Elena Brennan, Legislative Clerk, O&I; Adam Fromm, Director of Outreach and Coalitions; Brittany Havens, Professional Staff, O&I; Katie McKeough, Press Assistant; David Schaub, Detailee, O&I; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, O&I; Sam Spector, Policy Coordinator, O&I; Evan Viau, Staff Assistant; Hamlin Wade, Special Advisor, External Affairs; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Health Counsel; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Dino Papanastasiou, Minority GAO Detailee; Olivia Pham, Minority Health Fellow; and C.J. Young, Minority Press Secretary.

Mr. Murphy. Good morning, and welcome to our Oversight and Investigations Subcommittee hearing on "U.S. Public Health Response to the Zika Virus: Continuing Challenges."

Today, the subcommittee continues its examination of the Zika virus, and the subcommittee first examined the virus last year during the early stages of the outbreak across Central and South America.

As this year's mosquito season is about to begin, the time has come to review what has been done and what we have learned since then and to examine the challenges that our Federal health agencies continue to face. To date, every State in the continental United States, minus Alaska, has reported cases of the Zika virus, and two States, Florida and Texas, have reported cases of locally acquired mosquito-borne transmission.

As of March 2017, there were 84 countries, territories, or subnational areas with evidence of vector-borne Zika virus, and 13 countries have reported evidence of person-to-person transmission of the virus.

A recent report released by the Centers for Disease Control and Prevention, or the CDC, found that 1 in 10 women in the United States with a confirmed Zika virus infection during pregnancy had a baby with a virus-related birth defect.

Emerging infectious diseases present unique challenges to public health systems here and around the world. When the committee held its hearing on Zika last March, much was unknown about the virus and its impact on public health. I want to commend our public health agencies

for the work that they have all done. Diagnostic tools were quickly developed and approved under Emergency Use Authority, and more are in the pipeline now. Multiple vaccine candidates are in development, and much research into the virus and its effects have taken place. When instances of local transmission occurred in Florida and Texas, the CDC acted quickly in tandem with State and local partners to contain the spread.

But despite these efforts, the unknowns of this disease still outnumber the knowns. We don't know the actual number of infections in the United States. We don't know the long-term impact of Zika infection during pregnancy on children born to infected mothers. We don't know about the long-term impacts of infection on men or on people who exhibit no symptoms of Zika. There are difficulties with the diagnostic tests we have in use today, and we don't have good information or modeling on how the virus will spread this year, let alone beyond that.

The GAO is here today reporting on its evaluation of the U.S. public response to Zika, work commissioned by this committee. This is not the first time GAO has done such an analysis and response to emerging infectious diseases, and each time, GAO has found that HHS was reactive in its response to outbreak prevention, preparedness, detection, and response. Once again, GAO has shown that we are not fully prepared at the outset of the outbreak.

The GAO evaluated the U.S. public health response to Zika in three key areas: one, case definition and an understanding of how the disease

spreads into community and the factors that affect this distribution; two, the development and use of diagnostic tools; and, three, methods of mosquito control.

The GAO findings are sobering. While there have been many advances, actions are needed to address major challenges. According to the GAO, the lack of standardized Zika case definition at the beginning of the outbreak complicated the collection of consistent and timely data. The diagnostic tests varied in their ability to detect the virus and provide accurate results. Manufacturers of diagnostic tests faced multiple challenges, including gaining access to FDA-authorized tests for comparison use, and the users of the tests could not even determine the most accurate diagnostic tests based on the information provided.

And of great concern, the GAO report raises questions about CDC's and FDA's disclosure of test information and the treatment of CDC's own subject-matter expert, who was removed and then reinstated to his position after dissenting over concerns about the CDC Zika diagnostic tests provided to labs.

With regard to State and local mosquito control efforts, CDC developed technical guidance and provided funding and technical assistance. GAO identified challenges here as well for Federal agencies, including the need to effectively communicate information about the geographical distribution of the mosquito that primarily transmits the Zika virus. Much of the money appropriated by Congress last year to respond to Zika went to States and localities in the form

of grants, and effective communication is critical to ensure that our Federal tax dollars are spent wising.

It is clear that we have much to discuss today. We will hear from a panel of distinguished Federal witnesses, including the Centers for Disease Control and Prevention, the National Institutes of Health, the Food and Drug Administration, the Biomedical Advanced Research and Development Authority, as well as the Government Accountability Office.

I want to thank all of our witnesses for joining us this morning. I now recognize the ranking member of this subcommittee, Ms. DeGette, for a 5-minute opening statement.

[The prepared statement of Mr. Murphy follows:]

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

This committee has been examining issues related to disease preparedness for more than a decade. We have looked recently at preparedness and response capabilities related to Ebola, seasonal flu, and pandemic flu, and, of course, now the Zika virus.

As you mentioned, last year, the Zika epidemic spread across Brazil, Latin America, and into the U.S. There were more than 5,000 Zika cases in the U.S. and over 36,000 in the U.S. territories.

Now, as we continue to face challenges with these epidemics and global pandemics, we can't be satisfied with simply reacting to each new emergency. Instead, we have to devote efforts and resources to ensuring that we're prepared before the next threat occurs. Oftentimes, we don't even know where those will come from.

We need to do more at the Federal and State levels to combat emerging infectious diseases. As I pointed out over a year ago, the bipartisan Blue Ribbon Study Panel on Biodefense concluded that the U.S. is underprepared for bioincidents, whether they're deliberate attacks or naturally occurring events. This is still a problem, despite our assiduous attention to it. For example, just this month, members of this subcommittee released a comprehensive GAO report on avian flu. That audit uncovered shortcomings in our preparedness and raised key questions about our ability to rapidly respond to future outbreaks. GAO found that, while we can impose biosecurity measures after an emergency hits, our preparation is limited to voluntary actions, which are too often ineffective.

Today, we're going to hear again from the GAO, but this time on how our disease-fighting agencies are addressing the ongoing Zika threat and the remaining challenges. So, even though we're working on getting there, we're still not where we need to be when it comes to disease preparedness and emerging infectious threats.

I'm looking forward to hearing from all of the witnesses today about how we can improve processes in response to the GAO's recommendation.

I want to talk about another area, which is funding, and I know with the release of the President's budget today, everybody is concerned about funding. I'm really concerned about whether agencies have adequate funding to prepare and respond to a potential outbreak. We're fortunate to have premier public health agencies overseeing these efforts, but if their hands are tied with funding, those agencies can't do their work.

Last year, Congress made available $1.1 billion to fight Zika, but key agencies received far less money than they requested. In the end, agencies like the CDC had to reprogram funds to respond to this unfolding threat, diverting the funding from other top priorities.

This year, as I said, President Trump has proposed slashing HHS' budget and making deep cuts to public health agencies like the CDC or the NIH. This is so counterproductive. Now is not the time to make draconian threats -- cuts to the agencies charged with stopping Zika or any other health crisis. Although we don't know what funds the administration will need to address the Zika threat for 2017, I don't

have any reason to believe that they're going to need less than last year.

So I intend to ask the panelists whether they think that we're adequately resourced to go into the 2017 mosquito season. We don't want to find ourselves in the middle of this summer scrambling to cobble together another emergency supplemental.

And, finally, I want to welcome Dr. Petersen from Fort Collins here today. Dr. Petersen is the Director of the Division of Vector-borne Diseases, and that agency is in Fort Collins, Colorado. I went up and visited the facilities, Mr. Chairman, last year, and thanks to the efforts of former Congressman Bob Schaffer and myself, we were able to get new state-of-the-art facilities up there a few years ago. They're doing remarkable research, and I just want to thank you for adding your intelligence and your perspective today. And I also want to welcome all of our witnesses, of course.

And, with that, Mr. Chairman, I will yield back.

[The prepared statement of Ms. DeGette follows:]

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Mr. Murphy. Thank you.

The gentlelady yields back, and I will recognize the chairman of the full committee for a 5-minute opening statement.

The Chairman. I thank the chairman.

Thank you for holding this timely hearing on U.S. public health response to the Zika virus. I want thank all of our witnesses for being here today and for providing us with your testimony.

For well over a year, our bipartisan committee staff have been working diligently to examine our public health preparedness for Zika and other emerging infectious diseases. This is our second hearing since the outbreak of this virus.

First, I want to commend the agencies that are appearing before us today. Each agency has undertaken a huge effort to increase our knowledge of the virus, to develop diagnostic tests and vaccine candidates quickly, and to educate our communities about how to respond to this virus and the mosquito that carries it.

I also want to commend the State and local entities that are working hard to treat those impacted by Zika and to reduce the population of Zika-carrying mosquitoes. While much progress has been made over the past year, the GAO released a report today showing our understanding and preparedness to combat this virus and other biological threats still face significant challenges. Particularly as we head into the summer months, we must do better.

Though the FDA has authorized two different types of diagnostic tests under the Emergency Use Authorizations, there's still no

commercially available diagnostic tests on the market for the detection of the Zika virus. Currently, there are no specific therapies or vaccines approved by the FDA to prevent or treat the virus. Perhaps most concerning is we still don't know the full spectrum of health consequences associated with mother-to-child transmission, nor do we know what the short-term and long-term outcomes are for those who contract the virus with or without clinical symptoms.

We also continue to face significant issues in supporting mosquito control efforts and our ability to accurately model and predict the spread of viruses geographically. The number and implication of unknowns is frankly a bit alarming. It begs the question, how prepared are we for the next outbreak? Zika is not the only biological threat that we face today. As our society becomes increasingly global and world travel becomes easier, more efficient, and more frequent, the risk of spreading disease through human contact will increase rapidly.

Sadly, emerging infectious diseases, including Zika, Ebola, yellow fever, dengue, pandemic influenza, and others, perhaps many more that have yet to even be discovered threaten our human and bioterrorism defenses every day. The slides made famous on national television by our witness, Dr. Anthony Fauci, dramatizes the change from 30 years ago with just HIV as a global example of emerging infectious disease to a recent slide showing more than 40 examples.

Last year, the subcommittee held a hearing on the report of the Blue Ribbon Study Panel on Biodefense. It presented several concerns

and expert recommendations to improve U.S. biodefense. The experts on the panel made it quite clear we need to stop thinking of disease preparedness and response as occasional episodic events, a reactive approach that's left us constantly lagging in our response efforts. Instead, we must shift our mindsets and strategies toward a broader, more comprehensive, and proactive approach, one that considers the larger context of our preparedness for future infectious diseases and outbreaks.

Federal witnesses testifying before us this morning are uniquely positioned to help aid in our efforts, and I thank you all for appearing before the subcommittee.

And I yield the balance of my time to the chairman of the Health Subcommittee, Dr. Burgess.

[The prepared statement of The Chairman follows:]

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Mr. Burgess. Thank you, Mr. Chairman. Thank you for yielding.

So, to paraphrase the Rolling Stones, summer is here, and the time is right for fighting vectors in the street. I want to thank our panelists for being here today. Some new faces, and that will be good to get to know you a little bit better, and some people that we have talked with many times before.

And, Dr. Fauci, just thinking back to the 108th Congress, we talked about SARS, we talked about avian flu, we talked about swine flu, we talked about Ebola, and we talked about Zika. And every one of those illnesses, of course, has a particular impact upon women and pregnancy, and that has certainly been -- and I appreciate the focus that you have put on that during the times that we have had the privilege of having you before our subcommittee.

So I want to welcome our witnesses. Look forward to what your testimony is going to be today.

And, Mr. Chairman, I yield back.

[The prepared statement of Mr. Burgess follows:]

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Mr. Murphy. With that then --

Ms. DeGette. Will the gentleman yield? It is not the Rolling Stones. It is Bruce Springsteen.

Mr. Murphy. The record will stand corrected.

Mr. Burgess. No, no, no correction of the record. I will put my iTunes against yours.

Mr. Murphy. Thank you. Well, we reached a new level for this hearing. The gentleman yields back.

I recognize Mr. Pallone for 5 minutes.

Mr. Pallone. I won't comment because I don't know.

Thank you, Mr. Chairman, and thank you to all our witnesses for joining us this morning to discuss the Federal Government's preparations for the 2017 Zika season. I look forward to hearing from our panelists today about how they believe the Zika virus will spread in 2017, what they anticipate the upcoming mosquito season will look like, what challenges remain, and what additional resources they need to do their job.

In March of 2016, the committee held a hearing to examine the Federal Government's response to the spreading Zika threat. Since then, we have learned a great deal more about this virus. For example, scientific consensus now indicates that Zika infections in mothers during pregnancy can cause microcephaly in newborns, a severe birth defect of the brain.

As we'll hear from GAO today, although CDC and FDA took steps to respond to the unique challenges posed by the Zika outbreak last year,

there remains room for improvement. This is particularly true regarding our ability to predict the spread of Zika, to better coordinate and control mosquito populations at the local level, and to more rapidly develop diagnostic tests for detecting Zika infection.

These steps to improve preparedness should also go hand-in-hand with strengthening our healthcare programs. We must ensure that individuals affected by Zika, particularly pregnant women and children born with microcephaly, have access to ongoing screening and health services.

An integral part of that effort is the Medicaid program. Medicaid provides contraceptive services that help prevent Zika infection and diagnostic services to detect infection. Medicaid is also a vital source of care for children born with special healthcare needs like microcephaly.

Today, Medicaid covers one in three children in the United States. The President's budget is expected within the hour, and there are reports that he plans to propose slashing Medicaid by over $800 billion, and this would decimate the Medicaid program and endanger our ability to manage public health emergencies like Zika.

I also remain concerned about the status of Medicaid funding in Puerto Rico. As everyone in this room understands, Zika has wreaked havoc upon Puerto Rico, yet as we head into the 2017 mosquito season, funding for Puerto Rico's Medicaid program through the Affordable Care Act is on track to be exhausted as early as this October. And despite the $295 million allocated for Medicaid funding in Puerto Rico as part

of the recent continuing resolution, up to 900,000 people remain at risk of losing their health coverage at the end of this year.

So, in short, a strong public health infrastructure is also one of the best tools to fight epidemics, and Medicaid is an essential component in protecting us from threats such as Zika. Fighting Zika will not be easy, but the first step should be to maintain critical health services for those who may be affected and provide agencies with the resources they will need to respond to an outbreak.

Now I'm concerned about recent reports that nearly 700 positions at CDC are vacant because of the ongoing hiring freeze and that Federal support to States for Zika response may be discontinued. That's why Democratic members of this committee sent a letter to CDC last week asking whether the agency has sufficient funding to prepare and respond to Zika this year. It is critical that we give these agencies the tools they need to bolster our preparedness.

So let me conclude by saying thank you to the agencies before us today who work on a daily basis to fight this disease. I don't think anybody else wants to -- you would like to? I yield the balance of my time to the gentlewoman from Florida.

[The prepared statement of Mr. Pallone follows:]

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Ms. Castor. Thank you, Mr. Pallone, for yielding the time.

I'm very concerned for families all across American and particularly in the State of Florida and Puerto Rico because the birth defects related to the Zika virus are so severe and costly and because America's emergency public health response to Zika is at risk right now. After the Congress provided a billion dollars last year, we ramped up an emergency public health response that included our local communities, States, extensive surveillance, mosquito control, laboratories, development of vaccines, but as we stand now, there are too many unanswered questions about transmission of Zika and the medical consequences. Our families are at risk because of that.

They're also at risk because we're facing a funding cliff for the Zika emergency response. What is the most important in a public health emergency response is you have consistency. And right now, all of the agencies in local communities and States are looking at this cliff that's going to come to the end over the next few weeks, definitely by September.

I see great risk because of the hiring freeze that the Trump administration put into place that is now keeping public health professionals off the job at CDC and NIH and other important agencies. And then, with the budget that comes out today, we're going to have to deal with this overarching desire by the Trump administration to pull the rug out from under families because they're going to target cuts to medical research and the Centers for Disease Control all at the time where they say we're going to give big tax cuts to billionaires

who will have all the resources in the world to deal with a Zika diagnosis in their family, but meanwhile, families across America will be left with very serious consequences.

So this committee needs to develop a plan of action in the coming weeks, and hopefully the expert advice from this panel will help guide us there. Thank you very much.

[The prepared statement of Ms. Castor follows:]

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Mr. Murphy. The gentleman lady's time is expired.

At this point, I just want to say that I ask unanimous consent that the members' written opening statements be introduced into the record and, without objection, the documents be entered into the record.

I now would like to introduce our panel of Federal witnesses for today's hearing: Dr. Timothy Persons, Chief Scientist, U.S. Government Accountability Office; Dr. Lyle Petersen, Director, Division of Vector-Borne Diseases, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention; Dr. Luciana Borio, Acting Chief Scientist, U.S. Food and Drug Administration; Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, National Institutes of Health; and Dr. Rick Bright, Director of Biomedical Advanced Research and Development Authority and Deputy Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services. Thank you all for being here today and providing testimony.

We look forward to a very productive discussion and how we can better prepare for and respond not only to Zika virus but to all the emerging infectious diseases and biological threats to our Nation.

You are aware this committee is holding an investigative hearing and, when doing so, has a practice of taking testimony under oath. Do any of you have any objections to giving testimony under oath?

Seeing none, 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 one has indicated that. Then, in that case, will you please rise, raise your right hand, and I will swear you in.

[Witnesses sworn.]

Mr. Murphy. Thank you. You may all be seated.

Seeing that all have answered in the affirmative, you are now under oath and subject to the penalties set forth in title 18 under section 1001 of the United States Code. We'll ask you each to give a 5-minute summary of your written statement. Please pay attention to the light there.

Dr. Persons, you are recognized first for 5 minutes.

TESTIMONY OF TIMOTHY PERSONS, PH.D., CHIEF SCIENTIST, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; LYLE R. PETERSEN, M.D., M.P.H., DIRECTOR, DIVISION OF VECTOR-BORNE DISEASES, NATIONAL CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION; LUCIANA BORIO, M.D., ACTING CHIEF SCIENTIST, U.S. FOOD AND DRUG ADMINISTRATION; ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH; AND RICK A. BRIGHT, PH.D., DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, AND DEPUTY ASSISTANT SECRETARY, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

TESTIMONY OF TIMOTHY PERSONS, PH.D.

Mr. Persons. Thank you, Mr. Chairman. Good morning and good morning, Ranking Member DeGette and members of the subcommittee. Thank you for the opportunity to discuss our work on the Federal response to Zika virus disease outbreaks with particular focus on epidemiology, diagnostic tests, and mosquito control. As this committee has pointed out even this morning, emerging infectious diseases, such as Zika virus disease, are an ongoing threat to the health and livelihoods of people and animals worldwide.

Despite many advances in medical research and treatments during the past century, infectious diseases are still a leading cause of

death. Over the past few decades, several emerging infectious diseases have similarly taken the global community by surprise, including H1N1 influenza, Ebola, and Zika, among others.

In each case, the Department of Health and Human Services, though diligent in its work to address rapidly emerging threats, was nonetheless reactive in some respects, such as outbreak prevention, preparedness, detection, and response. Although HHS has key agencies working on various important aspects of this problem, currently no one person or agency is in charge of making sure the U.S. is ready for the next outbreak of an emerging infectious disease.

The Zika virus attracted attention from health officials here and abroad after causal links were suspected between increases in reported cases of Zika virus infection and reported cases of microcephaly in newborns and other neurological disorders in Brazil in 2015.

An effective response to an emerging infectious disease like Zika involves the establishment of a case definition, gaining an understanding of the disease's spread into the population, rapidly developing and deploying reliable diagnostic tools at the beginning of the outbreak, and, when the disease is vector-borne as Zika is, effective methods of mosquito control.

While recent Zika virus disease outbreaks have yielded new insights, several key unknowns remain, including the total number of infections, various biological mechanisms and risk factors, and the full spectrum of short- and long-term outcomes of Zika virus infection, among others.

We also identify two key challenges for Zika virus epidemiological research. One is the time and resources needed to better understand the short- and long-term effects of Zika virus disease, and the other is an insufficiency of data and a lack of computer models for predicting the spread of Zika virus. Moreover, at the beginning of the U.S. outbreak, there was no U.S. medical case definition, despite there being candidates from other affected countries.

Even though the U.S. had known about and was conducting surveillance on Zika virus disease outbreaks, including those in U.S. territories, no accurate and reliable diagnostic tools had been authorized. The FDA had authorized over 15 diagnostic tests for the Zika virus under the Emergency Use Authorization process following the public health emergency declaration.

Manufacturers of diagnostic tests face several challenges, including lack of knowledge of key scientific aspects of the virus, difficulty in accessing well-characterized clinical samples, getting access to EUA samples to use for comparison, gaining cooperation with international entities, and according to some, a lack of effective communication from the FDA.

One major issue users face with these diagnostic tests is that it was not possible for them to easily compare the tests based on information on the product insert. Users of the tests also identified challenges that included, for example, complying with a test EUA label specifying certain equipment required to perform the test and

determining the most accurate test, in part because of the challenges comparing performance characteristics reported in the EUA labels.

Turning to mosquito-control efforts, the Federal Government has a limited and indirect role in supporting them since they were implemented at the State and local levels. CDC developed technical guidance and provided funding and technical assistance to support State and local mosquito-control activities but does not serve, nor does any other agency serve, as a central coordinator for mosquito control nationwide.

We identify four challenges the Federal Government faced in supporting these mosquito-control efforts during the Zika virus outbreaks. One is the timing and availability of the funds, including the sustaining of expertise throughout the year. Second is the limited communication about the actual distribution of mosquitoes. Third is linking the effects of mosquito control to disease outcomes. And fourth is having limited information about mosquito-control entities themselves.

In short, our report indicates that there's still work to be done to better coordinate and more effectively implement mosquito control nationwide. In conclusion, HHS has led the way in making progress in our understanding of the Zika virus disease, but several challenges remain. Although the EUA process is aimed at getting the diagnostic tests out quickly in emergency situations, it is equally important to clinical users that the authorized tests be compared to one another with respect to key performance characteristics. That will allow them

to determine which is the most appropriate.

We have identified several areas where improvements can be made and have made five recommendations. HHS agreed with four, partially concurred with the fifth, and provided clarifying information. In response to our recommendation to include information on CDC-developed tests distributed to public health laboratories, HHS agreed that it should share information on such tests that have received EUA. However, HHS did not agree with our recommendation that it should share information on CDC's lab-developed tests that have not received EUA because CDC is unable to provide detailed information on the characteristics of these unstandardized tests.

Mr. Murphy. Dr. Persons, we are way over time. Do you have a final thought?

Mr. Persons. Yes, sir. We maintain that sharing information about the lab-developed tests that are used for comparison is important because it could help other diagnostic test users about which tests to adopt or recommend.

Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, this concludes my prepared statement. Thank you for your sustained attention on this issue, and I would like to thank the GAO team who made this testimony possible. I'll be happy to answer your questions.

[The prepared statement of Mr. Persons follows:]

******** INSERT 1-1 ********

Mr. Murphy. Thank you.

Dr. Petersen, you're recognized for 5 minutes.

TESTIMONY OF LYLE R. PETERSEN, M.D., M.P.H.

Dr. Petersen. Thank you, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, for the opportunity to discuss CDC's response to the Zika virus outbreak. I'm Dr. Lyle Petersen, Director of the Division of Vector-Borne Diseases in CDC's National Center for Emerging and Zoonotic Infectious Diseases. I also had the opportunity to serve as CDC's Zika response incident manager throughout most of 2016, and I would like to make three key points to start.

First, it has been almost 17 months since CDC activated its emergency operation center for Zika, and it is clear that this outbreak has resulted in CDC's most complex emergency response to date.

Second, we have accomplished a great deal very rapidly, in large part due to support in supplemental funding from Congress. However, we still have much to learn, and much remains to be done.

Third, Zika remains a significant threat today, particularly to pregnant women and their infants. We need to remain ready for Zika and for mosquito-borne diseases in general as we expect more to emerge in the upcoming years.

Looking at the response to date, we have learned a tremendous amount about a little known virus in a very short amount of time.

First, we confirmed the link between Zika virus infection during pregnancy and severe birth defects, including microcephaly. Along with State and local territorial partners, we have begun to quantify the risk of birth defects, which we now know affects about 10 percent of fetuses exposed to Zika. We also discovered that Zika can be sexually transmitted, and we also have better information about the geographic range of mosquitoes that can spread Zika.

The support efforts on the ground: CDC has provided $251 million in Zika-specific funding to State, local, and territorial health departments, as well as ongoing CDC technical assistance.

I want to briefly turn to one of the most challenging aspects of the response: diagnostic testing for Zika. Because Zika's impact on pregnancies can be devastating, CDC has recommended testing for all pregnant women who live in or have traveled to an area at risk for Zika. When the emergency response began in January 2016, women did not have access to even one Zika test authorized for clinical use. However, by March 2016, Emergency Use Authorizations were in place for two CDC-developed tests, allowing for distribution of these testing resources to State laboratories while also sharing information with manufacturers that were developing their own tests. CDC remains committed to improving Zika diagnostics, so that they're faster and more accurate, and will continue to share information with public health and commercial laboratories as it becomes available.

So, as we approach summer, it is impossible to predict with certainty what we will see in the way of local transmission of Zika.

However, we anticipate that the Zika virus will continue to circulate indefinitely in most regions in the Americas where it has been introduced. We will undoubtedly continue to see pregnant women test positive for Zika virus in both States and U.S. territories.

We expect fewer Zika cases this year in some areas outside of the 50 States, such as Puerto Rico, simply because a significant proportion of the population was infected in 2016 and is no longer susceptible to infection.

Within the continental United States, local outbreaks remain possible, such as those seen in this past year in Florida and Texas. Any local outbreaks will, of course, be of deep concern, and we must be prepared for different scenarios, including more extensive transmission.

Finally, we have learned to expect the unexpected when it comes to Zika. So it is critical to remain vigilant and sustain our response efforts.

So, in closing, CDC, our sister agencies within HHS, and our partners have accomplished much, but we continue to face numerous challenges. One major challenge is to continue learning as much as we can about Zika. We know of the most devastating effect of microcephaly, but we need to follow the development of these babies to understand the full spectrum of long-term effects.

Also, we can expect Zika to circulate for many years. So we must be prepared to scale up Zika prevention efforts at any time. Even after a Zika vaccine becomes available, other Zika prevention efforts,

including surveillance and mosquito control, will be required.

Lastly, the emergence of mosquito-borne diseases is accelerating. So we must address the threat of vector-borne diseases systematically and continually, rather than episodically and sporadically.

Thank you again for the opportunity to appear before you today.

[The prepared statement of Dr. Petersen follows:]

******** INSERT 1-2 ********

Mr. Murphy. Thank you, Dr. Petersen.

Dr. Borio, you're recognized for 5 minutes.

TESTIMONY OF LUCIANA BORIO, M.D.

Dr. Borio. Good morning, Chairman Murphy, Ranking Member DeGette.

Mr. Murphy. Is it on? There you go.

Dr. Borio. Good morning, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee. I greatly appreciate the opportunity to be here today and tell you about FDA's ongoing actions to respond to the Zika virus outbreak.

FDA plays a central role in the Nation's response to public health emergencies. In addition to responding to Zika, our teams are fully engaged in responding to the H7N9 influenza virus that has emerged in China and the most recent outbreak of Ebola in the DRC.

Since the 2009 influenza pandemic, multidisciplinary teams have worked collaboratively across the agency to respond to a number of public health crises. They bring vision, experience, and expertise to their work at hand, which, backed by FDA's flexible regulatory framework, allows for us to make important contributions to global health security. So today I'm here to assure you that FDA remains fully engaged with our partners to help minimize the impact of Zika virus.

We are focused on four work streams: supporting the expedited development and availability of diagnostic tests, investigational

vaccines, and therapies; working to advance innovative strategies for vector control; keeping the Nation's blood supply safe; and protecting the public from fraudulent products. And let me tell you more about some of these efforts.

At the start of this outbreak, there were no clinical diagnostic tests for Zika available for use. We have worked urgently with our colleagues at the CDC to make Zika tests rapidly available. In February and March of 2016, FDA authorized the use of two CDC-developed tests under our Emergency Use Authorities. We also immediately began working interactively with interested commercial manufacturers. We granted an EUA for the first commercial test in April of 2016.

FDA has taken several proactive steps to help advance the development and availability of Zika tests. We developed and made available to developers fillable forms that lay out the data requirements for an EUA. Our scientists generated reference materials to help developers assess the analytical performance of their molecular diagnostic tests. And our scientists in collaboration with both establishments are developing reference materials to help developers of serological tests.

There's some very complex scientific challenges associated with developing Zika diagnostic tests, as you heard from Dr. Petersen. This is especially true for serological tests designed to detect the presence of antibodies to Zika due to issues of cross-reactivity with other Flaviviruses like dengue and yellow fever. FDA continues to work interactively with dozens of developers as they try to overcome these

challenges.

FDA has held more than 15 face-to-face meetings, 150 teleconferences, and more than 3,500 written exchanges with developers to help guide their programs. This highly interactive approach has been extremely successful. To date, we have authorized the use of 16 diagnostic tests for Zika. And even after an EUA is issued, FDA and developers continue to work interactively to optimize the authorized tests. We have issued 21 amendments to EUAs designed to improve product performance, and thanks to these efforts, a broad range of Zika tests with a broad range of performance are now available in laboratories throughout the U.S.

As you heard from my colleague, Dr. Petersen, CDC projects that Zika will become established in the Americas, posing a continuing threat, especially to pregnant women. One of our highest priorities is to facilitate the development and availability of an effective vaccine. We are working closely with the NIH, BARDA, and the private sector on this, and there's reason for optimism, with several vaccine's candidates progressing at a rapidly expedited pace.

In addition, FDA continues to work with blood collection establishments to protect the safety of the blood supply. In August of 2016, after careful consideration of the evolving scientific and epidemiological data, we issued guidance recommending that all States and U.S. territories screen blood with an investigational screening test.

We are very appreciative of blood collection establishments'

efforts to implement universal screening for Zika across the U.S. in a timely fashion. To date, the screening has been prevented nearly 400 infected donations from entering the blood supply.

The FDA remains fully committed to sustaining our deep engagement and aggressive activities to support a robust response to Zika.

In closing, I would like to recognize and thank the more than 500 staff members at the FDA who approached this work with incredible dedication, innovation, and expediency. Thank you, and I'm happy to answer your questions later.

[The prepared statement of Dr. Borio follows:]

******** INSERT 1-3 ********

Mr. Murphy. Thank you, Dr. Borio.

Dr. Fauci you're recognized for 5 minutes.

TESTIMONY OF ANTHONY FAUCI, M.D.

Dr. Fauci. Mr. Chairman, Ranking Member DeGette, Vice Chairman Griffith, members of the committee, thank you for giving me the opportunity to present to you today in a few minutes the role of the NIH research endeavor in addressing the Zika outbreak. I have some visuals that I'll show if we can get them up.

As you know, I have testified about Zika before this committee before, and what I outlined for you was that the NIH's responsibility ranges from the fundamental basic research, clinical research, expansion of research capacity with the ultimate goal in mind to develop the countermeasures that we have been discussing thus far in the form of diagnostics, therapeutics, and vaccines.

With regard to diagnostics, the CDC, as you had mentioned and that Dr. Petersen responded, is primarily responsible for on-the-ground development rapidly of diagnostics that could address this outbreak. However, the NIH's role in that is to try and develop a pipeline of rapid, specific, low-cost diagnostic tools that are delineated on this slide. They're divided into a few subgroups.

The first are molecular tests to detect the presence of the virus itself in a highly sensitive and specific manner. The second are serological tests, which are the most problematic, namely to detect

the immune response of someone who has already been infected and to distinguish that immune response to infections to other Flaviviruses, such as dengue. And, third, research resources, namely to make reagents and viral strains available to our collaborators throughout the world.

In addition, we're responsible for clinical research. I will give you one example of that, and that has to do with the Zika in Infants and Pregnancy, or ZIP, study in which we are performing in collaboration with the Fiocruz Institute in Brazil. It is a prospective cohort study observational of 10,000 pregnant women, following them for the incidence of Zika infection, following their pregnancies to determine the incidence of involvement of the fetus with congenital abnormalities, and then following birth to follow the infants for at least 1 year of age.

However, probably the most important and impactful of what we do is the development of a vaccine. Now, this slide shows five candidate vaccines that are in various levels of development for Zika. The first one that is on the slide is the DNA vaccine. I want to caution the committee that just because something is temporally ahead of something else in development doesn't necessarily mean it is going to ultimately turn out to be the best vaccine. But we have been fortunate because we have been able to rapidly put several of these into trial, and I want to just mention one of these for the purposes of the discussion this morning. And that is the DNA vaccine. This is a vaccine that is a 21st century version of vaccinology; namely, we no longer isolate

the virus, grow it and activate it or attenuate it, but we use molecular biological techniques.

On this slide is shown how a DNA vaccine works. You get a circular piece of DNA, which is referred to as a plasmid. You insert a gene of a particular protein that you want to make an immune response to, and you then inject that into an individual, and then what happens is that, in response, a virus-like particle is formed, and the body makes a good immune response.

On March 2nd of 2016, I testified before this committee that we were still in animal model, and I said that we would get into a human phase 1 trial very likely by the fall of 2016. And, in fact, we did in September and then again in December, showing that the vaccine was safe and it induced the kind of response that you would at least predict would be protective.

We also said we hoped to get into a phase 2 trial by the first quarter of 2017. And, in fact, at the end of March of this year, we actually initiated a phase 2 trial: first, in Texas and Puerto Rico; and then, in the next few months, we're going to advance this into the countries shown by the red dots on the slide. We have a flexible capability so that, if there are outbreaks in one country more than the other, we'll be able to divert the resources to be able to get the vaccine deployed in an area where there is an outbreak.

Now there's no guarantee that this is going to be effective or that there are going to be enough cases to at least prove that it is effective, but we are at least on time in our endeavor, and I would

hope that, as we follow up on this in the coming year or so, we will be able to come back to this committee and say we do, in fact, have a safe and effective vaccine.

I'll stop there, Mr. Chairman, and be happy to answer questions later. Thank you.

[The prepared statement of Dr. Fauci follows:]

******** INSERT 1-4 ********

Mr. Murphy. Thank you, Dr. Fauci.

Dr. Bright, you're recognized for 5 minutes.

TESTIMONY OF RICK A. BRIGHT, PH.D.

Mr. Bright. Good morning, Chairman Murphy, Ranking Member DeGette, and distinguished members of the subcommittee. I'm Dr. Rick Bright, the Director of the Biomedical Advanced Research and Development Authority, otherwise known as BARDA. I'm also the Deputy Assistant Secretary for Preparedness Response in the Office of the Assistant Secretary for Preparedness Response, or the ASPR, within the U.S. Department of Health and Human Services.

I appreciate the opportunity to speak with you today. This is the first opportunity I have had to testify since being named the BARDA Director last November.

As a component of ASPR, BARDA was established to aid in securing our Nation from chemical, biological, radiological and nuclear threats as well as from pandemic influenza and other emerging infectious diseases.

BARDA supports the transition of medical countermeasures, such as vaccines, drugs, and diagnostics, from research stages through advanced development toward consideration for approval by the FDA and often into the Strategic National Stockpile. Our mission is accomplished through the successful public-private partnerships with industry to share the risk, improve efficiency, and accelerate

development, all while sustaining the marketplace for countermeasures that is vital for our national security.

BARDA also collaborates and coordinates very closely with our Federal colleagues through the participation in the Public Health Emergency Medical Countermeasures Enterprise, which is chaired by the HHS ASPR. To support the overall HHS response to Zika, BARDA has established three goals to address medical countermeasure gaps: first, the prevention of Zika virus infection through the development of safe and effective vaccines; second, for the rapid detection of infection through the development of diagnostics; and, third, to ensure a safe blood supply by the development of screening tests for Zika and technologies that will inactivate pathogens in donated blood products.

For diagnostics, our goal is to stimulate and accelerate the development of rapid and accurate serological tests. BARDA has partnered with five companies to support these tests. Some of these tests are laboratory based, and some of these tests are for point-of-care use.

BARDA is also supporting the development of two tests that are now being used under an FDA investigational new drug protocol to screen Zika virus in donated blood. BARDA is also supporting the development of four Zika vaccine candidates. One candidate began as a collaboration between BARDA, the U.S. Department of Defense, and NIAID. And it is currently in multiple clinical trials. This candidate has now transitioned to an industry partner for further development.

To introduce additional innovation into this outbreak, we are

also supporting the development of a vaccine candidate that is based on a novel messenger RNA platform that is now in clinical trials. This is a new vaccine platform that has potential to develop and produce vaccines rapidly. This is essential for an effective response to emerging threats.

Funding from Congress has been critical for our response to Zika. However, additional support will be needed to continue our progress. There is great value in keeping multiple candidates in the pipeline to increase the chance of success. Looking ahead, also having a Federal emergency response fund would contribute to a rapid medical countermeasure response for future public health threats.

BARDA and ASPR are committed to using innovative technologies and innovative contractual tools to accomplish our mission. A nimble and flexible, yet consistent and transparent approach is critical to successful public-private partnerships, not only to address the early valley of death, but also to address challenges of market entry and sustainability that our industry partners face when products are approved. It is important to sustain capacity, capability, and partnerships with the private sector to be ready and able to respond when we confront threats to our national security and public health.

Mr. Chairman, ASPR and BARDA are working with HHS colleagues, our interagency colleagues, and our private sector partners to prepare our Nation for range of national security and public health threats. Medical countermeasure development is a long, complicated, and a high-risk process. BARDA is greatly appreciative of the resources and

authorities that Congress has provided to us to accomplish its mission. I look forward to working with members of this subcommittee and your congressional colleagues. I'm grateful for the opportunity to address you today, and I'm happy to take your questions.

[The prepared statement of Dr. Bright follows:]

******** INSERT 1-5 ********

Mr. Murphy. Thank you.

That is quite a bit of knowledge here. So let me recognize myself for 5 minutes to start this process.

Dr. Fauci, I guess you have been around since 1968, working through about eight Presidents here?

Dr. Fauci. Yes.

Mr. Murphy. So you may have learned a thing or two about this, but I just wonder, how did the pace of this progress on Zika vaccine compare with how quickly vaccines were developed for some of the other viruses?

Dr. Fauci. Thank you for that question, Mr. Chairman. It actually is the fastest that we have done, because if you look at the time from the either isolation of a pathogen or sequencing of it so that you could do a molecular biological approach to the vaccine, Zika is the fastest we have done in history. It is about 3 months from the time that we actually had the sequence that we started putting it into an animal situation. So we really, from the standpoint of the development of a vaccine, which, as you know, with all the things that we have to go through with a vaccine, it takes some time to ultimately get the product, but to hit the ground running from the microbe to the actual vaccine in a preclinical is the quickest we have ever done.

Mr. Murphy. You also said in your testimony you require more time because of the recent decline in Zika case trials across the Americas. What kind of statistical power do you need here to give you enough numbers on clinical trials? Are you advancing with enough cases here?

Dr. Fauci. Yes. Right now, when you look at the activity that's going on right now, it would probably take a much longer period of time. It is a combination of the statistical power of the end with the amount of time that it would take to get it. So, if you have X number of cases a year, you may take 4 or 5 years to get it. If you get those amount of cases in a particular period of time, like a few months -- for example, if there's an outbreak in Puerto Rico as we get into the summer of this coming year in Puerto Rico, we may get enough cases to be able to get an efficacy signal. If there's not, then we may need to wait a longer period of time.

It is a combination of the more effective the vaccine is and the more number of cases, those both come together. If you have you a really effective vaccine and a modest number of cases, then you get your efficacy signal.

Mr. Murphy. Would this likely then move toward approval for the Emergency Use Authorization of the FDA?

Dr. Fauci. Well, that really depends, because if you get a good enough signal, you could get an expanded access; you might not even need to use an Emergency Use Authorization. It really depends on the data and the robustness of the data.

Mr. Murphy. Let me quickly ask another question here, because we focus a lot on neonatal and prenatal development, et cetera. Any news on studies on men and the impact of Zika virus on men?

Dr. Fauci. Well, we're continuing to study. As you are I'm sure aware, there was a study that showed, in adult mice, that there's an

effect on the testes with oligospermia and testicular atrophy.

Right now, there's no indication that that's the case of an adult male human who gets infected, but we're doing prospective studies now in individuals, and that's related to determining the persistence of Zika in the semen. And you could do two studies. You could see if there's Zika in the semen, and you could also do sperm counts. So we'll be able to know if, in fact, infected individuals have a degree of oligospermia. But that's something that we're looking at at the future.

Mr. Murphy. I appreciate that.

Dr. Petersen, according to an internal CDC investigative report, the CDC Chief of Diagnostic and Reference Activity in the Arboviral Disease Branch, who had become a whistleblower about the CDC's promotion of the trioplex test for Zika, was moved from that position by DVBD leadership in May 2016. You're the Director of DVBD, and the branch is a part of your division. Why was the CDC expert whistleblower moved out of his position in the middle of the Zika emergency response, and why was he then reinstated as Chief of July of 2016?

Dr. Petersen. Thank you for that question. I cannot speak to personnel issues, but I can present a little bit of background about the situation.

There was some discussion among our scientists about the analytic sensitivity of the CDC trioplex test versus a laboratory-developed test known as the monoplex test, and at the time, the trioplex test had actually been EUA approved and was already being distributed to State

public health laboratories and laboratories within the laboratory response network. So that test had been distributed already.

An investigation was done into the whistleblower complaint by an independent panel with our Office of Laboratory Safety and Science. And that panel concluded that there was no wrongdoing on the part of CDC. Those results were reviewed by HHS and the Office of General Counsel, which came to the same conclusion.

In the end, we had to make a very rapid decision because there were many women wanting test results. We decided to stay with the trioplex. In the end, it turned out that the trioplex, when tested with a larger panel of samples, was actually an extremely good test, in fact, one of the best out there.

Mr. Murphy. Thank you. I'm out of time.

Ms. DeGette, you're recognized for 5 minutes.

Ms. DeGette. Thank you, Mr. Chairman.

As I said in my opening remarks, I'm really interested both in our position going into the 2017 mosquito and travel season, but also our preparedness in the future.

Dr. Persons, in your audit, you found that agencies like the CDC and FDA face a number of challenges when it came to addressing the Zika threat. One of the challenges is that the Federal Government had insufficient modeling capability for predicting the spread of the Zika virus. Is that correct?

Mr. Persons. Yes.

Ms. DeGette. And you also found that the CDC and its public

health partner agencies faced challenges in establishing and implementing Zika surveillance systems. Is that correct?

Mr. Persons. Yes.

Ms. DeGette. And, also, Dr. Persons, your audit found that authorized diagnostic tests used for the Zika virus outbreak in the U.S. varied in both their performance and operational characteristics. Is that right?

Mr. Persons. Yes.

Ms. DeGette. Now, we're facing an increased array of pandemic threats: Ebola, avian flu, dengue, and now Zika. Although Zika is a unique virus, those challenges that we faced last year suggest the need for better preparedness overall. I'm concerned that what these things I just talked about have grave implications for our overall preparedness posture.

I'm wondering if you can comment briefly about what the broader implications of the challenges on Zika are as they relate to the overall preparedness and where we need to still look at having preparedness for other infectious diseases that might come along.

Mr. Persons. Yes, thanks, Ms. DeGette, for the question. As I think our study showed, Zika is a key issue at this point and another case, but it is still one of a type. So it is a pattern, as you all had pointed out. I think what is necessary is a more proactive framework for emerging infectious diseases that will include perhaps the idea of perhaps establishing a case definition earlier on, as soon as you can maybe iterate on that, rather than waiting until things

happen here in the U.S. and that has to develop and we have sort of a U.S. stamp on that.

Another thing is just getting data and information as quickly as possible about the accuracy and the limitations of reliable diagnostic tests. It also will be important to have evidence for diagnostic users or practitioners to have that, practitioners would be including scientists as well as clinicians, and certainly, whenever there's a mosquito- or vector-borne disease like this one, I think we're going to need to have more proactive standing infrastructure in terms of dealing with mosquito control.

Ms. DeGette. Dr. Petersen, does your agency feel like those are good recommendations and we can use those in the future?

Dr. Petersen. Those were very good recommendations. We certainly need a more proactive approach to dealing with mosquito-borne diseases, and the one thing we have learned, with the onset of, incursion of West Nile, then chikungunya, now Zika virus, is that these pathogens are coming to our shores at a more rapid rate than ever before, and we feel that we need to respond and prepare for the unexpected. Nobody would have predicted that Zika virus would be sexually transmitted. Nobody would have predicted any of the factors with that virus.

Ms. DeGette. Right. Thank you. You know, last year, Congresswoman DeLauro proposed the creation of an emergency fund that would allocate $5 billion in funds for public health response efforts in advance of disease outbreaks simply because these things are also

unpredictable, which would help us from having to scramble at the last minute to find this money.

Dr. Fauci what do you think about the idea of an emergency fund of this nature?

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[11:04 a.m.]

Dr. Fauci. I think it's a good idea, and I've actually suggested it myself, as has Tom Frieden, when he was the director of the CDC. And the reason that we did that is that the experience that you alluded to in some of the comments from the committee in that the President had asked for a certain amount of money in February of 2016, 1.9 billion. And it wasn't until the end of September --

Ms. DeGette. Right.

Dr. Fauci. -- that we got it. And that was really tough.

Ms. DeGette. Because the season was almost over by then.

Dr. Fauci. Yeah. And we had had to move money from other areas to be able to start our activities. And we moved them from Ebola. We moved them from other things.

Ms. DeGette. I remember. I was in those meetings.

Let me just ask you one more question, Dr. Fauci. What does Congress need to do to better help your agency and the other agencies on this panel better prepare for the next infectious disease epidemic?

Dr. Fauci. Well, I think, as this committee has done in the past -- and we are very grateful for that -- is that continuing support of the consistency of our support. Because this is not -- this is a marathon. If you have a sprint for every single outbreak, that's not good. This whole thing is a marathon, and we have to be prepared in

a consistent way over the years with consistent support.

Ms. DeGette. Over time.

Dr. Bright, you're nodding yes.

Mr. Bright. I absolutely agree. I think it's important that -- we've appreciated all the support from Congress, but I think it's important to keep it constant, keep it consistent, keep the process transparent so we can bring innovation to the table to be able to be more proactive for these threats and not less reactive.

Ms. DeGette. Thank you.

Thank you, Mr. Chairman.

Mr. Murphy. Thank you.

We will recognize Mr. Walden, chairman of the committee, for 5 minutes.

The Chairman. Thank you, Mr. Chairman.

I want to commend our public health agencies for their extensive and very valuable work that you've accomplished during the response to Zika last year. In particular, the pace of Zika virus vaccine research and development has been really impressive, and we've talked about this before, and I congratulate you on that.

Dr. Fauci, when do you think a Zika vaccine will be available for patients? What's your current view of that?

Dr. Fauci. Thank you for the question, Mr. Walden. But I have to be honest with you. I can't predict that. And the reason you can't predict it, it's going to be based on two factors: one, how inherently good the vaccine is and how long it takes us to prove how good it is.

So you might have a very good vaccine, and we have -- because of good public health measures or just luck -- we don't have a lot of cases of Zika -- it may take years before you finally prove statistically that it's good enough for the FDA to approve it. On the other hand, if you have a vaccine that's moderately effective but not really good effective, it still may take longer.

So the best case scenario from the standpoint of a vaccine, but not from the standpoint of the unfortunate people who suffer from the disease, is that if you have an outbreak over, let's say, the next season, and you have your vaccine implemented and deployed in place, you may be able to get an efficacy signal sometime, for example, in the beginning or mid of 2018.

And then how good that signal is, the FDA will, in an unbiased way, evaluate that and make a decision. That's the best possible scenario.

The Chairman. All right. So we're a ways off.

Dr. Fauci. Right.

The Chairman. Dr. Bright, I understand there are many candidates for diagnostic tests and vaccines in development today, far more than when we first learned about Zika last year. How do public-private partnerships expedite the development of medical countermeasures?

Mr. Bright. Thank you for your question. It's very important to understand and recognize the contribution of the private sector, especially in responding to a public health emergency. Many of these

companies are already focused on other more lucrative products and candidates in development.

And to be able to bring the public and private sectors together for these emergency responses allows us to share the risk of development of these candidates, allows us to share the cost of development of these candidates, and it reduces and mitigates some of the pitfalls that we will face in a traditional, less supportive approach to developing medical countermeasures. So the public-private partnership is a critical component of success.

The Chairman. All right.

Dr. Petersen, your written statement noted that, and I quote, "Alarmingly, the emergence of mosquito-borne diseases appears to be accelerating," close quote. Why does the CDC believe that the pace of emerging infectious diseases is accelerating? What's behind that?

Dr. Petersen. I think there's several causes. One of the major causes is world population growth. We have the growth of mega cities in places where these viruses normally circulate in the tropical world. Combined with increases in travel and trade brings these viruses very rapidly to every corner of the Earth in a very short period of time.

There's other factors that may be involved, such as climate change and other factors. And it's kind of a mixture of factors that's all promoting the emergence of these diseases.

The Chairman. And in your written statement, you also mention that we need to address the threat of vector-borne diseases systematically rather than episodically. How would the CDC suggest

that we address the threat systematically?

Dr. Petersen. Well, I think we need to do two things. One is we need to increase our efforts towards innovation and discovery. We need better mosquito control methods, for example. We need better surveillance, et cetera, which will help us with the incursion of any kind of a pathogen, vector-borne pathogen that's coming in.

The other aspect is, is that we need to develop a more national and sustained approach towards vector control and laboratory testing; in other words, a more comprehensive approach towards -- a programmatic approach towards dealing with these vector-borne diseases. Improving laboratory diagnostics, improving mosquito control, improving surveillance, for example. And this will require a sustained effort to rebuild the infrastructure that has been lost in the previous years.

The Chairman. All right. My time has expired. Thank you all for your testimony and your good counsel.

And I yield back.

Mr. Murphy. The gentleman yields back.

I recognize Mr. Pallone for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman.

It's clear to me that the ongoing Zika outbreak poses a serious threat to the health and well-being of the American public; in particular, pregnant women and infants are especially vulnerable. In the coming months, it will be crucial that pregnant women infected with Zika, as well as infants born with microcephaly, have access to necessary care and services.

So I wanted to ask a couple questions, first with Dr. Petersen. Can you speak to the role that contraceptives and preventive care services play in our efforts to combat Zika threat?

Dr. Petersen. First, I think it's important to keep in mind that about half of the pregnancies in the United States are unplanned, and about two-thirds of the pregnancies in Puerto Rico are unplanned.

Contraceptives and access for women to long-acting reversible contraceptives is one way that women can delay pregnancy, if they wish to. And so some women may choose to delay pregnancy, but it's not the Federal Government's role in advising women to delay pregnancy. But our goal is really to provide women with the most accurate information possible so they and their physicians can make the determination about pregnancy.

Mr. Pallone. Let me ask Dr. Fauci, can you describe what kind of treatment and longer-term care will be necessary for infants born with microcephaly?

Dr. Fauci. Well, in the tragic situations with individuals who -- babies who are born with microcephaly, the long-term care is both difficult and highly expensive. There have been estimates that the lifetime care of a microcephalic baby who actually survives could be measured in the millions of dollars.

Babies who are microcephalic and have severe defects very often do not live beyond a certain limited period of time. And during that period of time, the amount of medical care that's required, the amount of time, both emotional and physical, that's invested in the family

is extraordinary. So it's a very difficult and tragic situation that's both emotionally difficult and highly expensive.

Mr. Pallone. Well, unlike other countries, in the United States we're fortunate to have these elite public health agencies, like CDC and NIH, as well as a strong public health infrastructure to prevent outbreaks from becoming full-blown epidemics.

But, Dr. Fauci, why is a strong public health infrastructure in this country often key to avoiding the types of epidemics that we see play out in other parts of the world?

Dr. Fauci. I'm sorry. I didn't hear the last -- why is it --

Mr. Pallone. Well, in other words, my impression is that because we have such great public health agencies, we're able to prevent Zika outbreaks from becoming full-blown epidemics.

Dr. Fauci. Right. Yes.

Mr. Pallone. And that's not necessarily true in the rest of the world. So, you know, if you wanted to just comment on --

Dr. Fauci. Sure.

Mr. Pallone. -- how we're able to avoid these epidemics because of our public health infrastructure.

Dr. Fauci. Well, as infectious diseases and public health officials, as some of us -- maybe all of us -- at the table are, you'll never be able to prevent an outbreak of a new infection like Zika or Ebola. The trick is to prevent it from becoming an epidemic or a pandemic.

And I think the reason that we do so well is because of just what

you've alluded to, Mr. Pallone, that we have in place systems. And I think I can add a tip of the hat to the CDC because we have, in our Nation, unquestionably the best public health agency in the world by far.

And that's one of the reasons why we have the capability of doing what they do so well is to identify, to track, and to control. And they've done that with virtually every threatening outbreak that we've had and have done an extraordinary job. And not every country in the world has that capability.

Mr. Pallone. You know, with this in mind, of course, President Trump has proposed slashing Medicaid by over 800 billion. I believe this would decimate the Medicaid program, which plays a key role in our public health infrastructure. And cutting Medicaid would also further reduce our ability to provide care to those who may need it as a result of Zika, especially pregnant women and children born with microcephaly.

So, Mr. Chairman, you know, again, I think we should be building up our healthcare infrastructure to prepare and respond to Zika. And it's of the utmost importance that we ensure access to the care and services that will be necessary to mitigate this threat.

Dr. Petersen, very quickly, you mentioned contraceptives, but what about preventive care in general in our efforts to combat the Zika threat, not just the contraceptives but the preventive care?

Dr. Petersen. Well, first, we're trying to link pregnant women who may have been exposed to the virus to effective care through our

Zika Care Connect program, which we funded in a number of States and areas to do.

Again, we think that the best way to deal with Zika is to prevent it. And for that reason, we have issued travel advisories to more than 62 countries, and they're still working -- trying to get the right epidemiology to advise women appropriately on what measures they could take to prevent Zika virus, as well as what areas may or may not be safe to travel to to prevent Zika virus infection.

Mr. Pallone. All right. Thank you.

Thank you, Mr. Chairman.

Mr. Murphy. Thank you.

I now recognize Mr. Barton for 5 minutes.

Mr. Barton. Thank you, Mr. Chairman.

I would just point out to my good friend from New Jersey that what we've done with Medicaid is simply slow the rate of growth that we are going to save some money over a 10-year period. We're not cutting Medicaid. So I just want to set the record straight on that.

We seem to have the top people from all the various medical agencies that are fighting or investigating the Zika virus. Which one of you would be considered the number one official in charge of the research? Somebody answer.

Dr. Fauci. So I'm not sure what you mean by in charge of research. The NIH is the primary agency responsible for the research associated with what we're talking about today. The CDC is the agency predominantly responsible for the public health issues of detecting,

preventing, and responding.

BARDA is involved in helping the pharmaceutical companies and all of us develop products that are in intervention, such as diagnostic therapeutics. So there isn't one person that does all of that.

Mr. Barton. So there's no one in charge.

Dr. Fauci. Well, there is, because at the public health -- at the Department of Health and Human Services, all of this is under the PHEMCE, which is the Public Health Emergency Medical Countermeasures Enterprise, that involves BARDA, NIH, and CDC, and FDA.

Mr. Barton. But that person's not here?

Dr. Fauci. That person's not sitting here, but that person is -- there is a person that does that.

Mr. Barton. So there is somebody that is --

Dr. Fauci. Yeah, the assistant secretary for public health, for prevention and response.

Mr. Barton. I'm not trying to be argumentative. It would just seem to be, given the seriousness of this particular virus and the priority that we put upon funding to try to find a vaccine for it, that there would be a unified approach as opposed to all the various groups, all of which have super motives doing their own thing.

Dr. Fauci. Right. We have the assistant secretary here. So, Rick, do you want to comment?

Mr. Bright. I can add to that, what Dr. Fauci is explaining as well, yes. So the PHEMCE enterprise is chaired by the assistant secretary for preparedness response, the ASPR.

Right now, we have an acting ASPR, Dr. George Korch. In 2015 and early 2016, our ASPR actually was very proactive in leaning forward and coordinating a meeting across HHS called a disaster leadership group. In early December 2015, we had that first meeting.

In early January of 2016, we had additional meetings that included our partners across the PHEMCE organization, which is outside of the HHS department actually.

Mr. Barton. Well, this individual -- does that individual have the authority to direct funding to the various agencies?

Mr. Bright. That individual has the responsibility for the coordination and alignment of the activities to assure that we are working as efficiently as possible in reducing duplication so the resources are used most efficiently.

Mr. Barton. I'm not sure I understand that answer.

Dr. Fauci. The Congress gives us, individually, our resources.

Mr. Barton. So we --

Dr. Fauci. Right.

Mr. Barton. -- through the authorization and the appropriation process, we fund each agency --

Dr. Fauci. Yes.

Mr. Barton. -- and then this individual coordinates?

Dr. Fauci. Correct.

Mr. Barton. Well, I guess my bottom line question is, since you're on the front lines, each of those individuals here, do you believe that we have a unified approach and that money is not being

spent in duplicative efforts?

Dr. Fauci. Yeah, I believe we do. In fact, if you look at the Zika response that we've had right from the very beginning, as well as the Ebola response, we actually had the Secretary of HHS involved frequently on, like, weekly conference calls, and in the real hot part of it, multiple per-week conference calls.

But the description that Rick just mentioned is the assistant secretary for preparedness and response, the ASPR, is the one individual that coordinates what we do -- BARDA, FDA, NIH, and CDC -- and that's been the case throughout the outbreaks.

Mr. Barton. Okay. I've only got about 30 seconds.

Dr. Fauci, you're certainly the senior person here in terms of service. You didn't really give a direct answer to Chairman Walden's question about when we might expect an effective vaccine. Can you give us a little more definitive, next 2 years, next year, 3 to 5 years? You put some charts up in your testimony. Just give us kind of a ballpark figure. I'm not holding you to the exact date and second, and just generically.

Dr. Fauci. Yeah. A long time ago, a Secretary of HHS gave a ballpark figure for an HIV vaccine, and I think she's still regretting having said that. So I'm not going to give you a time when we'll have a Zika vaccine, except to say that the process for getting to that vaccine is right on time. And I would think it would be measured in several years at the most and maybe a couple of years at the best.

Mr. Barton. That's good enough for me.

Dr. Fauci. Okay.

Mr. Barton. Thank you, Mr. Chairman.

Mr. Murphy. Thank you.

Ms. Castor, you're recognized for 5 minutes.

Ms. Castor. Thank you, Mr. Chairman.

GAO's report today identified several areas of concern with our country's ability to surveil, track, and respond to Zika. Dr. Persons, is it accurate that the Zika virus case counts likely underestimated the total number of Zika infections, and would you explain that?

Mr. Persons. That's correct. When you talk about the Zika virus, a person can be infected but then not have symptoms in four out of five times. So 80 percent of the folks walking around are called human reservoirs and may not know they have that, and that's where the risk of mosquito control, person-to-person, and/or sexual transmission.

Ms. Castor. Right. So given these challenges, how will we be able to conduct predictive modeling to forecast the number of cases in the future and prepare for an outbreak?

Mr. Persons. It's going to be a matter of collecting high-quality data, taking models that are currently in existence and trying to modify them. There are, for example, computational models on sexually transmitted diseases. There's computational models on mosquito-borne and vector-borne diseases, but never the twain shall meet until this point. And so that is going to be a key focus in terms

of getting data for that and then testing those models against the datasets as the epidemiology.

Ms. Castor. That's not something that we should start and stop. We need consistent pathway forward?

Mr. Persons. Consistent research will be required for something this complex.

Ms. Castor. And, Dr. Petersen, I'm aware that there were a number of presumptively positive Zika tests that never went onto confirmatory testing. How many of those are out there?

Dr. Petersen. I do not have an exact number, but one of the biggest problems we actually had was in Puerto Rico, because what we found in Puerto Rico is because people who had a previous exposure to dengue -- which 90 percent of the population there has -- even the confirmatory test could not -- for the antibody test -- could not separate -- even wasn't good enough to differentiate dengue from Zika.

Ms. Castor. So was that an issue confined to Puerto Rico, or did we have a presumptively positive Zika test here in the U.S. that also didn't go onto confirmatory testing?

Dr. Petersen. The vast majority of women in the Continental United States, we were able to confirm the antibody test result simply because most of those women did not have previous exposure to dengue, which then causes the test to cross-react.

Ms. Castor. So how did you decide which specimens would get tested or not?

Dr. Petersen. So in the Continental United States, we tested

them all with a confirmatory testing as part of the algorithm. In Puerto Rico, we found out that didn't work, and so we stopped that confirmatory test with a test known as the PRNT.

Ms. Castor. Okay. Since the States and all of the agencies started keeping track of how many -- since we started keeping track, how many cases of babies born with birth defects tied to Zika have there been?

Dr. Petersen. Right. Well, one of -- I do not have that number off the top of my head. I can get back to you with that. What we do know is that this is an ongoing process, because many of the women that have been infected so far have not delivered yet. And so this is an ongoing process of --

Ms. Castor. Certainly, the CDC would have, to date, just since we started keeping track, the number of cases of microcephaly and other birth defects tied to Zika, knowing that we have to monitor these babies probably for many years.

Dr. Petersen. So as far -- so I think it's very important to monitor these women as they deliver and see the ultimate impact on their fetuses, both at delivery and long-term consequences. We do know that in the U.S. territories, there's been more than 3,700 women that we've identified who have become infected during their pregnancy and about 1,700 in the Continental United States.

Ms. Castor. Right. I have -- based upon the CDC update last week, we've had about 5,640 pregnant women with a known Zika virus. And I was just trying to get to how many we have today born with birth

defects, and so if you can please provide that.

And these are heartbreaking consequences for these families. And I do know, based upon recent research, that they are calling this a spike in birth defects across America because of Zika. Would you characterize it that way?

Dr. Petersen. I think there is a spike of infections -- I mean, of these birth defects simply because this outbreak was so large last year and these women are now delivering.

I was just handed the answer to your question.

Ms. Castor. Okay.

Dr. Petersen. And in Puerto Rico, they're currently reporting 35 cases with birth defects and 72 in the Continental United States. However, we know from our studies that about 10 percent of the women who were infected during pregnancy will go on to deliver a baby that has been affected by Zika virus.

Ms. Castor. There are so many other questions, Mr. Chairman. I look forward to the committee's continued attention to this. Thank you.

Mr. Murphy. Thank you.

I now recognize Mr. Griffith for 5 minutes.

Mr. Griffith. Thank you very much, Mr. Chairman.

And I'm going to start with Dr. Bright. In your just general info on BARDA, it says: BARDA meets its mission by supporting product innovation, advanced development, acquisition and stockpiling, and building manufacturing infrastructure.

Given the threat of emerging, infectious mosquito-borne diseases, would BARDA's mission for developing medical countermeasures also include the development of mosquito-control technology?

Mr. Bright. Thank you for that question. It is a very important question. And currently, the short answer is no, our scope does not include a vector control. However, we have been monitoring it very closely as an innovation in vector control and are considering is there data to support that vector control can also be associated as a medical countermeasure in the reduction of the disease. And so we are working closely with the companies to better understand those technologies.

Mr. Griffith. That's interesting, and I'll see what I can figure out, but I agree. It's probably something that ought to be in your wheelhouse, so to speak.

I'm going to switch and jump off of some of the issues that we've heard today. And Dr. Petersen talked about the situation in Puerto Rico a few minutes ago related to dengue and the testing to determine whether or not Zika is there when you have a population that has been exposed to dengue.

And, Dr. Fauci, that raises the question, when you were testifying about the vaccines and the DNA vaccine where you take a part of the gene of the Zika virus and the body then responds to the protein, because of the close relationship with other diseases like dengue and chikungunya, does that mean that there's a possibility, and should we be looking for it, that the vaccine, for one, will inadvertently or maybe intentionally create a vaccine for all three of those diseases

which are so closely related?

Dr. Fauci. Well, we should be so lucky. But unfortunately, that's not the case. Because even though there's cross-reactivity of antibodies, for example, from Zika to other flaviviruses like dengue and yellow fever, there's not cross-protection. So if you have an antibody against one, you don't protect against, even though they can be confused in a laboratory test. They're not physiologically protective.

But having said that, Mr. Griffith --

Mr. Griffith. I was hoping.

Dr. Fauci. Well, wait a minute, hope springs eternal. Because having said that, there is work going on right now to actually try and develop a universe of flavi vaccine where you get the component of the vaccine that you present to the body is a common part of the flavivirus that actually is in all the flaviviruses. Whether or not that part is going to induce a protective response is unclear, but there is work thinking exactly as you're thinking right now, can you actually get a universal -- the same ways we're trying for universal influenza vaccine.

Mr. Griffith. All right. I appreciate that. Thank you.

Dr. Petersen, you raised the issue, of course, about Puerto Rico and dengue, and they, of course, had so much exposure last year to Zika that they won't show as much exposure this year because such a large percentage of the population was already exposed. And I was just wondering, what work is being done.

And I'm going to switch gears on you just slightly, so bear with me. I read a report and was somewhat concerned that -- even though it was a very small study that -- back in March, the American College of Cardiology said that there's a link between Zika and heart disease. And since we have a large population that was, in fact, exposed to Zika, is there any work being done to see if there's a larger study that could be done to determine what the links between Zika and heart disease, if any, are out there?

Dr. Petersen. We do not have a specific study looking at heart disease -- looking at that link between heart disease and Zika. What we are looking at is of the general spectrum of syndromes associated with infection with the Zika virus, heart disease being just one of them.

There's a variety of neurological conditions that we're looking at as well. So it's part of a longer, larger effort to look at the complete spectrum of disease manifestations with Zika virus.

Mr. Griffith. And when you say you're looking at other neurological issues, that's not just in newborns or the fetus. Is that correct?

Dr. Petersen. Correct.

Mr. Griffith. All right. I appreciate that.

Dr. Persons, GAO reports that the grant funds awarded for mosquito control may not make it to some local control districts and that the CDC does not directly monitor mosquito control entities for the use of grant funds.

Assuming that is correct, what do we need to do to make sure that the money we're spending is actually being monitored and it actually goes to where we think it's going, which is to control mosquitos?

Mr. Persons. I just thank you for the question, Mr. Griffith. I think persistent oversight, guidance, perhaps changes in policy in terms of the rules or the structure in which CDC does these block grants so that they can be specifically targeted only for mosquito control efforts and not for other things that a State may wish to sponsor, I think is --

Mr. Griffith. I appreciate it.

Dr. Petersen, I'm sorry, I'm out of time. So I would give you a chance, but I don't have the time to respond, so I have to yield back. Or to give you a response.

Mr. Murphy. Thank you.

Ms. Schakowsky, you're recognized for 5 minutes.

Ms. Schakowsky. Thank you.

First, let me apologize. I'm the ranking Democrat on a hearing that's going on upstairs, and so I apologize that I missed your testimony.

Given the importance of developing a Zika vaccine, hundreds of millions of Federal dollars have been obligated to conduct clinical trials. I understand there's 32 vaccine candidates that are being studied in the U.S., and the U.S. Government has helped to partially or fully fund a number of those vaccine candidates.

So it's my understanding also that the drug manufacturer Sanofi

has received over $40 million from the U.S. Army to conduct a phase 2 trial for one of the vaccines, with the possibility of accessing up to 130 million more in taxpayer funding for phase 3 trials. All told, nearly $300 million of Federal dollars have been obligated for vaccine development to date. So stick with me for a minute.

While it's critical that we develop and manufacture an effective vaccine to combat Zika virus, it's just as critical that the vaccine be available to everyone who needs it. I'm also very concerned that Sanofi recently rejected the Army's request for a, quote, "fair," unquote, price for the vaccine.

Earlier this year, I led 10 of my House colleagues in sending a letter to the Army raising concerns about their plans to issue an exclusive license to Sanofi for the vaccine that U.S. taxpayers helped develop. In addition, Governor Edwards of Louisiana, one of the States that has hit largest -- hardest by the Zika virus, sent a letter to the Army that raised similar concerns.

I'd like to ask unanimous consent to enter both of these letters into the record.

Mr. Murphy. Could we review this? I'm assuming that would be okay, without objection.

[The information follows:]

******** COMMITTEE INSERT ********

Ms. Schakowsky. Okay. Dr. Fauci, given the enormous investment of taxpayer dollars into the development of a Zika vaccine, do you agree that we need to use every tool of the Federal Government to ensure that the vaccine is affordable?

Dr. Fauci. The answer to that question is yes, but it is a complicated issue, Congressman, as you well know, because we don't really have the mechanisms to influence pricing of a product, even products in which we make a major investment for the development of.

Certainly, we feel, as scientists and public health officials, that the work that we do in the development of vaccines should be available to everyone and anyone who needs it. So if you're asking is that the answer to the question, it is absolutely, I feel that we need to do that. Whether or not we have mechanisms in place right now to guarantee that, I don't think we do.

Ms. Schakowsky. But it is true, isn't it, that vaccines are most effective when the vast majority of the public is immunized? So if it's priced out of reach of many, won't this be a problem in getting control of the whole disease?

Dr. Fauci. Sure. Yes, it would, obviously, it would be. I mean, if you cannot vaccinate the people who need it -- and you correctly said that a vaccine, particularly in an outbreak situation, is that the more people that get vaccinated, the more control you get over the outbreak. So I agree with you that it's essential, to the extent that we can do that, to vaccinate where appropriate as many people as we possibly can.

Ms. Schakowsky. It's just a big concern to me since the Army actually said that they would not guarantee a fair price, and yet we're prepared to use taxpayer dollars to lay out perhaps as much as $130 million --

Dr. Fauci. Right.

Ms. Schakowsky. -- to them potentially without any ability to control that.

Let me just raise another concern. It's important also to remember the damaging impact that the repeal bill that just passed the House of ObamaCare and the Trump budget would have on Medicaid and our ability to respond to public health crises, like another Zika outbreak.

The per-capita cap included in both the -- in TrumpCare and the Trump budget would make it nearly impossible for States to expand services and the number of eligible individuals during a public health emergency, as Michigan did during the Flint water crisis.

Moreover, under a per-capita cap, there is simply no way any State could provide access to a high-priced drug to all of its Medicaid beneficiaries. And depending on how the final Zika vaccine is priced, Medicaid programs could already face challenges in trying to pay for the drug, and those problems would only be compounded if Medicaid was drastically restructured as Republicans have called for.

As this committee investigates the public health response to the Zika virus and considers how we might prepare for future challenges, it's critical to remember the important role that Medicaid has played in responding to public health emergencies and the devastating effect

that Republican proposals to cap Medicaid would have on our ability to respond to those emergencies.

I yield back.

Mr. Murphy. Thank you.

Dr. Burgess, you're recognized for 5 minutes.

Mr. Burgess. Thank you, Mr. Chairman.

And I would just point out that Bill Clinton, in 1995 and 1996, proposed a per-capita cap for Medicaid because he was worried about running out of other people's money. And he was praised by the editorial board of the New York Times at the time, and every Democratic Senator then sitting wrote a letter to the President wishing him success in that endeavor.

So I actually have a question that I'm going to ask, but it's going to be for the record. We did hear comments about an emergency fund proposed by one of the appropriators. And for just general purposes, we are an authorizing committee. We're not an appropriating committee.

The difference between authorizers and appropriators -- and, of course, at the NIH and the CDC you know this -- the difference between authorizers and appropriators is there are no buildings named for authorizers. But we are the authorizing committee, and I think we have already authorized that that Representative DeLauro asks for.

And I'm referencing now a compilation of the U.S. Code from January 4, 2012, title 42, chapter 6(a), subchapter 2, Powers and Duties, under part B in general: "The Secretary shall award

competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies."

So I believe the authorizing language is already there. And so my question that I'm going to submit to you for the record is, is that a correct statement? Do you feel that you have the authorization that you need and now we need to pay attention to the appropriations side of this? Or is, indeed, there different authorizing language that you would require?

Dr. Petersen, let me just ask you, because you -- I wasn't going to bring this up, but then you referenced it and so you provoked me, and now I'm going to do it. You said the best way to deal with this disease is to prevent it. And I agree with that. I agree wholeheartedly. And when you said that, I went on your website and I looked at your Zika page and I looked at your travel warnings.

And can I just tell you, they're muted. Someone talked about the computational models for the dispersion of this virus throughout various populations. I don't think there was any computational model that predicted what happened in the country of Brazil a few years ago. I mean, I think it caught people by surprise. I don't think the computational models for Ebola 2 years ago quite conformed to what people thought they would.

So while I'm sympathetic to the fact that computational models can help, my concern is, especially with Zika -- I mean, I'm one of two States where Zika has been locally transmitted. But, I mean, these

are rare, rare, rare conditions. Most of the people that get Zika had to go somewhere and get it and then bring it home to Texas or Florida. Is that not correct, Dr. Petersen?

Dr. Petersen. That has been the experience to date as true.

Mr. Burgess. And, again, along your lines of wanting to prevent it is the best strategy, and I agree with that, I'll just say, I think we should be doing more as far as educating the public. When we've had discussions with the State Department and your agency, it seems to be this: We're pointing to each other to do the work. Someone needs to tell people don't go if you don't want this disease, particularly at certain times of the year.

Now, I recognize that there's certain altitudes you can go to and won't be affected, but generally it is not a good idea, particularly if you're in a family that is contemplating a pregnancy somewhere in the future. Maybe you might not want to do this.

Dr. Borio, let me just ask you -- and I know we've talked about this before, but it has been some time ago. And you had in your written testimony the issue of vector control with the Oxitec mosquito.

And there was great concern last summer, this was a public health emergency that was declared by the President, and yet the difficulty with getting the technology for that genetically modified mosquito into areas where it could actually help, it seemed to be very difficult.

In the 1950s, they eradicated the screw-worm fly -- and I don't recommend googling that during brunch -- but they eradicated the screw-worm fly rather effectively with using that same type of

technology, maybe a little bit different now than it was then, but terribly effective.

And one of your statements says that perhaps there's guidance coming from the FDA that we could approach this in a different way now than what we did last August?

Dr. Borio. Thank you for your question, Dr. Burgess.

So, you know, first, I would just like to stress how important vector control is, and it's an area of unmet need. It's quite challenging to control the vectors that we need to control, as we were till last year, in the areas of local transmission. And as a physician and scientist, I have to stress that this technology seems very promising, and it really deserves to be evaluated more thoroughly. It's in early development, but it deserves its chance to show whether it can assist in this area of unmet need.

The company had a plan to do a field trial in the area of Key Haven, Florida, last year. And for a variety of reasons, including significant resistance by the population that voted against in the local area, the study did not proceed. We continue to maintain a very open line of communication with the company to explore additional studies.

In the meantime, we have published draft guidance that would transfer the authority for oversight of this technology to the EPA, and we are in the comments period right now. We're reviewing comments received.

But the goal for this draft guidance would be to provide a more

consistent and cohesive framework for regulating these type of technologies under a more, you know, consistent regulatory agency, which really has a lot of responsibility for vector control when they're for pesticides.

Mr. Burgess. Thank you.

Mr. Murphy. Before I recognize Mr. Tonka, Ms. DeGette, you have a request.

Ms. DeGette. I just wanted to renew Ms. Schakowsky's request for -- unanimous consent request for the two letters, which I agree with them, but also just to make the record complete for Sanofi's response dated May 22, 2017.

Mr. Murphy. Without objection, those will be accepted.

Mr. Tonko, you're recognized for 5 minutes.

Mr. Tonko. Thank you, Mr. Chair.

I'd like to look at the diagnostic testing of Zika. To effectively respond to a Zika epidemic, we must be able to determine who is infected. But diagnostic testing of Zika remains one of the most pressing challenges. There's a number of diagnostic tests authorized by FDA, but these tests have limitations.

GAO's report today identified these challenges. Specifically, GAO stated that certain tests detect the presence of a virus, which may or may not be Zika.

So, Dr. Borio, why has it been difficult for some tests to isolate the Zika virus?

Dr. Borio. Sure. So these are -- there's inherent scientific

challenges with developing diagnostic tests for Zika, especially the serological tests. But I think it's important to recognize that all of the tests that have been authorized by the FDA meet performance standards, all of these tests. And if used appropriately, as recommended by the CDC, these tests perform well and should be able to give an answer to patients about whether they've been exposed or infected with Zika virus.

The only remaining challenge today with the tests that are available really has to do with the population in Puerto Rico, which, as Dr. Petersen explained, because of coinfection with other flaviviruses it may not be really possible to make a definitive diagnosis.

Other than that, we have developed -- you know, used the limitations of the performance of these tests, but relied on algorithms to be able to give us the answers we need. They all meet standards.

Mr. Tonko. Okay. Thank you.

And, Dr. Borio, I also understand that the window during which the Zika virus can be detected is relatively short. How does that complicate diagnostic testing?

Dr. Borio. Sure. So the window really impacts on the utility of the molecular-based test, the PCR-based test, which is able to detect a virus in the clinical specimen in the acute period of infection. If the window is so limited, it's possible that all the tests might miss detecting the virus when it's present.

For that reason, the CDC algorithm recommends that for those

patients for the population that is being tested, a negative test should be followed by the serology test, which measure the antibodies against Zika.

Mr. Tonko. Thank you.

Dr. Persons, according to your report, a total of 15 diagnostic tests are authorized and vary in their performance. But your audit found a number of issues with developing accurate diagnostic tests. So my question is, why is it key that when an infectious disease confronts the U.S. we quickly developed an effective diagnostic test?

Mr. Persons. Yeah. So thank you, Mr. Tonka, for the question. The answer is simple in terms of the efficacy of the diagnostics goes right to the data that feeds into the epidemiology, which feeds into the clinical treatment, which feeds into the modeling and things that might be required to be more predictive and proactive in these things. So it's all a system that's complex and adaptive, but it hangs together. And diagnostics are very important to this conversation.

Mr. Tonko. So what does it mean for our overall preparedness that there were these difficulties regarding diagnostic test development for the Zika virus?

Mr. Persons. I think it just means that in taking a more proactive approach, we need to try and get -- a lot of our recommendations are really data or information providing oriented.

For example, if you're a manufacturer, you need to get well-curated data samples to understand, you know, which one contains Zika, in this case, which one does not, so you're really getting down

to those very important metrics on performance.

Also, just getting out to the user, so whenever you have the best available science and those numbers, those test results from the diagnostic testing regime, that they get put out to the user base so they efficiently are able to compare apples to apples and do a risk-based analysis at the point of care on which ones might be available and might best be used.

Mr. Tonko. Are there other things that we should be doing differently?

Mr. Persons. As I mentioned before, I just think the idea of a more proactive framework on doing that data is gold in this case, so really focusing on that. Putting resources on that data is not going to come for free, but maybe being more expansive about which data you might be able to get.

Again, having a framework for the rapid divulgence of science and best available competitive science as well as information to the marketplace so that they can develop rapidly and go through the regulatory process under EUA in this case.

Mr. Tonko. Thank you very much.

Mr. Chair, I yield back.

Mr. Murphy. Thank you.

Before we recognize the next, Dr. Burgess, you have a UC request.

Mr. Burgess. Mr. Chairman, I ask unanimous consent to insert an article from the journal of [off mic] emerging infectious diseases.

Mr. Murphy. Without objection, we'll include that article in the

record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Murphy. Mr. Collins, you're recognized for 5 minutes.

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

If I'm a young woman watching this hearing, I want to ask a few questions because there might still be some confusion. So, Dr. Borio, if a woman wants to know if she has contracted Zika, would you simultaneously recommend she get a PCR test and an ELISA test, I mean, just to pick up either the antibodies or in the PCR?

Dr. Borio. Dr. Petersen might correct me, but my understanding is that if a woman who is at risk for Zika infection is pregnant, she should be tested. And the algorithm requires that she will have a PCR-based test, and if it's negative, you'll be followed up with a serology test. And that way --

Mr. Collins. So you wouldn't do them simultaneous. You'd make her come back a second time?

I mean, if the PCR test is negative -- I mean, clearly that -- it may have just passed her bloodstream and then she -- would she have to come back and have another test done? Why wouldn't we do them --

Dr. Petersen. The same blood -- both tests could be done on the same blood sample, so it would not necessarily require her to come back.

Mr. Collins. Okay. So the protocol would be they draw her blood, they test it with the PCR test. If that comes back positive, well, then she knows she's been infected. If it comes back negative, using the same sample, she doesn't have to come in again. Protocol would be run through an ELISA.

Dr. Petersen. Right. Well, it's complicated, but there's actually two different scenarios. Somebody that has symptoms -- as opposed to an asymptomatic pregnant woman. For somebody who has symptoms, the algorithm depends on the time that they present to medical care after their symptoms develop. That will determine what algorithm is actually used.

For an asymptomatic pregnant woman, the current guidelines suggest that she has an IgM test first and an antibody test followed by a PCR test. We are reconsidering those recommendations at the current time, and we expect to have a new algorithm in the upcoming weeks as new information becomes available.

So we are working actually on trying to streamline the testing algorithm to try and make it both simpler for the woman as well as the physician ordering the test.

Mr. Collins. I mean, I would think there's a lot of asymptomatic women that just want the peace of mind and that that would be a fairly normal thing.

So another question maybe, Dr. Petersen. We've heard that if a woman is tested positive for Zika, she's not pregnant, do you have a timeframe during which she would feel comfortable or safe in getting pregnant subsequent? Is it 3 months, 6 months, a year? Or at what point in time would a young woman who has tested positive for Zika would she feel comfortable getting pregnant?

Dr. Petersen. Well, there's two issues here. One issue is does infection before conception actually lead to birth defects, and that

answer is still not known. We have no evidence that that's the case so far, but out of an abundance of caution, we are advising women to wait -- I can't remember the exact number -- 2 to 3 months -- 8 weeks. Sorry. Thank you, Tony -- 8 weeks to conceive after potential exposure.

Mr. Collins. Again, that would be good information.

Now, Dr. Fauci, you did mention, you know, the individual thought we might have an HIV vaccine at some point, which we don't. So HIV is an RNA-based virus, so is influenza, so is Zika. So on these viruses that tend to mutate, like that's why we have to come up with a different strain of influenza year after year after year and -- what would be different about Zika compared to something like influenza or HIV where we wouldn't have a single definitive vaccine, but yet would have to keep looking at potential mutations each season?

Dr. Fauci. That's a very good question. And there is a big difference between the mutations of the RNA virus influenza and the mutations of viruses like dengue, like Zika, like yellow fever.

The mutations that are associated with influenza have a major impact on the efficacy of a vaccine. So you can have mutations that have no impact on the virus's phenotype, namely what the virus looks like and how the body sees it. That's not the case with influenza. When influenza makes those mutations, you almost have to get a new vaccine. That's the reason why we get a new vaccine every season practically.

But when you have other RNA viruses, like flaviviruses, when they

mutate, they tend to have mutations that don't have a functional effect, usually. I mean, you'll have an exception to that, but the mutations that generally occur with flaviviruses are mutations that don't impact with the vaccine.

So, for example, yellow fever is an RNA virus. That will have mutations. If you do sequences of one versus the other, you will always see mutations because RNA viruses like to mutate. The critical issue is the mutation functionally relevant. And for the most part, for the ones we're talking about today, they're not functionally relevant.

Mr. Collins. So that should give us all a little more optimism --

Dr. Fauci. Yes.

Mr. Collins. -- related to Zika compared to things like influenza.

Dr. Fauci. You're right. You're absolutely correct.

Mr. Collins. Thank you for that clarification.

I yield back.

Mr. Murphy. Congressman Ruiz is recognized next for 5 minutes.

Mr. Ruiz. Thank you very much.

I'm really glad that we're having this hearing. It's the right topic at the right time. We really sincerely and genuinely have to learn from the past and what we did the first time so that we don't make mistakes that are detrimental to people. And why is that important? Because these are real people who have to take the burden of the human toll.

And what's most distressing to me and we know most distressing

to all of us, but me as a physician and now as a father, is the toll it has on children that are born with microcephaly, the developmental problems, the lifelong distress and concern and stress on that kid and the neighborhood and the parents, not to mention, the illnesses that may appear on adults and kids that we still don't know yet but that confirms with Guillain-Barre, heart disease, and other things that may appear 10, 15, 20 years down the line -- down the road.

So I want to focus on the funding and the approach to pandemics. First, Dr. Petersen, did you get what you asked for? Did the CDC get what they asked for in the initial round? And if not, what was the gap?

Dr. Petersen. The CDC got a sufficient amount of funding to then mount a very robust response to the outbreak. It wasn't what we asked for, but it was sufficient to certainly prioritize resources to the highest risk areas, such as Puerto Rico, Texas, Florida, et cetera.

Mr. Ruiz. So when you say that you didn't get what you asked for and yet you say that you have to do the research that you need, if you don't get what you ask for, if you don't get what you need, then that can delay the research that needs to be done in order to expedite a vaccine, expedite treatment, expedite understanding. Correct?

Dr. Petersen. I think what's important to know --

Mr. Ruiz. No. I'm asking about whether or not the funds that you get on the front end will affect the time it takes to develop a vaccine and the treatment and the research to understand how to combat it better. Is that correct?

Dr. Petersen. Yes.

Mr. Ruiz. Yes. And what are the consequences, therefore, meaning that if you don't have a vaccine, if you don't have a treatment, if you don't understand, then we can be a year, 2 years, 3 years delayed, and making sure that we're prepared the next time this happens.

Dr. Fauci, I want to talk about the response and the approach that we did on the last pandemic that approached our territories and also in the U.S. There is a difference between the wait-and-see approach, because we just don't have enough information, we don't know what this is going to look like, or the rapid response prevention so that we can contain a pandemic at the site so it doesn't spread and have a human toll, whether it's in the territories, in the U.S.

Tell me why the wait-and-see approach with pandemics is the wrong approach to treat a pandemic.

Dr. Fauci. Well, it depends, sir, what you mean by wait and see to do what. With regard to the vaccine, which I'm responsible for, we didn't wait to see anything. The virus was isolated. It was --

Mr. Ruiz. The wait-and-see approach in terms of, once you identify, do we go and respond to contain the virus or do we wait to see how virulent and how intense or how rapid it will spread?

Dr. Fauci. Well --

Mr. Ruiz. Do you wait to contain and see what happens or do you want to go rapid response to prevent it at the scene?

Dr. Fauci. Okay. So that's a question that's a CDC question, and the CDC didn't wait. And I'll hand it over to Dr. Petersen

because --

Mr. Ruiz. No. I'm not saying they waited. I'm talking about our ability to fund the programs initially. It was Congress that waited to give the funds.

Dr. Fauci. Well -- okay. So if you're talking about funding, then let's just go back and reframe the answer. When we were aware of the difficulty, both the CDC and ourselves and the FDA and BARDA, we actually proposed a budget for each of us that the President asked for, and we didn't get that until months later. However --

Mr. Ruiz. There was some delay time. And I think that the point I'm making is that there's a latency, and sometimes you don't see the immediate effects of a virus until later through the years and that all depends on the virus. It's not as gruesome as the Ebola.

Let me take a step back and look at the big picture. If you were a Zika virus and you wanted to wreak havoc on this world and you wanted to infect as many adults and as many children as possible, then you would want to decrease funding to stop or slow down the development of a vaccine, the treatment, or mosquito vector transmission prevention programs, and you would want to decrease funding in the NIH budget and the CDC budget.

If you were a Zika virus and you wanted to infect as many women and children as possible, then you would think about maybe finding a way to deny coverage for maternity care or make it optional --

Mr. Murphy. The gentleman's time has expired.

Mr. Ruiz. -- and even oral contraceptives. And that's exactly

what we have to think about.

Mr. Murphy. The gentleman's time has expired. I think the gentleman should be careful with the accusations you're saying on that.

Who's next?

Mr. Walberg, you're recognized for 5 minutes.

Mr. Ruiz. For the Zika virus, maybe.

RPTR TELL

EDTR ZAMORA

[12:05 p.m.]

Mr. Walberg. Thank you, Mr. Chairman.

Dr. Fauci, while much has been learned about Zika virus, we talked about that today, many unknowns remain. With regard to research into the link between the Zika virus and microcephaly, is there any research about other factors? For example, since mercury has been linked to microcephaly for microcephaly cases in northeast Brazil, is any research being conducted on the levels of methylmercury and the mothers of the microcephaly babies?

Dr. Fauci. To my knowledge, Mr. Walberg, the idea of looking at mercury as a factor in this is not being done, and I believe -- not I believe, I know the reason why we're not focusing on that is that the evidence that the virus itself is capable of causing these defects is now pretty overwhelming as being the cause. Now, the idea of there being other secondary cofactors, there's no evidence offhand that there is any other contributing factors such as mercury.

Mr. Walberg. Okay. Well, similarly then, is any research being conducted into the effect that a previous infection with another flavivirus, such as dengue or chikungunya, could have on the rate of severity of microcephaly?

Dr. Fauci. Yes. That is a good question and a good point. And the answer is we are looking now from an epidemiological cohort study

of individuals who have prior exposure, because there is this phenomenon that may or may not be relevant, we don't know, of antibody enhancement at least in individuals who get infected with one form of dengue, one serotype and then another serotype. There's no solid evidence that preexisting response to one flavivirus like dengue has an impact on another flavivirus like Zika or yellow fever. There's no evidence yet that that's the case, but we are looking at that.

Mr. Walberg. Okay. Thank you.

Mr. Petersen, what research has the CDC undertaken or what research do you plan to undertake into the link between Zika and microcephaly and other birth defects?

Dr. Petersen. Right. So I think we've definitively established that Zika virus causes microcephaly, and I agree with Dr. Fauci, the studies we've done have not identified other cofactors, to date, that would influence that progression towards severe diseases in infants.

It's important that we -- to know that we really don't understand the full spectrum of Zika virus infection and its effect on fetuses and children born to mothers exposed to the Zika virus. So it's important that we continue our birth defects registries, as Dr. Fauci has mentioned, both here and in the U.S. territories so that we can really establish the full spectrum of diseases, disease outcomes associated with this virus.

Mr. Walberg. Dr. Persons, could you identify some critical challenges that could likely arise with the next emerging infectious disease outbreak?

Mr. Persons. So, yes, thank you for the question. The critical challenges we would see, again, is if we're more reactive, you're going to see a lot of the same sort of things. If it's particularly in the case of mosquito-borne, we're going to be much more reactive in terms of how we're dealing with that. We're going to be surging this way and lurching that way as an entire system. You're going to have a lot of rush to try and do something, and then, of course, that's always counterbalanced against the idea of getting, you know, getting data but then getting quality data and then acting upon that data and building your response effectively. So those are the things that we think will continue to happen.

Mr. Walberg. Okay. I yield back.

Mr. Murphy. Mrs. Walters, you're recognized for 5 minutes.

Mrs. Walters. I would like to thank the chairman for holding this hearing and the witnesses for their comments.

On March 31, the California Department of Public Health announced that two breeds of mosquitoes that can carry the Zika virus have been found in 10 California counties, and my district is located in one of those 10 counties.

Dr. Fauci, just recently, it was determined in Laos that there is a third mosquito more prevalently found throughout the United States that can carry the Zika virus. Is this correct?

Dr. Fauci. Yes, that is correct, Mrs. Walters, but I think it's important to point out, since this subject always comes up, that the demonstration, the potential of a particular mosquito that can transmit

the virus is not necessarily correlated with that mosquito in the field transmitting it.

Right now, it's very clear that the overwhelming dominant mosquito that is responsible for this is the Aedes aegypti. Even though there have been studies in the lab where you take a group of mosquitoes of different species and you see if, in fact, the virus can survive in those mosquitoes, and the answer is yes, there are multiple mosquito types that can. The question is will they, in fact, in the field do that? And there's very strong doubt that that is the case right now.

Mrs. Walters. So would you say that this would present any additional risk to the United States?

Dr. Fauci. No. I wouldn't say zero, but I think that what we've seen over the past now 2 years is the dominance of the Aedes aegypti mosquito. And if you look at, for example, the risk that we've seen now in Florida and in Texas, the mosquitoes that are in that area on the Gulf Coast area are the Aedes aegypti mosquito, and it is almost certain that that's the mosquito that's doing the kind of local transmission that we've seen in Florida and the local transmission that we've seen in Texas.

Mrs. Walters. Okay. While the Department of Public Health has acknowledged that the transmission risk of Zika throughout the State of California is low, we must still be diligent in combatting the spread of invasive mosquitoes. Part of that includes education efforts that encourage residents to focus on controlling mosquito growth through

proactive measures like eliminating all indoor and outdoor standing water and using window screens. Significant strides have been made, but more work and outreach is needed to avoid a Zika epidemic.

Dr. Bright, what role has mosquito or vector control played in our response to Zika in the United States?

Mr. Bright. Thank you for your question. So right now, the CDC has had the lead on vector control and understanding vector control and repellants and insecticides, and their use and how it will impact and reduce the spread of Zika.

BARDA has not been focused, at this point, as a vector control as a form of a medical countermeasure, so we haven't supported those areas, but CDC has the lead on other vector control.

Mrs. Walters. What would you say that the role of the Federal Government should play in mosquito control?

Mr. Bright. I believe if the data would support that vector control and reduction of mosquitoes carrying the disease that can cause significant public health impact, then there would be a significant role for the government to ensure that that medical countermeasure or that approach is used as an effort to reduce the transmission of that disease.

I do not think at this point we have a significant amount of data that show clearly that even if you reduce the population of certain mosquitoes, it correlates with a reduction of disease in those areas. So we need to get additional data in that area.

Mrs. Walters. Okay. Is spraying insecticide an effective

solution when dealing with breeds that carry Zika?

Mr. Bright. I don't have data on that. I would defer to my CDC colleague, Dr. Petersen, to address that.

Dr. Petersen. What we do know is that in Florida, the mosquito-control efforts that we did there appear to have stopped the outbreak in south Florida. It's important to know that spraying pesticides is just one part of a comprehensive strategy to mitigate against vector-borne diseases such as Zika virus.

Mrs. Walters. Okay.

I yield back the balance of my time. Thank you.

Mrs. Brooks. [Presiding.] The chair now recognizes the gentleman from Pennsylvania for 5 minutes.

Mr. Costello. Thank you. Currently, there is not a specific therapy or vaccine approved for the Zika virus by FDA, but several vaccines are in various stages of development, with one experimental vaccine currently in phase 2 trials being tested in humans.

Dr. Fauci, that's correct?

Dr. Fauci. Yes.

Mr. Costello. And are there preliminary test results for the vaccine that is in the phase 2 trial?

Dr. Fauci. Yeah. So right now, the data that we have so far in the DNA vaccine, the one to which you're referring to, Mr. Costello, is that clearly there are no safety red flags. The signals that we're having is that there does not seem to be any safety issues.

In the phase 1 study, in the early part of the phase 2 study, it

has become clear that this vaccine induces the kind of response that you would predict from an extrapolation to the animal model that it would be protective. In other words, the titers of antibody are high enough that are induced by this vaccine that you would make a prediction if it acts like the virus acts in the nonhuman primate model, that it would be protective upon exposure.

Mr. Costello. And this question may have been asked, I apologize if it has, an updated timeline as to the completion of the vaccine that is in the phase 2.

Dr. Fauci. Sure. The phase 2a, and now we're going to go into 2b in a few months, is scheduled for about 2,500 individuals. That may go up to 5,000 individuals. The timeline of when you're going to get an efficacy signal is very variable because it depends on two things. One, what the inherent efficacy of the vaccine is, because a very effective vaccine is going to give you a signal more quickly. The other probably more important determining factor is going to be how much infection there is in the community in which you're testing.

So if there's a very, very low level of Zika this coming season, particularly, for example, in the summer in Puerto Rico, it may take a few years before you get enough cases in the vaccine versus placebo to say it works. So that's the reason why when I answered a similar question, I said it's really unpredictable. It can be as soon as a couple of years, a year and-a-half, 2, or as far as 3 or 4 or 5 years.

Mr. Costello. Thank you.

Does anyone else have anything to add to that?

If not, I'll yield back.

Mr. Burgess. Will the gentleman yield?

Mr. Costello. I'd like to yield my time to Dr. Burgess.

Mr. Burgess. Dr. Fauci, in 2014 when we were dealing with Ebola at the end of August, early September, that we were about at this phase with the Ebola vaccine, then the Ebola epidemic sort of went away, do we have an Ebola vaccine at this point, based on the work that was done in September of 2014?

Dr. Fauci. Yes. And then I'll get to it just in a sec the difference between those two, and they're really quite different.

So with Ebola, when we did a randomized placebo-controlled trial in Liberia, by the time we got it going and there was enough individuals in Liberia, it just stopped. There were no cases. So you couldn't test the efficacy of it. The similar vaccine, the same one was used in a ring vaccination trial in Guinea. It wasn't the design of a trial to definitively prove that something worked, but it looked really good from the standpoint of the data.

So we do have vaccine candidates, one of which has some considerable data that it looks like it might be effective, but we haven't definitively proven that yet. And right now, we're doing a trial in Guinea and in Liberia comparing two vaccines: the VSV vaccine, which was the one that was used in the ring vaccination study in Guinea, versus what's called an adenovirus plus an MVA boost from Johnson & Johnson, and we're comparing those two.

Just one last word about the differences between the two is that

Ebola is the kind of disease, there's an outbreak, and then it goes away. Just like we've seen right now in West Africa. When you have a mosquito-borne virus like flavivirus, it almost certainly is not going to disappear completely. So we may not have enough cases of Zika in Puerto Rico this summer or in Brazil the next few seasons, but it isn't going to go to zero. And that's the big difference between Ebola and this flavivirus.

Mr. Burgess. Let me just ask you one other question. Are you to the point with the Ebola vaccine that you can communicate to Dr. Bright that he ought to consider the purchase of that vaccine for the national stockpile?

Dr. Fauci. I'd yield that to Dr. Bright, but I think his answer is going to be no.

Mr. Bright. Actually, we were quite encouraged by the progress in the development and the data supporting the Ebola vaccines. Again, some of these vaccines could be considered for use in the ongoing outbreak now we're seeing in the Dominican Republic and Congo.

Mr. Burgess. But part of the issue is, I guess, what Dr. Fauci said, it was hot as a pistol in August of 2014 and then it's not. So for the utility of BARDA to be able to purchase to provide that substrate that the companies that are manufacturing need the dollars to purchase their product, that's you, right?

Mr. Bright. Yes. So, actually, at least one of these vaccines we do plan to transition over to purchase for the strategic national stockpile for Project BioShield support in this coming fiscal year,

in the next fiscal year. It's important to remember that Ebola is not just a public health threat, it is also a national security threat. It is considered and has been deemed a material threat determination. And so we do support the use of those vaccines and procurement of those with Project BioShield.

Mr. Burgess. Thank you for clarifying.

Ms. Chairwoman, I yield back.

Mrs. Brooks. Thank you.

The chair will now recognize myself for 5 minutes.

And staying on that line of questioning, Dr. Bright, as you know, specific language was included in last year's 21st Century Cures to restore the contracting authority back to BARDA as it had been originally executed when the authority was established. And our intent was, in reaffirming the underlying statute, was to remove unnecessary layers of bureaucracy, increase your flexibility, and make sure BARDA can be nimble in making those development decisions without being second-guessed and slowed down through the extraneous layers of review which caused the delays and uncertainty.

And so now that this is law or again it has been made law, what's been the impact of this provision specifically on getting development contracts in place on Zika virus?

Mr. Bright. Thank you for your question. And that's a very important area. And we actually are very grateful that Congress has recognized the need for improved efficiency, especially improved efficiency in our contracting ability and working with industry to be

able to move as quickly and nimbly as possible to respond to emerging threats and in our daily work for other threats that we address our Nation.

We are grateful for the 21st Century Cures Act and its passage. To date, it has not been implemented yet, as we are waiting for the permanent ASPR to take position hopefully in the near term, and we will be able to work hand-in-hand with that ASPR for full implementation of every provision in the 21st Century Cures Act.

Mrs. Brooks. So it's actually because the ASPR individual has not been named, confirmed, that is holding up the execution and use for Zika vaccine?

Mr. Bright. We are working very hard at drafting proposals for the ASPR to consider. As you know, BARDA is a part of the ASPR, the assistant secretary for preparedness response, and so it's critical that we have that permanent ASPR in place to ensure that what we're putting in place for long-term is going to be coordinated and work hand-in-hand with the vision of that ASPR.

We have not yet implemented and changed the contracting authority back to BARDA at this point; however, we are working as efficiently as we can with the ASPR's office of contracting to be able to move forward.

Mrs. Brooks. Okay. And I guess I'd just like to make sure I understand, because that provision was signed into law, and so it's unknown when a permanent ASPR -- there's an acting ASPR individual, is there not?

Mr. Bright. There is an acting ASPR, yes.

Mrs. Brooks. And do we not have the Secretary of Health and Human Services in place that's been in place for some time, does the Secretary realize that that part of the law has not been implemented yet?

Mr. Bright. I'm not able to speak on behalf of the Secretary, but I do know the Secretary recognizes the importance of efficiency and the importance of our ability to work with industry as efficiently and nimbly as possible. I do know that the acting ASPR is working with us on proposals, but we have not moved forward in implementing that yet.

Mrs. Brooks. Do we have a timeframe on which the acting ASPR is going to, you know, put this matter before the Secretary?

Mr. Bright. I do not have a timeframe on that.

Mrs. Brooks. Okay. How much money was provided to BARDA in 2016 through the emergency funding to assist in the development of a Zika vaccine?

Mr. Bright. In 2016, BARDA received $132 million, and that was distributed for vaccines and diagnostics in our pathogen reduction technologies. So vaccine specifically in 2016, we spent about $94 million.

Mrs. Brooks. And can you describe then how BARDA did use these funds for the development of the vaccines, the 94 million?

Mr. Bright. Yeah. Those funds were to support the technologies we have in our portfolio now, four different companies, who are working on Zika vaccines, and it supported the development and the initial

manufacturing of those vaccine candidates and the movement of those vaccine candidates into phase 1 clinical studies. It was with the additional funds we received in fiscal year 2017 from the Zika supplemental, an additional $245 million, they were able to put to work to move those vaccines and diagnostic candidates into midstage phase 2 clinical trials. And at that point, that is as far as we can move with the funding that we have.

Mrs. Brooks. Thank you. And I'm going to switch very briefly.

Dr. Borio, one thing we have not brought up and you brought up in your testimony, can you please describe the impact, as quickly as possible, of the Zika outbreak on the blood supply and how those blood supplies are currently being screened?

Dr. Borio. So this is an area that we have worked very early on to mitigate the threat to the blood supply. Initially, before a screening test became available in the areas of Puerto Rico, for example, BARDA was very proactive and helped us ensure adequate blood supply to Puerto Rico, so the blood supply was imported into the island from the Continental United States. Eventually, blood donor screen tests became available under IND, and those were deployed.

It became apparent last year that, with a number of travelers returning to the U.S., pretty much the entire continent was at risk of the blood supply of the entire United States, and we implemented guidance to make sure that all the blood supply then was screened for Zika.

Mrs. Brooks. Thank you. Thank you. My time is up.

I now call on Mr. Carter of Georgia for 5 minutes.

Mr. Carter. Thank you, Madame Chair, and thank all of you for being here. Folks, what we do up here is important, but what you do is lifesaving, and we recognize that. We appreciate all your efforts of that.

I have the honor and privilege of representing the entire coast of Georgia, over 100 miles of coastline where a third of the saltwater marsh in the country on the Atlantic Coast is located. We have mosquitoes. We have them bad. We're concerned about this, and I think rightfully so.

I've had the opportunity to visit a number of mosquito control centers in our area, particularly in the two most populus counties in the coastal region, and they're doing a great job. I dare say that we could not, regardless of Zika, just the mosquito problem, we could not inhabit that area if we didn't have mosquito control, so it's extremely important.

I wanted to ask just a couple of questions real quick. And, first of all, I have a question, Dr. Petersen, about the pregnancy register and registry, because from what I understand, and staff has told me, that there's some concerns that possibly it's not fully effective and that the outcomes that -- and we're not getting the outcomes that we should in the people that are listed.

Have you got any concerns with it? Is there anything we can do to assist you to help with any problems you might be having with it?

Dr. Petersen. I think that the pregnancy registry so far has been

very effective in terms of trying to figure out what the risks of Zika virus infection in the mother is on their developing fetus. What we really don't know and what we need continued support for is trying to figure out the whole spectrum of the illness associated with this virus. And that's just going to take time.

Because what we know now is that some of the babies that may appear completely normal actually aren't. And so trying to figure out over a period of time and long enough followup is exactly needed to determine what the whole clinical spectrum of this disease actually is.

Mr. Carter. What's the problem between the territory and Puerto Rico and America? I understand there's a significant difference there in the registry. Is there a reason for that or is there a concern there?

Dr. Petersen. Right. So in the beginning, of course, we didn't really know much about the clinical syndrome associated with Zika. In the Continental United States, we took a very -- used a very broad definition to try and capture all the potential outcomes associated with this infection. Puerto Rico, on the other hand, used a very narrow definition. They were really focused on the most severe cases of microcephaly. And so that led to some discrepancies in numbers between the Continental United States and Puerto Rico.

However, we have reconciled this. Puerto Rico is now using our case definition for congenital Zika syndrome and will be reporting out shortly similar numbers to what we have in the Continental United States.

Mr. Carter. Okay. All right.

Dr. Borio, I want to ask you about public-private partnerships and how we can use them to speed up the vaccines and the development to market. Have you had experience with these? Is this something that does help that we can work on?

Dr. Borio. Sure. The FDA has established public-private partnerships. I mean, this is very much a model that we work with to support the vaccine development. We have an important role as regulators, and we have to maintain some firewalls between us and the development.

Mr. Carter. Right.

Dr. Borio. But I have to explain to you that, you know, our technical teams are deeply involved with all the different working groups that are developing vaccines and providing very much in realtime feedback and active guidance --

Mr. Carter. Very quickly, any hurdles that you see that perhaps we can assist you with?

Dr. Borio. No. We deeply appreciate the support we have. We feel like we have the authorities today. And this year, we received resources to be able to support the Zika response. We're in pretty good shape. Thank you.

Mr. Carter. Good, good.

Very quickly, Dr. Bright, I wanted to ask you, it's my understanding in your testimony you mentioned that you're working with a company in Brazil to come up with a vaccination. Just out of curiosity, their regulations and their licensing arrangements and

clinical trial requirements, et cetera, et cetera, are they significantly different from what we have here in America? Can you see of anything that we can do better here in America to help along this line?

Mr. Bright. Thank you. They have an independent regulatory authority, Anvisa. We've worked with the companies in Brazil for the last 10 years in developing, manufacturing, and vaccine development capacity for pandemic influenza and other vaccines, and we've also noticed they are very closely collaborating with our U.S. FDA. So there's an agreement between our U.S. FDA and the Brazilian regulatory authority that allows them to exchange information and best practices and protocols to accelerate the development of vaccines, actually in our country, as well as theirs.

Mr. Carter. I'm encouraged to hear that. In fact, I want to compliment all of you. I'm encouraged by what I've heard today, and I appreciate your work on this. And from what I'm hearing, we're making progress. So thank you very much.

And I yield back.

Mrs. Brooks. Thank you.

The chair now recognizes the gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. Bilirakis. Thank you, Madame Chair. I appreciate it. Thank you for allowing me to sit in on the hearing, because I'm not on this subcommittee, so I really appreciate it. And I want to thank the panel too. I'm from the State of Florida, so obviously we've been

affected by the Zika virus, so I appreciate all your assistance. I have a few questions.

Dr. Persons, could you discuss how we can best streamline agency coordination to prevent bureaucratic overlap and redundancies, which can lead to waste and unnecessary delays and hamper the effectiveness of response?

Mr. Persons. Thanks, Mr. Bilirakis. So I appreciate the question.

Mr. Bilirakis. Sure.

Mr. Persons. I'll answer it in two ways. One is GAO has a standard manual for internal controls, and it's called the Green Book. So just the efficacious implementation of those internal control standards, which primarily often have to do with interdepartmental communication and things which often is at the core of this. As you know, all the agencies here have very important -- they're doing very important work, very important roles in things, but that systematic look at something and being able to coordinate is easy to say but harder to do and yet very important and critical to a timely response.

The second answer I would say is related to just our overall work. GAO, as you may know, does work on overlap and duplication, and so we have a standing methodology on looking at what constitutes overlap, duplication, or even fragmentation among Federal programs. That report just went out recently, and there's methodology behind the thinking on that that might be commendable to this conversation.

Mr. Bilirakis. Thank you.

Next question for Dr. Bright. With a coordinated interagency response, are there interagency goals that drive responsive preparedness strategies? If so, what are those goals?

Mr. Bright. Our goals. So our assistant secretary coordinates all of our research efforts and response efforts to the Zika response and other public health emergencies. And so we established, early on in the outbreak, an awareness of the Zika outbreak that we would have interagency alignment and vaccine production and diagnostic production and other countermeasure development. And we established and drafted HHS-wide, U.S. Government-wide goals to achieve the milestones for those vaccines and diagnostics.

Mr. Bilirakis. Thank you.

Dr. Petersen, CDC established a Zika registry last year. What data is captured in this registry? How is this data being utilized?

Dr. Petersen. So we gather data on evaluations that are done on the mother and fetus throughout pregnancy, and importantly, also on the condition of the fetus and medical consequences of infection following birth. We hope to continue this work and to follow these infants born to mothers infected during pregnancy to determine what the full impact of the virus infection in the mother actually is on the fetus. And that's still an open question.

Mr. Bilirakis. Okay. What's the value to researchers of tracking beyond 1 year or tracking 5 years? What are the benefits to that?

Dr. Petersen. Well, I think the benefits are primarily, number

one, telling people what to expect. Two is to provide appropriate medical care and social services for those infants in this condition.

Mr. Bilirakis. So you would recommend tracking 5 years as opposed to just one?

Dr. Petersen. Recommend follow -- excuse me?

Mr. Bilirakis. Yes, you would recommend the 5 years?

Dr. Petersen. I think we need to follow these infants up for, you know, probably 5 years or possibly even longer, depending on what we find.

Mr. Bilirakis. Even longer? Very good. Thank you very much. Good information.

Dr. Persons, earlier this year, the administration released a brief budget outline that proposed a coordination point for Zika-related activity. Can you share observations on how such a central coordinating point could help?

Mr. Persons. So, yes, thank you for the question. I think this again is -- this incidence with Zika as an emerging infectious disease is one of a kind, and it's unique in one way, but we've seen the pattern before. And so I think as you shift more toward a stronger central coordinating factor, I would say, for example, there's the importance Dr. Fauci mentioned earlier on ASPR and that within or interdepartmental coordination with HHS is certainly critical. There's also sort of a whole-of-government thing that I think was on display when the previous administration had appointed an Ebola czar back during the Ebola timeframe, just because there are oftentimes

things, even outside of big HHS and all the important work they're doing, there's often whole-of-government response that may involve, for example, DOD, or in this case with mosquito-borne vector disease, you're talking about the regulator of pesticides, EPA, or various other things.

So I think there's some potential commendable thinking on what that central function coordinating might look like even in the whole-of-government sense on something this complex and this rapidly evolving.

Mr. Bilirakis. Okay. I want to thank all of you for your efforts, and I look forward to working with you. We can combat this virus. So I really appreciate the testimony.

And I yield back, Madame Chairwoman. Thank you.

Mrs. Brooks. Thank you to our colleague from Florida.

And to close out --

Ms. Castor. Yes. Madame Chair, I wanted to thank you and Congressman Murphy for organizing this hearing on Zika, and thanks to all of our expert panelists.

We've got to remain vigilant and address the funding cliff that's coming up, and also the elephant in the room today with the Trump budget; we're never going to be able to protect our families and businesses across this country if we don't keep America as the world leader in medical research and in disease prevention. Proposed cuts to things like CDC's Center on Birth Defects would come at the exact wrong time when we're seeing an increase in birth defects largely driven by Zika.

Democrats and Republicans came together in the last funding bill and said, we are the world leader and we're going to keep it that way in medical research and disease prevention. And I trust that we can all work together to keep it that way again. And thank you again.

Mrs. Brooks. And I'd like to thank all of the witnesses. Thank you for your incredible dedication. And I'd like to thank all of your agencies for continuing to work together in the most efficient and most effective way, because the issue of Zika is obviously not going away. Issues of other infectious diseases, whether it's Ebola in West Africa, whether it's cholera in Yemen and other diseases, we must make sure that we as a government are keeping our citizens safe, that we're learning as much as we can based on all of the outstanding work of your agencies. And we will continue to work with you to make sure that you do have the resources that you need.

And in conclusion, I'd like to thank all the witnesses and members that participated in today's hearing. Remind members they have 10 business days to submit questions for the record. I ask that the witnesses all agree to respond promptly to those questions.

[The information follows:]

******** COMMITTEE INSERT ********

Mrs. Brooks. And the subcommittee is adjourned. Thank you.

[Whereupon, at 12:37 p.m., the subcommittee was adjourned.]