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RPTR BRYANT

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THE STATE OF U.S. PUBLIC HEALTH BIOPREPAREDNESS: RESPONDING TO BIOLOGICAL ATTACKS, PANDEMICS, AND EMERGING INFECTIOUS DISEASE OUTBREAKS

FRIDAY, JUNE 15, 2018

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 9:01 a.m., in Room 2123, Rayburn House Office Building, Hon. Gregg Harper [chairman of the subcommittee] presiding.

Present: Representatives Harper, Griffith, Burgess, Brooks, Collins, Walberg, Walters, Costello, Carter, Walden (ex officio), Degette, Schakowsky, Castor, Ruiz, and Pallone (ex officio).

Also Present: Representative Eshoo.

Staff Present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Adam Fromm, Director of Outreach and Coalitions; Ali Fulling, Legislative Clerk, Oversight

and Investigations, Digital Commerce and Consumer Protection; Christopher Santini, Counsel, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Austin Stonebraker, Press Assistant; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; C.J. Young, Minority Press Secretary; and Perry Lusk, Minority GAO Detailee.

Mr. Harper. Good morning. Today, the subcommittee continues its longstanding oversight of the U.S. public health system's preparedness to respond to biological threats and emerging infectious diseases that endanger the public health. The purpose of today's hearing is to hear from top public health experts on the good work being done at their agencies to protect the public and to explore where improvements need to be made.

The biological threats facing the United States in today's global society are varied, ever-evolving and, in some cases, intensifying. The CDC just reported that the seasonal influenza claimed the lives of 172 children during the most recent flu season, making it the deadliest seasonal flu season for children on record.

In recent years, the U.S. has also seen an increase in the number of antibiotic-resistant bacteria. Around the world, viruses are emerging, adapting and, in some cases, reemerging. Currently, there is an Ebola outbreak in West Africa and a Nipah virus outbreak in India that has killed at least 17.

In recent years, we have also seen humans in China contract the H7N9 strain of influenza which has been confined to birds. The H7N9 influenza strain is rated by the CDC's influenza risk assessment tool as posing the greatest risk to cause a public pandemic.

The 2013 ricin mailings addressed to President Obama and Senator Roger Wicker that originated in my home State of Mississippi, as well as the 2001 anthrax mailings and foreign terrorist threats, is a reminder of the risk of intentional biological attacks.

Today's hearing is especially timely, given that the committee is considering bipartisan legislation sponsored by Mrs. Brooks and Ms. Eshoo to reauthorize the

Pandemic and All Hazards Preparedness Act, PAHPA, which is set to expire at the end of September. Passage of PAHPA's reauthorization would not only provide critical certainty for public health agencies and industry partners, it would also bring about some much needed reforms. One such reform proposed in the legislation is transferring control of the Strategic National Stockpile from the CDC to HHS' Office of the Assistant Secretary for Preparedness and Response, to improve management of the stockpile.

A year ago, HHS' Office of Inspector General reported systemic issues with security and inventory management of the stockpile, risking CDC's ability to deploy the stockpile during a public health emergency. These issues need to be addressed, as does improving the training of State and local stakeholders on deployment of medical countermeasures.

Administrative reforms are also of interest. For example, are there ways to improve the timeliness of the decisionmaking process on threat assessments and appropriate countermeasures? Effective threat detection has been a subject of committee oversight. In 2016, the committee questioned the CDC about the effectiveness of its Laboratory Response Network, or LRN, which is responsible for developing assays for public health labs to test for the presence of Federal select agents.

In a May 2017 letter to the committee, the CDC reported that the LRN had only developed three assays approved by the FDA to detect specific Federal select agents. While the LRN has also had those cleared by the FDA under emergency use authorization, after nearly 20 years of this program, with about $135 million in funding over the last decade, could the LRN have cleared a significantly higher number of assays through the most rigorous FDA 510(k) process?

Finally, maintaining public confidence in critical Federal biopreparedness research is essential. In response to safety lapses in 2014 and to an expert panel's recommendations, the CDC and FDA each formed new offices in 2015 to centralize and elevate oversight of laboratory safety, with the directors of those offices reporting directly to the agency head.

These changes sent a strong message that lab safety was a top priority, backed by the clout of direct backing from the agency head. Unfortunately, both agencies seem to be backtracking from this good direction.

In the FDA's case, less than a year after this administration approved the direct report organization -- or reorganization, the sudden change is curious and would seem to be a step in the wrong direction. So we need to hear more details about the basis for this new direction.

I would like to thank the distinguished members of our panel for being here today and for your service to our country.

I now recognize the ranking member of the subcommittee from Colorado, Ms. DeGette, for 5 minutes.

[The prepared statement of Mr. Harper follows:]

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Ms. DeGette. Thank you, Mr. Chairman.

I know we agree that preparing this country for a bioincident is of critical importance. The threat, as you said, is real and it's growing.

In April, the CDC reported that in 2017, Colorado saw 25 cases of an antibiotic-resistant bacteria known descriptively as the nightmare bacteria, because 50 percent of those infected by it die. Thankfully, those cases were isolated, but the same CDC study noted that it's possible for these germs to, quote, spread like wildfire. If that happens, we need to know that we're able to respond.

We've looked at this issue in this subcommittee many times over the years, as our panel well knows. It's a regular appearance, and I want to thank you for coming again. And again and again, we've found that the Federal Government has to scramble to address biosafety incidents.

Those of us who were here during the fall of 2001, vividly recall the chaos that a few small envelopes of anthrax caused on Capitol Hill. Offices were closed. Buildings were fumigated. Some congressional business was suspended, and thousands of staffers and other personnel lined up for days to get tested for exposure. Far worse, some of the workers in our Postal Service were infected and died.

In 2009, we again had to scramble to produce sufficient doses of the H1N1 swine flu vaccine to protect against this new strain of the disease.

In 2014, hospitals and healthcare providers were not adequately prepared to deal with the arrival of Ebola patients in America. In one case, a hospital in Dallas failed to diagnose Ebola in a patient who had traveled to West Africa and discharged him. The virus was later transmitted from that patient to two healthcare workers. In the days

and weeks that followed, important questions were raised about how this event was handled and were we adequately prepared for the larger event.

And then, of course, in 2015, the Zika outbreak underscored the need for the U.S. Government to focus on disease preparedness every day. And I know our panel here today does just that.

I'd like to know today, though, what lessons we've learned from these incidents, and I want to know how the agencies are using what we've learned to better prepare for the next crisis, because there will be one.

For example, do we have adequate medical countermeasures in place to respond quickly when an outbreak occurs or a toxin is released? Do we have the capacity to quickly deliver these countermeasures to the doctors and nurses who will actually use them? And do the healthcare workers understand how to deploy the countermeasures?

Similarly, research into emerging pathogens and existing pathogens that have mutated is key to helping us quickly respond to new and expanding outbreaks. How is this research informing our surveillance and detection methodologies? Are we prioritizing research into threats of greatest concern? And are we dedicating adequate resources to the threats?

I also want to hear more about how all of our agencies -- CDC, ASPR, NIAID and FDA -- coordinate their research, surveillance, and response efforts. Because while each one of these agencies today has a specific valuable role to play in ensuring preparedness, nobody can operate effectively alone.

In fact, one major finding of the Blue Ribbon Panel's 2015 report on biodefense preparedness was these agencies must ensure they're equipped to work together to

respond to pandemics. The Blue Ribbon report also found that the Federal Government must dramatically increase the support provided to local jurisdictions to help them build and sustain their biodefense capabilities.

Local providers like hospitals and healthcare workers will be on the front lines in a public health emergency. I want to ensure that we're adequately supporting these providers, as well as State and local Health Departments, so they are equipped to detect incidents when they happen and respond appropriately.

Mr. Chairman, I'm really hoping we'll hear today that we've made tangible, measurable progress in this area, but, again, I urge us to revisit the work of the Blue Ribbon Panel and some of its findings to determine what more we need to do to better prepare the Nation for the threats that we will be discussing today.

I just can't thank our panel today enough for the tireless work that they put in to keeping America safe. We always have a great opportunity to hear from you, and we know that you're working hard. We think by having you come up here and take the time, it really helps us represent our constituents, and it helps all of us be better prepared for the next emergency that faces us.

Thank you, and I yield back.

[The prepared statement of Ms. DeGette follows:]

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Mr. Harper. The gentlewoman yields back.

The chair now recognizes the chairman of the full committee, the gentleman from Oregon, Mr. Walden, for 5 minutes.

The Chairman. Thank you very much, Mr. Chairman. To all our committee members, thanks for your work on this. And to our panelists, thank you, not only for your guidance on this issue, but also what we tap into you for along the way. And so we appreciate your professionalism and your assistance in our policy debates.

The topic of biopreparedness really hits home for me. I think I was the first Member of Congress to be diagnosed with H1N1 years ago. Not a distinction I was glad to get, but one apparently I had. But more than that, 30 years ago, a religious group called the Rajneeshees moved to Oregon. You may have seen the documentary on Netflix called Wild Country. And if you read Judith Miller's book Germs, you'll find it was the largest bioterror attack in the Nation's history, but it took the Federal Government a year, I think she wrote, to admit that that's really what it was. They grew their own salmonella and then sprinkled it over salad bars in Dallas, Oregon, and sickened 751 people, many of whom I know.

Deliberate biological attacks are just one risk. With more global travel, there's, of course, increased risk of spread of infectious diseases. As we've seen with influenza, our vaccines must be constantly updated to keep up with the latest strains. Meanwhile, other pathogens can develop antibiotic resistance, and our ability to quickly recognize evolving diseases and respond to new outbreaks is reliant on the testing and treatment and capabilities in the men and women who do the work that you all oversee.

Lack of preparation is not an option. A mock pandemic exercise hosted last

month by Johns Hopkins Center for Health Security with a group of current and former government officials, including our own colleague Susan Brooks, I'm told was quite eye-opening. The exercise resulted in a failure to develop a vaccine within 20 months, and that led in this exercise to 150 million deaths globally. So obviously, we've got to do more to be prepared for these types of outbreaks.

So that's where the reauthorization of the Pandemic and All Hazards Preparedness Act comes in. PAHPA originally was adopted in 2006. It's set to expire at the end of September. We intend to move forward with legislation prior to that.

Our Health Subcommittee met just last week to consider a bipartisan discussion draft to reauthorize this law and continues to fine-tune it. It's critically important Congress reauthorizes this law in time and to make sure that all levels of government are well-equipped to handle, not just current and emerging biothreats, but also chemical attacks, radiological emergencies, cybersecurity incidents, and mass casualty events.

Through letters, hearings, and investigations, the committee has raised numerous issues regarding biological threats to the U.S. and our Nation's ability to respond to infectious disease outbreaks. For example, the committee has examined concerns about the CDC's management and the security of the Strategic National Stockpile and the capabilities of CDC Laboratory Response Network. The Trump administration is set to transfer management of the stockpile from the CDC to the Assistant Secretary for Preparedness and Response, known as ASPR. And we look forward to hearing more details about how this transfer will work.

Another area of interest to the committee is the improvement of our biosurveillance capabilities. Innovation in this field could bolster our public health

response in the event of an attack or epidemic. So I'll be interested in learning more about that as well.

One thing we do know, the Federal Government needs to act faster to identify and determine material threats. The Department of Homeland Security in March 2018 made a material threat determination for pharmaceutical-based agent such as Fentanyl. It took 2 years for the DHS to make this designation, yet carfentanil, a highly potent form of Fentanyl, was used in a terrorist attack more than 15 years ago. So it's only after that designation is made that the Public Health Emergency Medical Countermeasures Enterprise can approve countermeasure development and acquisition. If we knew about it 15 years ago and it took 2 years to get that designation, we can do better.

Maintaining public support for critical biopreparedness research relies on Federal scientists and researchers working with these diseases and dangerous pathogens in a safe and secure manner. Following several safety lapses at CDC and FDA labs in 2014, both FDA and CDC created new offices to oversee and prioritize lab safety. These are positive steps. The recent proposals at these agencies to lower the status of their lab safety offices raises concerns with this committee.

So I thank you for being here today.

And I'd like to yield the balance of my time to Dr. Burgess and hopefully to Mrs. Brooks.

[The prepared statement of Chairman Walden follows:]

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Mr. Burgess. Thank you, Mr. Chairman.

And this issue is one that is important and timely for this subcommittee. And last week, the Health Subcommittee had a hearing on the discussion draft of the Pandemic and All Hazards Preparedness Act authored by Representatives Brooks and Eshoo. At that hearing, we heard from witnesses with firsthand experience in combating these biological threats to our Nation and received input on the draft legislation.

Certainly, our witness panel today is well-known to us and they are all experts. I look forward to hearing from our witnesses.

And I thank you, Mr. Chairman, and I will yield to Mrs. Brooks.

Mr. Harper. Maybe with unanimous consent, due to your leadership role in this, 30 seconds.

Mrs. Brooks. Thank you, Mr. Chairman.

And thank you to our witnesses for your work on this public health and national security issue.

Last February, our subcommittee here held a hearing examining how we best combat biological threats. And I'm pleased we're once again examining the state of our preparedness as we prepare to reauthorize PAHPA.

As everyone here knows, it is not a question of if we face a threat; it's a question of again, once again, when we face a threat. And we've been reminded by the stories that we've heard here today that these types of incidents have already happened in our country over the last decade and a half.

Created in 1999, the National Stockpile is the repository of vaccines, antibiotics,

and supplies used in the event of an attack or an outbreak. But HHS OIG, in June of 2017, issued a report identifying serious systemic issues within the CDC's management of the stockpile.

I look forward to hearing from our witnesses today how we are going to ensure that our stockpile is properly managed and that we can be prepared as a country for whatever threat we are and may face.

I yield back.

Mr. Harper. The chair now recognizes the ranking member of the full committee, the gentleman from New Jersey, Mr. Pallone, for 5 minutes.

Mr. Pallone. Thank you, Mr. Chairman.

Ensuring that our Nation is equipped to respond to pandemics, natural disasters, and the accidental or intentional release of toxins is a key part of protecting public health. Past work by this committee has suggested that our Nation has not always been as prepared as we need to be, so I'm glad that we're having this hearing today, and I hope to hear that we have made tangible progress towards increasing our Nation's preparedness.

In 2015, the Blue Ribbon Panel on Biodefense conducted a comprehensive review of the Federal Government's biopreparedness efforts. The panel found that, and I quote: The Nation is dangerously vulnerable to a biological event. It produced an extensive report recommending 30 action items for our public health infrastructure to address.

While the Blue Ribbon Panel was the most recent high-level commission to examine our Nation's biopreparedness, it was not the first. In fact, for many years, experts have warned that our ability to respond to biologic and other emerging threats

must be improved.

These recommendations remain important today, because the emerging health threats this country faces continue to grow. Just this week, officials announced that a child in Idaho had contracted bubonic plague. Last year, an outbreak of this plague killed 200 people in Madagascar.

In March, we heard at a hearing that the threat of pandemic flu is among the greatest concerns in the public health world. And antibiotic resistance also poses a major threat to public health, killing 23,000 Americans every year and making everyday procedures like surgery and chemotherapy increasingly risky. In May, a study showed that warming temperatures were associated with higher levels of antibiotic resistance in common strains of bacteria.

Extreme weather events can also lead to serious public health emergencies. The hurricanes in Puerto Rico, the Virgin Islands, Texas, and Florida last year were a stark reminder of this fact. We must be prepared to address threats from all these sources.

The Blue Ribbon Panel produced many recommendations for improving our biopreparedness, and I hope our witnesses will show that we have made real progress. For example, I hope to hear that the agencies have established a plan for who will take the lead in response to a public health threat and how the efforts will be coordinated.

Along these same lines, I hope we will learn how CDC, NIH, ASPR, and FDA are working together to identify the greatest threats and to prioritize the research, surveillance, and response capabilities needed to target these threats.

We must also focus on how these agencies collaborate with State and local health departments as well as healthcare providers, such as hospitals. These entities are likely

to be the first to see patients impacted by an infectious disease outbreak or other incident. In most cases, they'll be the ones to dispense countermeasures and to treat those impacted.

In 2014, for example, we witnessed the negative consequences that ensued when our healthcare infrastructure was unprepared to diagnose and treat patients with Ebola. A hospital failed to detect the disease in the patient in Dallas, and that patient later transmitted Ebola to two healthcare workers. This incident led to a serious question about whether we would be able to handle a larger scale event or incident. And we must make sure everyone on the ground has all the resources they need to respond effectively in such a crisis.

We also want to hear more about how we are conducting surveillance so that when an outbreak happens or a toxin is released, we know as soon as possible. While we cannot anticipate every possible new or mutated pathogen, if we can quickly detect when such a pathogen has emerged, we can respond much more effectively.

And along these same lines, I understand the CDC is gathering a substantial amount of data from laboratories, public health departments, and clinicians across the country every day. So we must ensure that this agency has the resources it needs to effectively use and analyze this data as it comes in.

And finally, I want to hear more about what we're doing to prioritize development of medical countermeasures to help us respond to a biosafety incident. Countermeasures include preventative measures like vaccines as well as therapeutics like antibiotics and antivirals.

BARDA, I understand that you work closely with the private sector to develop

many of these products, and I hope that we will hear today about how these partnerships have produced useful, safe, and effective products that truly address the challenges we face.

So, Mr. Chairman, I'd like to thank our panel once again for being here. Preparing for these threats is certainly not easy, but I'm confident that you're up for the task as long as we do our part and provide you with all the resources that you need.

I yield back, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

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

Mr. Harper. The gentleman yields back.

I ask unanimous consent that the members' written opening statements be made part of the record. Without objection, they will be so entered into the record.

And additionally, I ask unanimous consent that Energy and Commerce members not on the Subcommittee on Oversight and Investigations be permitted to participate in today's hearing. Without objection, so ordered.

I would now like to introduce our witnesses for today's hearing. First, we have Dr. Rick Bright, director of Biomedical Advanced Research and Development Authority and deputy assistant secretary at the Office of the Assistant Secretary for Preparedness and Response. Next is Dr. Anne Schuchat, principal deputy director at the Centers for Disease Control and Prevention. Then we have Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. Finally, we have Rear Admiral Denise Hinton, chief scientist at the U.S. Food and Drug Administration.

We welcome all of you.

And you are each aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath. Do you have any objection to testifying under oath?

Let the record reflect that all of the witnesses have reflected that they do not.

The chair then advises you that under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel. Do you desire to be accompanied by counsel during your testimony today?

Let the record reflect that each of the witnesses reflected that they do not.

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

[Witnesses sworn.]

Mr. Harper. You are now under oath and subject to the penalties set forth in title 18, section 1001 of the United States Code. You may now give a 5-minute summary of your written statement.

And I will begin with you, Dr. Bright. Welcome back.

TESTIMONY OF RICK A. BRIGHT, PH.D., DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, DEPUTY ASSISTANT SECRETARY, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ANNE SCHUCHAT, M.D. (RADM, USPHS), PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES

OF HEALTH; AND DENISE HINTON (RADM, USPHS), CHIEF SCIENTIST, U.S. FOOD AND DRUG ADMINISTRATION

TESTIMONY OF RICK A BRIGHT, PH.D.

Mr. Bright. Thank you.

Chairman Harper, Ranking Member DeGette, and distinguished members of the subcommittee, it's a pleasure to speak today on behalf of our Assistant Secretary for Preparedness Response to discuss the state of the Nation's health security preparedness.

I'm Dr. Rick Bright, the director of the Biomedical Advanced Research and Development Authority, BARDA, and the deputy assistant secretary for Preparedness and Response.

ASPR's mission is to save lives and protect Americans from 21st century health security threats. BARDA is a component of ASPR created to ensure that we have products to protect people from numerous dire threats that we face as a Nation. ASPR's staff is dedicated to preparing for and responding to these threats.

We are currently coordinating HHS' response to the Ebola outbreak in the DRC and monitoring H7N9 influenza in China. In communities affected by last year's hurricanes, we're there for the long haul, helping local health officials manage recovery and build resilience.

ASPR coordinates across the Federal Government to support State and local partners in emergencies. We enhance medical search capacity through our National Disaster Medical System and Hospital Preparedness Program, and we oversee the

development and procurement of medical countermeasures. We've made great progress in public health preparedness response since Congress established ASPR and BARDA in 2006.

BARDA was created to bridge government and industry to accelerate the development of life-saving medical countermeasures that would not otherwise be available. We use flexible authorities, multiyear advanced funding, public-private partnerships, and deep technical expertise to push vaccines, drugs, and diagnostics towards FDA approval. In our 12 years, BARDA has formed over 200 public-private partnerships with industry to accomplish our mission.

I want to pause for one second to acknowledge the hard work of our partners who, together with the U.S. Government, work very hard to create a more secure Nation with not only products but capabilities to respond when needed. These partnerships have led to 35 FDA approvals of products that form a protective shield for our Nation against a range of the most serious CBRN and pandemic and emerging infectious disease threats.

Through Project BioShield, BARDA has supported 27 vaccines, drugs, and devices to address national security threats, including smallpox, anthrax, botulinum, rad/nuc and chemical exposure. Fourteen of these are now in the Strategic National Stockpile for use in an emergency, and seven have now achieved FDA approval. These outcomes are the spirit of PAHPA: leadership, coordination, partnerships, and capabilities, working together to protect our Nation.

While this effort has created life-saving products to be procured by the SNS, it has also created challenges to acquire and sustain sufficient quantities to address the

requirements needed for each threat. Critically, each product also represents a company with a response capability that must be sustained to ensure we have these products available when they're needed. Project BioShield and the SNS together represent a marketplace for these products that would otherwise never exist and the products would quickly vanish without it.

PAHPA, ASPR, BARDA, and BioShield have all played valuable roles in enhancing our preparedness. However, the threats continue to evolve, and technology to modify and create new deadly threats have become simpler. We must modernize our capabilities, emphasizing an end-to-end approach, ranging from early detection through the last mile of administering vaccines and treatments to patients.

With new technologies and innovation, the time is here to apply transformative approaches to these daunting health security problems. Last week, we announced a new initiative called DRIVe, a nationwide business-friendly approach to identify, capture, and accelerate life-saving innovation. Using authorities you enacted in the 21st Century Cures Act, DRIVe brings together innovators, government, and now the investment community to create solutions for today's threats.

As you consider reauthorization of PAHPA, important changes to BARDA's authorities would sustain and enhance our capabilities. First, advanced appropriations for Project BioShield will attract more partners to support our mission. Without this consistent and guaranteed market, the companies are reluctant to work with us. Second, an authorization of appropriation for BARDA's pandemic influenza program will sustain our domestic flu vaccine production capabilities, modernize our vaccine technologies, and bring new treatments and faster diagnostics into the homes across

America.

I look forward to working with members of this panel, this subcommittee, your congressional colleagues, and I'm grateful for the opportunity to present to you today and look forward to your questions.

[The prepared statement of Mr. Bright follows:]

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

Mr. Harper. Thank you, Dr. Bright.

The chair will now recognize Dr. Anne Schuchat for 5 minutes. Welcome.

TESTIMONY OF ANNE SCHUCHAT, M.D.

Dr. Schuchat. Thank you.

Chairman Harper, Ranking Member DeGette, and members of the subcommittee, thank you so much for the opportunity to testify before you today to describe CDC's role in preparing, detecting, and responding to biological attacks, pandemics, and emerging infectious disease outbreaks.

Today I'll highlight CDC's role in protecting the Nation against health threats. I'll describe our role in three areas: preparedness, detection, and response.

The three themes I'd like you to take away are, first, the work CDC does every day in public health lays the foundation for responding to emergencies. Second, the CDC's world-class scientific and medical expertise ensures we're ready to respond to any threat. And third, our longstanding connection to State and local health departments ensures that public health systems function effectively, both day-to-day and during emergency response.

Let me first address how we prepare for emergencies. CDC works every day with State and local health departments. In fact, we have 590 staff assigned to State and local health departments. We fund the Public Health Emergency Preparedness Cooperative Agreement Program and the Cities Readiness Initiative.

Public Health Emergency Preparedness grants go to every State, eight territories,

and four cities. These funds support staff, enable exercises to test and validate capabilities, and pay for laboratory and communications equipment.

The Cities Readiness Initiative funds this Nation's 72 largest cities, to develop and test plans to receive and dispense medical countermeasures from the Strategic National Stockpile.

CDC expertise helps assure protection of vulnerable populations against diverse threats. For example, CDC worked with the American Academy of Pediatrics, the FDA, and other stakeholders to address gaps in existing countermeasures for anthrax in children, taking advantage of the agency's scientific and clinical expertise and longstanding relationships with AAP.

Turning now to detecting threats. The CDC's lab and surveillance systems are able to detect and identify agents causing illness, ranging from infectious agents to chemical or radiation exposures. Every year, labs from all over the world send specimens to CDC, because they know we'll be able to identify pathogens that other laboratories cannot.

Rapid identification of disease permits intervention before a health threat becomes a crisis. CDC's Laboratory Response Network maintains an integrated, scaleable, and flexible system of 125 Federal, State, and local laboratories. The development of this laboratory network established in 1999 has provided a larger capacity to test and report more quickly than was previously possible. For example, during the Zika virus outbreak response, CDC and our Laboratory Response laboratories processed over 207,000 specimens just for Zika.

Now I'll turn to response. When there's a crisis, CDC responds. We're able to

rapidly deploy scientific and medical experts anywhere in the world. By the end of the 21-month Ebola response, 3,700 CDC staff had shifted from their day-to-day duties to assist with the response. 1,500 of our staff deployed to West Africa, making over 2,000 trips. Today, we're responding to a much smaller Ebola outbreak in the Democratic Republic of Congo.

During health emergencies, CDC communicates. For example, during the 2009 H1N1 response, CDC held 39 full press conferences and 21 telebriefings. During the Zika response, CDC published 51 morbidity and mortality weekly report articles to make sure the public health and healthcare professionals had the latest and best information.

Being able to prepare, detect, and respond to public health threats is a top priority for us at CDC. Our preparedness and response capabilities are built on broad and deep scientific, medical, and program expertise. Our longstanding partnerships with State and local public health authorities ensures an integrated approach wherever that approach is needed, resulting in better responses and better public health outcomes, which translate to better protection of the people we serve.

Thank you, and I'll be happy to answer questions.

[The prepared statement of Dr. Schuchat follows:]

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

Mr. Harper. Thank you, Dr. Schuchat.

The chair will now recognize Dr. Fauci for 5 minutes for your opening statement.

Dr. Fauci. Thank you very much, Mr. Chairman.

Chairman Harper, Ranking Minority DeGette, members of the committee, thank you very much for giving me the opportunity today to present to you the role of the National Institute of Allergy and Infectious Diseases in addressing biodefense and emerging infectious diseases.

Our role in this really dates back many years, but was really solidified following the attacks of 9/11 with the anthrax attacks, which prompted us, together with our colleagues at HHS, to develop a strategic plan and a research agenda. For our role in that, as you know, the NIH for years, with regard to any emerging infectious disease, is involved in having a number of approaches, stemming from basic and clinical research, research resources for both industry and academic communities, with the ultimate goal of developing vaccines, therapeutics, and diagnostics.

We have been in a very strong partnership with BARDA in developing the concepts for interventions, which were then handed over to them for advanced development.

This slide just shows a representative example of some key achievements directed specifically at the category A agents that were in our strategic plan. Very briefly, for example, a better smallpox vaccine, next-generation vaccines for anthrax, antitoxins for botulism, antibiotics for plague, and, interestingly, the development of an Ebola vaccine, which long antedated the outbreak that we experienced in West Africa in 2014.

Having said that, it is important to point out, as we have in the past and as shown in this interesting article from Newsday of 2001, the worst bioterrorist may actually be

nature itself.

It is interesting to point out, Mr. Chairman, that I have been testifying before this committee for the last 33 years. The first time I did, I drew a map, and it's shown here. And the reason I drew the map is I wanted to point out that there would be emerging and reemerging infectious diseases. And the first time I testified before this committee, I put HIV on the map as shown there.

Today, the map is the same structurally, but this is what it looks like. And these are the emerging and reemerging infectious diseases. Many of them, many of them are curiosities and are not really of great public health impact, but others are really important and we've experienced them recently, such as Ebola, Zika, and the threat of a pandemic influenza.

Now, let's take one of these, Ebola. You mentioned in your opening statement, as others have, about the West Africa outbreak and the recent outbreak in the Democratic Republic of the Congo. It's important that the CDC, the NIH, and other agencies of the Public Health Service responded very rapidly there.

One thing that was proven that's important is that you can do good research in the context of an outbreak. And we developed, with others, a vaccine, which is called the VSV vaccine, which was first tried in a Phase I trial right in Bethesda at the NIH Clinical Center, and then went over to Africa in a Phase II trial. This is the vaccine that was used in the ring vaccination program that was actually involved in the West Africa outbreak.

If you then fast forward a couple of years to where we are today, with the outbreak in the Democratic Republic of the Congo, we have actually learned a lot and are applying what we learned to that. Let me give you an example. The experimental

vaccine that was used in the ring vaccination program has now been deployed to the Democratic Republic of Congo, and even as we speak today, it is being used in a ring vaccination with 50 rings and 150 vaccinations per ring.

Interestingly, and as I mentioned before we came, that in 1995, there was an outbreak in Kikwit in the Democratic Republic of the Congo. To just show you the connection between clinical care and research, we brought one of the survivors of Kikwit to Bethesda, took their B cells, cloned it, made a monoclonal antibody. And now the Democratic Republic of the Congo has asked us to ship that to them for their discretion use as a countermeasure in the epidemic. So it came full circle that our collaboration with them came back with something that perhaps could help them.

I want to close in the last couple of seconds with influenza. I wrote this article just a few months ago, talking about the need for a universal flu vaccine. And, in fact, we have developed a strategic plan and a research agenda because of the threat, not only of getting a better seasonal flu vaccine, but also a threat of a pandemic. And we could only do that with a vaccine that essentially is able to protect us against all subtypes of influenza.

And I'll close on this last slide -- this is not working very well, sorry -- which is an article that I actually wrote 17 years ago, but it's very relevant today. And what it says is that emerging infections are a perpetual challenge. We've always had them, we have them now, and we always will have them. So if they are a perpetual challenge and a perpetual risk, we must meet them with perpetual readiness and, hopefully, we'll be able to do that.

Thank you.

[The prepared statement of Dr. Fauci follows:]

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

Mr. Harper. Thank you very much.

We now have the privilege of hearing from Rear Admiral Denise Hinton.

Admiral Hinton, you are recognized for 5 minutes.

TESTIMONY OF REAR ADMIRAL DENISE HINTON

Admiral Hinton. Thank you.

Chairman Harper, Ranking Member DeGette, and members of the committee, thank you for the opportunity to appear today to discuss the state of biopreparedness.

Medical and public health preparedness and response is critically important to the health and security of our Nation. And I am pleased to be here today to discuss how FDA is working towards the shared goal of making sure that we have the medical products necessary to protect our Nation from a range of public health threats, whether naturally occurring, accidental, or deliberate.

The outbreak of Ebola virus disease in the Democratic Republic of the Congo serves as a reminder that biological threats can and often do emerge with little to no warning and can rapidly become global challenges. I can assure you that FDA is dedicated to helping end this outbreak as quickly as possible, as we are actively engaged in supporting international response efforts.

FDA plays a critical role in facilitating preparedness for and response to biological threats. Our focus -- our role focuses largely on facilitating the development and availability of medical countermeasures, or MCMs, such as vaccines, therapeutics, and diagnostic tests to protect against and respond to these threats.

Toward that end, we work closely with our HHS partners testifying here with me today as well as other U.S. Government partners, product developers, and nongovernmental organizations to facilitate the development and availability of MCMs. FDA also works closely with the Department of Defense to facilitate the development and availability of MCMs to support the needs of our Nation's military personnel.

Prior to joining FDA and the U.S. Public Health Service Commissioned Corps, I proudly served as an officer in the United States Air Force. So these efforts are near and dear to me, and we are fully committed to closely working with our colleagues at the DOD to support the unique needs of the U.S. military personnel.

At FDA, we have made it a priority to utilize our authorities to proactively work with our private sector and government partners to help facilitate the translation of discoveries in science and technology into safe and effective MCMs as part of advancing public health and strengthening our national security.

We share Congress' goal of having safe and effective MCMs available in the event that they are needed, and we have made significant progress towards this important goal. For example, since 2012, FDA has approved, licensed, or cleared more than 120 MCMs, including supplemental changes to already approved products and modifications to diagnostic devices for a diverse array of threats, including anthrax, botulinum toxin, plague, smallpox, and pandemic influenza.

We have also issued more than 60 emergency use authorizations since 2005 to enable access to products to respond to threats, including for Zika virus, Ebola virus, H7N9 influenza virus, and the Middle East Respiratory Syndrome Coronavirus.

While the close collaboration and coordination among the agencies represented

here today has achieved many successes in the development of MCMs, I would emphasize that developing MCMs is highly complex and there remain regulatory science gaps that can challenge development programs, such as a lack of models and biomarkers to enable the extrapolation of data generated in animal models to humans. Without such tools, it is difficult to generate the data necessary to support regulatory decisionmaking.

Addressing these regulatory science gaps remains a high priority for the FDA, and we have established a broad and robust portfolio of cutting-edge research under our MCMs Initiative regulatory science program to develop these tools and to promote innovation in the development of MCMs.

FDA is acutely aware that biothreats can emerge from an accidental release or exposure to threat agents during the course of conducting research. As such, we are working to ensure that our laboratories and workplaces are operated in a safe and secure manner to protect employees, the surrounding communities, and the environment. As the FDA's chief scientist, I can assure you that the laboratory safety is a high priority for me and the agency.

FDA remains deeply committed to working closely with its partners and fully using the authorities Congress provides to help facilitate and accelerate the development and availability of safe and effective medical countermeasures. While we have made significant progress, we know that more work remains to be done. We look forward to partnering with Congress and stakeholders as we work together to further enhance biopreparedness.

Thank you for inviting me to testify today. I look forward to answering any

questions you may have.

[The prepared statement of Admiral Hinton follows:]

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

Mr. Harper. Thank you very much.

I ask unanimous consent that the contents of the document binder be introduced into the record and to authorize staff to make any appropriate redactions. Without objection, the documents will be entered into the record with any redactions that staff determines are appropriate.

It is now time for members to have the opportunity to ask you questions, and I will recognize myself for 5 minutes.

Let me begin by saying that in my 10 years of service in Congress, I don't know if I've ever been at a committee hearing with a better lineup of witnesses. And so thank you all for being here. We look forward to your responses today.

And this is a question that will go rather quickly for all of you. And for each witness, which biological threat is of greatest concern to you and why? Let's start with Dr. Bright and then go down.

Mr. Bright. That's a difficult question. As Dr. Fauci has laid out, there are so many threats. They're constantly emerging. And I wish I could take some of them off the table, but they keep coming at us. And even more concerning is technology advancing so much that they can change the biological threats that we know today into something different that we may not be prepared for.

I think our greatest threat for any of those is our response capabilities and being able to respond to anything that comes our way.

Mr. Harper. Dr. Schuchat, is there one biological threat that is at the top of your list? I know they're all important, but is there one that gives you the greatest concern?

Dr. Schuchat. I think influenza needs to be at the top of my list. It can affect

everyone rapidly and is constantly changing. And with pandemics, all of the population of the world can be susceptible. So the threat of a pandemic has to be at the top of the list, because it can all happen fast.

Mr. Harper. Dr. Fauci.

Dr. Fauci. My number one and maybe number two and number three is influenza also. I agree, for the reasons that Dr. Schuchat has mentioned.

When you have a respiratory virus that can be spread by droplets and aerosol, and then you have the situation if there's a degree of morbidity associated with that, you can have a catastrophe. I mean, we've experienced in real world those types of things. The one that we always talk about is the 1918 pandemic which killed between 50 and 100 million people.

It is likely that it would be an influenza, but if not influenza, an influenza-like respiratory virus. I mean, we had a scare with SARS. Fortunately, public health measures were able to contain it, but influenza first or something like influenza is the one that keeps me up at night.

Mr. Harper. Admiral Hinton.

Admiral Hinton. Thank you for the question. I would say the threat that would keep me up at night would be the unknown. If we don't know what that threat may be, we have to be able to anticipate. So with the emerging spectrum of diseases, it would be the unknown that would keep me up at night.

Mr. Harper. Thank you.

For each witness, what area of biopreparedness is of the highest priority and why? Dr. Bright.

Mr. Bright. The area of biopreparedness of the highest priority would be the ability to rapidly detect something that has entered our community or has been used as a weapon. The sooner we detect something, the sooner we can turn on the machinery and call in the capabilities to begin making vaccines and drugs.

Mr. Harper. Dr. Schuchat.

Dr. Schuchat. You know, I would say our global health security would be at the top of my list, because, as you know, a threat anywhere is a threat everywhere. And I think our greatest vulnerabilities are in the weakest countries of the world.

We saw in Ebola how rapidly West African countries were overwhelmed, and that was an issue for us as well. So I think being able to strengthen the ability of every country to be able to prevent, detect, and respond to threats is where I'd place my focus.

Mr. Harper. Dr. Fauci.

Dr. Fauci. I would agree with those two. But let me add an additional one that may not necessarily be my first, is in our ability to respond, for example, with a vaccine, the modern day 21st century technologies of platform technology, where you don't have to wait 6 to 7 months to get a vaccine, where you can really get it out there within a period of a couple of months, which is doable if we put our mind and our resources to it.

Mr. Harper. Thank you.

Admiral Hinton.

Admiral Hinton. Our continued efforts in the Ebola, and then making sure that we contain it within the specific regions and not letting it cross the borders.

Mr. Harper. Thank you.

Dr. Bright, if I could ask you, obviously, the need to rapidly respond to a biological

threat is essential. Does the public health system have the capability to deliver and administer medical countermeasures rapidly and effectively in a timely manner as you sit there today?

Mr. Bright. As we sit here today, we are much better and can respond much more quickly than we were in the past 10 years. We've built a national response capability and an international capability incorporating new sciences and technologies. There is a lot of room for improvement. It still takes too long to respond to respond adequately to protect everyone in our Nation.

Mr. Harper. Thank you very much.

I will now recognize the ranking member, Ms. DeGette, for 5 minutes for her questions.

Ms. DeGette. Thank you very much.

Well, building on the question by the chairman just now, Dr. Bright, what changes do we need to make to make the system for developing countermeasures work more effectively and efficiently? ASPR has been a good start, but, you know, where do we need to go?

Mr. Bright. Well, given the 12 years' experience with ASPR and the enterprise, working across government and working with our public-private partnerships, we've learned a lot in the past 12 years. Not everything is working as effectively or efficiently --

Ms. DeGette. So what do we need to do?

Mr. Bright. We need to improve our communications and our transparency and how we work with our -- bridge our different agencies and bridge government with

industry. We need to ensure there's consistency in funding and availability so the partners that we work with can better align their business models with our government models as well. And we need to improve the efficiency at which we communicate and respond to proposals and other contractual mechanisms that we use to work with our industry partners.

Ms. DeGette. Are efforts underway being made to do all of those things?

Mr. Bright. Yes, efforts are underway.

Ms. DeGette. And is there something Congress can do to help you?

Mr. Bright. Congress has been very generous with the authorities to date. There are things that we can do to improve our language in our other transactional authorities to be able to work more fluidly and flexibly with our industry partners, and we would be happy to submit language to assist in that.

Ms. DeGette. We would be delighted to have that language. That would really help.

Dr. Fauci, none of these hearings can go without me asking you about what's going on with pandemic flu. And you had said that we are getting closer to being able to develop a universal vaccine. And you've said that before, because you've been trying to do it for a long time.

What does your timeframe look like now and what are the barriers?

Dr. Fauci. Congresswoman DeGette, the timeframe really varies about the level that you're talking about. There's not going to be one home run universal flu vaccine. There will be various iterations.

So I would say the timeframe. And I know every time when asked about a

timeframe, people back off, and I don't want to get in court to be able to say something that's not going to be able to deliver. But since we spoke last, we have put into a Phase 2 trial a universal flu vaccine with a company called BiondVax, which is a multiple peptide prime followed by a killed vaccine boost.

Being in a Phase 2 trial means that you're another step closer to getting a product that you'll be able to use.

Ms. DeGette. Right.

Dr. Fauci. So I would think that if you --

Ms. DeGette. How long is this trial going on for?

Dr. Fauci. The trial will probably take -- it's a Phase 2 trial, so that probably is going to take at least a year to determine if this induces the kind of response that you would predict would have some broad protection.

The first iteration of a universal flu vaccine is not going to be against all flu, absolutely. What we're hoping for is that the first iteration will cover, for example, all of a particular type, like all of the H3N2s. If we get that successful, then maybe all of the H1N1s.

There are two major groups of influenzas. The ultimate perfect one would be one that covers all of them. I think that's years and years and years away, but the first iteration may be five or so years away.

Ms. DeGette. And I'll ask you the same question I asked Dr. Bright. What can Congress do to help you?

Dr. Fauci. You know, I think Congress has been extraordinary in their positive effect on us in helping us. For example, in the 2018 omnibus, we were given an

additional $40 million to develop a universal flu vaccine, and we're getting additional money in the proposal of the House for our 2019 budget. So you've been very supportive and we really appreciate it.

Ms. DeGette. We think it's a high priority. I think I can speak for everybody in this room.

One more question. You're developing lots of different vaccines: smallpox, flu, anthrax, Ebola. How do you prioritize your efforts to target the pathogens and toxins that provide the greatest risk?

Dr. Fauci. That's a very good question. We do two things, Congressman. We target specific pathogens based on the threat. If you're talking about a bioterror threat, it's the intelligence that we get. And if you're talking about the possibility of an emerging infection, it's very difficult to guess what's going to come out.

Ms. DeGette. Right.

Dr. Fauci. So we know, and it was mentioned in one of the opening statements, that H7N9, for example, if you look at the CDC chart, it's way up there as a threat. So we clearly made an investment of a considerable amount of money to develop a vaccine for that.

But as I mentioned in answer to one of the other questions, it's to develop platform technologies that's applicable to any disease, as opposed to picking out all the diseases and preemptively making a vaccine. In other words, making a kind of a vaccine that you could easily apply to whatever is the outbreak.

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

Mr. Harper. The gentlewoman yields back.

The chair will now recognize Dr. Burgess for 5 minutes.

Mr. Burgess. Thank you, Mr. Chairman, and thanks to our panel for being here today.

Dr. Fauci, I wasn't going to do it, but you brought it up. And you said sometimes you'll give a timeframe, and then if it doesn't work out, then people will point that out to you. A couple of years ago, I think you gave us an 18-month figure on a Zika virus vaccine. How close are we today?

Dr. Fauci. Thank you for that question. So when you're proving that a vaccine works or not, in the classical way, you have to get what's called an efficacy signal. There has to be infections in the community to get an efficacy signal.

Right now, thankfully for the countries involved, the Zika infections have plummeted almost to very, very few. However, the Phase IIb trial that I spoke to you about some months ago is still ongoing, and it's accruing volunteers in the study. So there's an interesting possibility here.

Let's say there are no -- not enough Zika cases to be able to get an efficacy signal. We have been in discussions, with a lot of help from the FDA, about the possibility that if we get a considerable amount, and I say thousands of volunteers with safety data, immunogenicity data, namely inducing the kind of response that you would predict would be protective, and you bridge it to the animal studies, there's a possibility that they would at least consider that there would be an accelerated approval. You never can guarantee anything, but that's at least on the table.

So my short answer to your question, Congressman Burgess, is that we are on the road to getting a Zika vaccine, and I feel pretty confident about that.

Mr. Burgess. And from the FDA's perspective, that expedited approval that was talked about, is that something we can look for?

Dr. Fauci. Well, I'll let the FDA speak for themselves, but you never want to anticipate what they're going to do. You can just give them the data and the information that they ask for, but --

Mr. Burgess. I may submit that in writing, because I do want to ask you about another -- on the golly gee whiz slide that you put up with all of the things that can happen to us, enterovirus D68 was included on that list.

Dr. Fauci. Yes.

Mr. Burgess. And CDC has put out a paper on acute flaccid myelitis and the incidence of that. And I recognize that it's low, but it does seem to peak every other August. So as we are coming up on one of those every other Augusts, do we know any more about this illness and why it has had the effect that it has?

Dr. Schuchat. Yeah. You know, the outbreak of severe respiratory disease in children from the enterovirus D68 a few years ago was of concern. It was contemporary with the outbreak of acute flaccid myelitis. Very difficult to confirm that one caused the other, but there's a good probability that they did.

The family of enteroviruses are known to be able to cause neuropathic problems. And when you have a very common set of infections, it could be that that was a real rare end of the spectrum among the common ones.

So I think we do need to be ready for that. Unfortunately, there are so many different enteroviruses that it's very difficult to pick one that you would necessarily focus on for countermeasure development. There's some work on antivirals that might be

promising as, you know, having a broader protection, but that's the state of it right now.

Mr. Burgess. As you'll recall, fairly frightening when that did occur, the concern we heard from parents.

Dr. Schuchat. Exactly. It was happening the same time as Ebola in Africa. When the President visited CDC, he was briefed on Ebola and on enterovirus D68.

Mr. Burgess. Admiral Hinton, let me ask you. When Ebola was really a much more significant problem, September of 2014, the monoclonal antibody ZMapp was in trials, and then FDA put a clinical hold on it. My understanding at the time, there was a Herxheimer-type reaction that was fairly severe and so we stopped looking at it.

Is there a way -- when we've got a problem of that order of magnitude going on, I guess I want some reassurance that the regulatory side is not going to interfere with the delivery of what may be a very potent tool, because several people have mentioned ZMapp. I mean, it's now a recognized tool in the toolbox. Is that correct?

Admiral Hinton. That's correct. And Dr. Fauci can please feel free to add in, but that is correct. And the FDA is not there to be a roadblock; it's to ensure that the drugs are safe and efficacious. So the reasons behind that may not be privy to us, but we do make sure that we have safe and effective available drugs on the market to treat these and in emergency situations as well.

Dr. Fauci.

Dr. Fauci. So ZMapp was part of a randomized controlled trial that was run by the NIH. It was published in The New England Journal of Medicine. The results, because of the diminution of cases at the time, were very strongly suggestive of efficacy, but not enough to be statistically significant. So the trial is technically still on. And

right now, in DRC, they could use ZMapp either on a trial or, if they want, as compassionate use. But it is available.

Mr. Burgess. It is available. Thank you all very much. Thanks for your testimony this morning.

Mr. Harper. The gentleman yields back, who also serves as the chair of our Health Subcommittee.

Mr. Burgess. Mr. Chairman, I'm also going to ask unanimous consent to place into the record the report of the Independent Panel of the United States Department of Health and Human Services to the Ebola response from 2015.

Mr. Harper. Without objection, so entered.

[The information follows:]

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

Mr. Harper. The chair now recognizes the gentlewoman from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. Schakowsky. Thank you, Mr. Chairman. I want to agree with you, Mr. Chairman, that this is an extraordinary panel.

Dr. Fauci, 33 years before this committee, that's a long time, and we appreciate you every time we see you.

I also want Dr. -- I looked this up. Dr. Schuchat, it looks like you're about 28 years. Is it more than that? How many?

Dr. Schuchat. It's 30 in July.

Ms. Schakowsky. Okay, 30 in July. And such experience in all of you. It's just really remarkable. I wanted to -- I thank all of you for being here today.

I'm particularly concerned about the improper and overuse of antibiotics that's driving the growth of antibiotic resistance around the world. I noticed, Dr. Fauci, in your new map with all the lines, right at the top was antibiotic resistance on the left there.

I feel an obligation to raise this issue too for my sister and colleague, the late Louise Slaughter, who was always raising this issue. In the United States, somewhere between 20 and 50 percent of all antibiotic prescriptions in hospitals are either unnecessary or inappropriate. Evidence suggests that antibiotic stewardship programs in hospitals can improve prescribing practices and help reduce the occurrence of antibiotic resistance.

So I'm interested in hearing more from our witnesses on this program. Whoever wants to -- these programs -- wants to go first. Dr. Schuchat.

Dr. Schuchat. Yeah. The problem with antimicrobial resistance is a

transformational challenge for us because it obviously threatens modern medicine. CDC has been investing in efforts to improve stewardship of antibiotics, and at this point, by our latest data, two out of three hospitals had an antibiotic stewardship program, which is a big increase from before. But we think that there's much more to be done.

In addition, we have 850 hospitals around the country are reporting on their antibiotic use data to the National Healthcare Safety Network. So we're tracking data.

What we find in the healthcare system is when you track antibiotic use and feed back to clinicians how they're doing, they can improve. You know, a lot of clinicians are test takers, and we like to do really well on those tests. And so learning that we're not doing as well as our peers in terms of the appropriateness of our prescribing can help improve that.

We're also tracking resistance. And we've really invested, thanks to the congressional support, we've been able to invest in much better timely, accurate, quality antimicrobial resistance detection around the Nation. It's where we got those nightmare bacteria reports that we came out with recently.

So I would say that behavior change in clinicians is difficult, but we're making progress. And a stewardship program in every hospital is a good start, but it takes more than the hospital to make that happen. We need the whole plans, the outpatient prescribers as well, to be part of the system.

Ms. Schakowsky. But you're saying that we do have a tracking system now for clinicians, for hospitals?

Dr. Schuchat. Right. What we have is 800 -- in our National Healthcare Safety Network, I'm told that 850 hospitals are already reporting to us on their antibiotic use.

It includes 80 VA hospitals and 30 military hospitals. And they're having that be part of their -- you know, it's voluntary, but it's part of their ability to monitor what's going on in their own institution and then look across institutions.

Ms. Schakowsky. What percentage of hospitals does that represent, do you know?

Dr. Schuchat. I don't actually have that information, but we could get that for you.

Ms. Schakowsky. Okay. Has the CDC identified any obstacles to successfully implementing stewardship programs? If so, how are you addressing those?

Dr. Schuchat. You know, I would say that incorporating the outpatient facilities in the stewardship is important. We also found that rural areas, critical areas, we're challenged in being able to do all the things that we recommend in terms of antibiotic stewardship.

Our program convened a batch of the rural or critical area hospital stewardship leads, who had figured out ways to make a difference, and we're working with them to share their best practices more broadly. So I would say that large hospitals are really on the case now, and helping the smaller facilities get up to speed is important.

Ms. Schakowsky. Thank you. In the remaining seconds, does anybody else --

Dr. Fauci. Yes. How we address antibiotic resistance is really governmentwide, and it's a program called CARB, Combating Antibiotic-Resistant Bacteria, that was established years ago, a few years ago, that involves what Dr. Schuchat had mentioned regarding the CDC. It involves the FDA research component from the NIH to develop new drugs to understand the mechanisms of resistance to harness the immune system,

but also an organization called CARB-X, which BARDA has a major role in.

So maybe, Rick, you want to just mention that briefly.

Mr. Bright. Very briefly. So since 2010, BARDA has invested over a billion dollars in addressing the development of new antibiotics to address antimicrobial resistance. We have, just in the last year, had the first antibiotic drug licensed in our program. We have several more in Phase 2 and Phase 3.

We also realized that the early stage pipeline was not sufficient to have a stream of new candidates going into advanced stage development. So we did launch a public-private partnership called CARB-X, in collaboration with NIAID, also sponsored by Wellcome Trust, now Bill and Melinda Gates Foundation in the U.K. Government. So we have now funded 34 different novel technologies to address new mechanisms of action for new antibiotics and vaccines.

Ms. Schakowsky. Thank you. My time is up, but I hope that in addition to development, that we're looking at prevention here as well.

Thank you for your courtesy, Mr. Chairman. Thank you.

Mr. Harper. Thank you. The gentlewoman yields back.

The chair will now recognize the chair of the House Ethics Committee and a valuable member of this subcommittee, the gentlewoman from Indiana, Mrs. Brooks, for 5 minutes.

Mrs. Brooks. Thank you, Mr. Chairman.

Dr. Schuchat, and if, Rear Admiral Hinton, if you could pass that binder, please, over to Dr. Schuchat. The last page of that binder has a chart that I would like to enter into the record and ask unanimous consent to enter into the record. It's PHEMCE's

budget report for fiscal year 2016-2020.

Mr. Harper. Without objection.

[The information follows:]

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

Mrs. Brooks. A large percentage of the CDC's Strategic National Stockpile budget appears to not go to procuring and updating medical countermeasures for the stockpile, but instead, goes to a category entitled nonprocurement costs. And in an effort to inform the discussion today, committee staff did ask CDC to provide a breakdown for what is in this nonprocurement, but we never got it.

Can you please share with us very briefly, and you might need to supplement with written response, what makes up the nonprocurement spending for the Strategic National Stockpile?

Dr. Schuchat. Thanks so much for your question. As you know, the Strategic National Stockpile has an inventory of about $7 billion. So the annual appropriation is just a piece of that. Most of the dollars that are in the nonprocurement go for sustaining and operating. So that would be the rental space, the security for the warehouses, the staff that work, you know, the salaries for the staff, as well as the clinical expertise that's helping with the guidance on how to use the product.

Mrs. Brooks. Thank you. Could we get a written breakdown of what that is?

Dr. Schuchat. Absolutely.

Mrs. Brooks. Because we could not tell what that was.

Dr. Schuchat. That should be on its way to you.

Mrs. Brooks. Thank you very much.

Dr. Bright, last year, HHS OIG issued a report after conducting five site audits at the various Strategic National Stockpile locations over a 2-year period, and they talked about systemic issues, putting that $7 billion that was just mentioned into great concern.

So, Dr. Bright, what actions does ASPR plan to take in the transfer that is

anticipated October 1 to ensure the Strategic National Stockpile assets will be available in case of public health emergencies?

Mr. Bright. As you probably know, we have several working groups working very closely between CDC and ASPR to evaluate various components of the stockpile transfer. So we are still --

Mrs. Brooks. Can I interrupt one second? We just heard, in her opening testimony, Dr. Schuchat talk about all the many things CDC does relative to public health and these emergencies. And so are you going through all of those things to make sure there is coordination? And is that what the working groups are actually doing, figuring out what part CDC is going to maintain and what part ASPR will have? Is that what the working groups are doing?

Mr. Bright. Absolutely. There's five different working groups. They're meeting weekly actually, and some of them have daily communications, to understand the various components, understanding how we maintain and sustain the best science and expertise that's currently in the SNS, understanding how we're building and augmenting the relationship with States and locals to ensure that that is also maintained for a robust SNS enterprise. We're also looking at the contracting and the financing. We're looking at the nonprocurement cost as well.

We assure you that we are doing everything we can to make sure that those nonprocurement costs are supporting the SNS and its mission.

Mrs. Brooks. I have a question with respect to -- I understand there have been instances where BARDA -- and you mentioned it -- had to use Project BioShield funds to procure FDA-approved clinical countermeasures or medical countermeasures, because,

for whatever reason, CDC declined to procure those countermeasures for the stockpile.

How does that uncertainty affect BARDA's ability to partner with industry, and is that being addressed in your working groups?

Mr. Bright. That uncertainty is critical. As you know, it's very difficult to make these countermeasures. It's very lengthy, very risky, and the companies put aside other very profitable and successful endeavors to work with us in these areas. That marketplace assurance is absolutely essential to them working with us.

So we realize that, as we've been more successful with our partners and making additional countermeasures, it has created an additional burden on the SNS. We are working with the SNS at the CDC and our internal staff now to make sure that we are able to address those lapses or those gaps in communication or transparency to make sure that we have a successful --

Mrs. Brooks. Thank you. I'd also like to enter into the record a letter from the Blue Ribbon Study Panel on Biodefense that was sent to Dr. Kadlec with a very detailed seven recommendations to improve our biodefense posture.

Mr. Harper. Without objection.

[The information follows:]

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

Mrs. Brooks. And among those was the need to improve the coordination with State and local partners and to address problems that have existed in the past.

Can you tell us how ASPR plans to engage with State and local partners once it assumes control of the stockpile, which is of great concern to State and local partners?

Mr. Bright. I agree that it is an essential part of an effective enterprise, the end-to-end approach, from early detection down to distribution. The State and local and Tribal and territorial partners are the front line. They are the ones who are distributing and administering the vaccines and treatments. So we are dedicated to working with them, making sure they have a voice in the structure, in our system, to understand how they need those medical countermeasures and how they need them to be delivered most effectively.

It doesn't do us any good to make new drugs and vaccines if they're not suitable for our frontline workers at the State and local and Tribal and territories to deliver and administer those.

Mrs. Brooks. And so they know how to deliver and administer.

Mr. Bright. Absolutely.

Mrs. Brooks. Thank you. With that, I yield back. Thank you for your time.

Mr. Harper. The gentlewoman yields back.

The chair will now recognize the gentlewoman from Florida, Ms. Castor, for 5 minutes.

Ms. Castor. Thank you, Mr. Chairman.

Good morning. Last year, Florida recorded 262 known cases of Zika. They were overwhelmingly travel-related cases, but of those known cases, 136 were pregnant

women, and three babies were born in Florida with congenital Zika syndrome. Thankfully, those statistics are down substantially from 2015 and 2016, but the threat to young women of childbearing years and families remains very serious.

A study was just published where researchers from the CDC and the Annenberg Public Policy Center determined that most people have let their guard down now, that they're not taking the precautions that they should when it comes to Zika.

So, Dr. Schuchat, now that you have the results of that study and the threat of congenital Zika syndrome remains very serious, what do you plan to do to help keep families informed and make sure they're taking all precautions?

Dr. Schuchat. Thank you. You know, Zika was such a devastating new problem to have. You know, for a mosquito bite to be able to cause birth defects, not something that was on any of our radars, really.

I think you know that, in May, we issued one of our monthly high-visibility reports of vital signs on mosquito and tick-borne diseases, which have really been increasing, trying to get that word out in advance of the mosquito season so people would take these threats seriously.

We have another report that's focused on Zika that will be coming out in about 2 months, really highlighting what have we learned from the, unfortunately, thousands of pregnancies that were complicated by Zika in folks who reside in the 50 States, to show what the followups have been and what has happened to the babies as they develop.

We need to make mosquito protection much easier for individuals and we need to have better tools for countering mosquitoes, in terms of environmentally safe and acceptable tools for them. We have been appreciative of the investments in

strengthening our vector control so that there's better surveillance for vector-borne disease, and also better understanding of resistance patterns so we have the right products that can be used.

Ms. Castor. And there must be more we can do to communicate to young women and young men, especially now that -- I mean, it was very strange that Zika became transferable via sex as well. So --

Dr. Schuchat. Yeah. You know, the signs are still up in the airports, but people turn them off. So I think continuing to raise concerns is a challenge when people become complacent. So it's sort of our perpetual challenge in prevention.

Ms. Castor. Thank you.

Responding to public health emergencies requires us to have a good understanding of what is happening on the ground in real time. And doctors and nurses and others who work directly with patients are likely to be the first to interact with individuals affected in a public health emergency.

How does CDC gather data from these clinicians to detect emerging illnesses and other threats?

Dr. Schuchat. We have a variety of surveillance systems to try to identify both the known threats and then the unknown or the new unusual clusters. Most important is for there to be a close connection between the clinical community, the doctors and nurses on the front line, and their local and State public health authorities.

You know, the first cases of West Nile virus disease in New York City were detected, you know, there were some animal losses, but it was that link between clinicians and the local health department. So part of our day-to-day everyday public

health system is vital for the unknown emerging --

Ms. Castor. And CDC has a Laboratory Response Network that plays a vital role in biopreparedness by ensuring that we are able to quickly diagnose public health threats using rapid testing methods known as assays, but I understand that right now, there are no assay kits or rapid tests available for many dangerous pathogens and toxins.

What is going on here, and what are the barriers to developing assays targeting a wide variety of pathogens and toxins?

Dr. Schuchat. Yeah. What I would say is that the Laboratory Response Network, or LRN, is a group of 125 hospitals around the -- or laboratories around the country that are within a 2-hour drive of 85 percent of all of the population. They are equipped to use validated, standardized assays to detect a variety of conditions.

The CDC has the ability to detect and confirm a longer list of the select agents and dangerous pathogens, and we prioritize which of the detection methods or assays need to be deployed close to where people live, which ones can be deployed and maintained centrally, because it's quite expensive to have the standards high enough to be able to reproduce the results, you know, in all of the 125 hospitals.

So while there's 45 select agents, we have assays for nearly all of them. Many of those are managed at the CDC or at Regional Centers of Excellence, while the 125 laboratories can test for the things that we think are the most likely, including things like MERS, where we rolled out an emergency use authorization for a new diagnostic test for that, you know, Ebola, et cetera, you know, the H1N1 initially. So we try to deploy distally the assays for the threats that are the most important to have local ability to detect rapidly.

Mr. Bright. If I can add just a second on that too. I mean, that is another area of innovation that BARDA has been focusing on with our industry partners is to drive diagnostics, not only out of centralized labs to augment that centralized laboratory network, but put the diagnostics in the hands of the physicians in the physician's office at point-of-care testing. And even go further now, to drive diagnostics into the home, so people will know earlier when they've been infected with something so they can take responsible action to either get treated sooner when drugs are more effective and also to take activities to reduce the further spread or transmission of that virus. This area is ripe for innovation to augment our national laboratory support system.

Ms. Castor. Thank you very much.

Mr. Harper. The gentlewoman yields back.

The chair now recognizes the gentleman from New York, Mr. Collins, for 5 minutes.

Mr. Collins. Thank you, Mr. Chairman.

I want to thank our witnesses and follow up a little bit more on the Laboratory Response Network, Dr. Schuchat. I understand that's been around about 9 years or thereabouts, since I think 1999?

Dr. Schuchat. Yes, since 1999.

Mr. Collins. Actually, I've lost 10 years. Twenty years. I deliberately lost those 10 years, by the way.

So I know you mentioned 125 labs here in the country, but this is, from what I understand also, there's international labs. I mean, we all know the key to a lot of this is early detection, whether it was Ebola or some other things, SARS, which initially people

thought they had the flu, even anthrax. But early detection's the key to jumping on top of this, which means the laboratories who are -- that are located outside the country. And I know this is a collaborative effort.

Are you, let's use the word "comfortable," and how is that collaboration between the United States and other countries around the world -- as you mentioned, in many cases, these could be in Africa and other places -- for the ability to identify these select agent?

Dr. Schuchat. The Laboratory Response Network is in other countries as well, but I would say there's other means, other laboratories that we collaborate with around the world to help have that rapid detection and response. And actually, that's really what the global health security agenda is about, making sure that there are abilities to find, stop, and prevent epidemics wherever they occur, natural or not.

And the international collaboration, I think, is strengthened by the daily links we have in partnership on other threats. You know, as you heard, we're working on Ebola in DRC right now. The Nipah virus detection in India was based on training that CDC had given to the laboratory in India years before so that India could recognize that pathogen themselves without having to take the time to ship the specimens out of the country.

Mr. Collins. So, you know, following up on that, the, you know, what I would call proficiency testing that we do for all of our labs, whether it's on influenza or HIV or any of the STDs, I'm assuming there's also a proficiency testing program related to our LRNs, which is always maybe a little more complicated because the 45 select agents are not nearly as prevalent as influenza. But can you speak to the proficiency program, how often these laboratories are tested, their workers, how their grades are, so that, in fact,

we're comfortable that, if there is an outbreak, they're properly identifying it?

Dr. Schuchat. Yes. The proficiency testing and assuring the quality of the laboratory test is vital. That's one of the reasons that we don't have assays for every one of the select agents in each of the LRN labs, because we want to certify that lab for that test and make sure that they maintain their reagents adequately and that everyone who's working on that test is doing it the right way. So we really try to prioritize which assays will be run regularly in every lab, because we do have to make sure that every -- year in and year out, they're getting the accurate results. Otherwise, it makes no sense to run the test.

Mr. Collins. Is that done yearly, more than yearly? How often is that done? And does the CDC conduct the proficiency tests themselves or do you use outside agencies like CAP or someone like that?

Dr. Schuchat. Let me get the details on that for the committee in followup, because I don't have all of them myself.

Mr. Collins. Okay. Thank you. I think that's an important piece.

In the remaining time, Admiral Hinton, egg-based versus cell-based vaccines, could you comment? You know, is the FDA looking at -- as we're moving forward certainly through our influenza season, are you making progress on the cell-based? Are you seeing positive potential there?

Admiral Hinton. Absolutely. And we actually have -- we have both. We have the egg-based versus the cell-based vaccines available, and continue to do evaluation and work in that area. But both are available, both are promising.

Mr. Collins. Because, you know, there's always been some folks -- if anyone else

would like to comment on potential problems with the egg-based. Are we seeing positive steps in the other or --

Admiral Hinton. We are seeing positive steps in the other direction. And then as far as the egg-based, I know we run into issues with people having allergens and the like to them and not being able to have them. So having different options there to be able to provide and treat people with is promising and is available.

Mr. Harper. Dr. Fauci.

Dr. Fauci. There are other problems with egg-based, which is the reason why we're really trying to get away from egg-based and get more towards more advanced platform technologies.

One of the accidental mismatches that we had in 2016-2017, particularly in Australia, was that the virus was chosen for the vaccine, was put into eggs, and as it mutated in the eggs as it was growing, it mutated so that the virus that came out of the eggs was not the virus that you put into the egg. So we had an accidental mismatch.

I mean, that doesn't happen all the time, by any means, but the idea of having to grow a virus in a 6-month process is something that we really need to, as I often say, graduate into the 21st century and do it a little bit better with more advanced technologies.

Mr. Collins. Thank you for that.

Mr. Chair, I yield back.

RPTR MELHORN

EDTR ROSEN

[10:25 a.m.]

Mr. Harper. The chair's is going to allow Dr. Bright to finish his response that he wanted to make here quickly.

Mr. Bright. Thank you very much. I'd like to add just a little bit more to that as well. I mean, it's very important to understand the need for diversification, diversified vaccine production systems for influenza. Influenza's a tricky virus. Eggs have been a reliable vaccine substrate for a number of years. We are working to find ways to not only diversify and augment our cell-based and recombinant-based influenza vaccines, but also to improve egg-based vaccines. It's important not to completely discard a reliable technology without having a modernized technology to replace that. So we are working with each of the manufacturers now to identify ways to make our flu vaccines more effective now while we wait for that universal flu vaccine candidate in the future.

Mr. Harper. The chair will now recognize the gentleman from California, Mr. Ruiz, for 5 minutes.

Mr. Ruiz. Thank you, Mr. Chairman.

Emerging infectious diseases are a major threat to the health of American citizens and to people around the world. This includes both new diseases that emerge in populations, as well as previously known diseases that re-emerge.

In just the past 2 months, for example, we have seen outbreaks of Ebola in the Congo and Nipah in Northern India.

Dr. Schuchat, what steps are we taking to monitor emerging and re-emerging infectious diseases in the developing world, and how are we partnering with international players on this?

Dr. Schuchat. Yes. CDC works closely with dozens of ministries of health around the world, as well as with international partners like the World Health Organization and the World Food Organization to -- or the World Animal Health Organization to be able to find, stop, and prevent epidemics.

Mr. Ruiz. Give me an example of how you do that in a very underdeveloped, poor infrastructure nation.

Dr. Schuchat. Right. As you know, in Liberia, they suffered from a devastating outbreak of Ebola in 2014. We have a country office in Liberia that's working closely with them focused on four key areas: strengthening laboratory systems, strengthening surveillance, strengthening emergency operation centers and rapid response, and workforce development through the disease detective program that we call the field epidemiology training program.

That means they can shorten the time to recognition of Ebola or something else and respond capably.

Mr. Ruiz. Thank you.

And in 2014, 2016, the Ebola epidemic killed more than 11,000 people in West Africa, and we know in October 2014, a physician who traveled from West Africa to Dallas in Texas died of Ebola; two others that contracted the Ebola virus survived.

What did we learn from that experience? And what are the changes that you've made because of that?

Dr. Schuchat. There are three key lessons learned. One was that we need every country to have the ability to find, stop, and prevent epidemics, and that's what we call this Global Health Security Agenda.

A second thing was that we need the world organizations, the global organizations, to be able to surge rapidly when a country's capacity is overwhelmed. And that has actually happened effectively in the Democratic Republic of Congo with this Ebola outbreak recently.

And the third thing that we've learned is that infection control is essential; that an issue that is one illness or a couple illnesses can amplify into a very large-scale problem when we don't have adequate infection control. That's important in the United States for antimicrobial resistance, it's important in developing countries for TB, and it's very important for Ebola in SARS.

Mr. Ruiz. This patient and these two other healthcare workers who contracted Ebola, obviously, were in emergency departments, went to emergency departments, were treated in emergency departments. The first line of defense against any emerging infection or outbreak in the United States is going to be the emergency departments and also the first responders.

So what are you doing in terms of the CDC to coordinate to make sure that they are well-equipped? And then I'm going to ask Dr. Bright that same question.

Dr. Schuchat. Yeah. We have a family of efforts to educate and keep up-to-date clinicians that include tens of thousands of clinicians regularly getting updates from us, whether it's through phone calls --

Mr. Ruiz. It's hard for very busy clinicians who, you know, work in emergency

departments seeing, you know, 20 patients at once to --

Dr. Schuchat. Right. And that's --

Mr. Ruiz. How do you integrate that into their daily practice?

Dr. Schuchat. Yeah. The system changes are really important. When I saw a doctor at Emory last week, before I could even talk to anyone, I was asked, Have you traveled out of the country the last 3 weeks? It's actually on their phone line before you make an appointment.

So institutions instituting systemwide checks can help make sure that you don't have problems with human error.

Mr. Ruiz. Dr. Bright?

Mr. Bright. Also, I'd like to highlight that ASPR has spent a lot of time with our hospital protection program and our healthcare coalitions to establish now even a national Ebola training center and education center, so we can train the hospital and first responders.

We now have 178 Ebola assessment hospitals. We have 69 State or jurisdictions designated Ebola treatment centers. We have 10 regional Ebola and other special pathogen treatment --

Mr. Ruiz. Well, I think that -- I'm an emergency physician. I have to take exams like crazy just to keep my board certifications and my licensing. So I think integrating it as part of their continuing medical education and training would be very essential.

Now, the President's budget -- or the administration wants to move the strategic National Stockpile under the ASPR. I'd like to ask Dr. Schuchat what are your competitive advantages and why should I think about even considering keeping it at the

CDC?

Dr. Schuchat. What I could say is that there's already been an administrative decision to move the stockpile, and so currently, CDC is working diligently very closely with ASPR to make that transfer as seamless as possible and to mitigate any negative consequences that may have been unintended but that may occur.

I think the critical areas that we are going to focus on are to make sure that State and local support is seamless, and that, you know, we work with State and local health departments every day on a variety of things and know them and know where our gaps are and where we need to make progress. We need to make sure that that close relationship continues in a way that doesn't jeopardize the American public.

Second area is the deep scientific expertise that we have across the agency that has been -- contributed to maintenance of the SNS so that when we need clinical guidance for children for anthrax countermeasures, we can get that best advice incorporated. We need to make sure that that continues, but we are well on the way of executing that seamless transition.

Mr. Harper. The gentleman yields back.

The chair will now recognize the vice chair of the subcommittee, the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. Griffith. Thank you, Mr. Chairman.

After a series of safety lapses in 2014 involving the mishandling of anthrax and smallpox, in response to recommendations from a lab safety expert panel, both the FDA and CDC formed new offices to provide centralized oversight of laboratory safety and

science.

Rear Admiral Hinton, I have several questions for you regarding the FDA's Office of Laboratory Science and Safety.

First, how many labs does the FDA have, or oversee?

Admiral Hinton. The FDA has 56 lab facilities.

Mr. Griffith. And do you oversee more than that?

Admiral Hinton. No. We have -- no.

Mr. Griffith. And do you -- are those all -- are you counting everything in a single building, or is that all your labs combined?

Admiral Hinton. Those are the facilities. Within those facilities, there might be a total of 2,800 rooms, with those rooms, you know, being described as, you know, a space, you know, an office, a closet.

Mr. Griffith. Yes, ma'am.

How many safety inspections of these labs were conducted by the OLSS over the past year?

Admiral Hinton. No inspections have been conducted by OLSS in the past year. However, their labs have been inspected by other entities.

Mr. Griffith. Okay. Have there been any laboratory-acquired infections at FDA labs during the past year?

Admiral Hinton. There have been two noted infections within the last year. The staff that had acquired those infections have been observed and the case is closed.

Mr. Griffith. All right. And can you get us the reports on those two incidences, please?

Admiral Hinton. I'll work with my staff to get that to you.

Mr. Griffith. Thank you very much.

Likewise, have there been any potential exposures to threat agents at FDA labs during the past year?

Admiral Hinton. Not to my knowledge. No.

Mr. Griffith. All right. At tab 5 in the document binder is a September 2016 letter to the FDA sent the committee indicating its intention to hire 13 permanent full-time employees in the Office of Laboratory Science and Safety, OLSS.

The FDA told the committee this week that OLSS is staffed by only three permanent full-time employees, and three detailees.

Why doesn't the OLSS have the 13 permanent employees that were promised in a September letter of 2016?

Admiral Hinton. Sir, we have put forth the proposal, and as soon as we have the dedicated budget for OLSS, we expect for their current staff to double.

They actually have three permanent staff and three detailed working on this space.

Mr. Griffith. That still only puts you at six as opposed to the 13 that was indicated in 2016.

Admiral Hinton. I agree. And we note that, and then with the approval of the upcoming budget, we will be able to double that and they will have the 13 staff.

Mr. Griffith. The FDA, in the September 2016 letter, committed to this committee, and in July of 2017, published a notice in the Federal Register evaluating the OLSS so the office would directly to the FDA commissioner instead of the chief scientist.

Earlier this week, the FDA told committee staff that the FDA has decided to reorganize again, and that under the new proposal, OLSS will no longer be a direct report to the commissioner and will report to the chief scientist again, just as they did when we had the lapses back in 2014 and contrary to the expert panel's recommendations.

I just would like to know, first, is the chief scientist reporting to you now?

Admiral Hinton. I am the chief scientist. But the Director of OLSS --

Mr. Griffith. Is OLSS reporting to you?

Admiral Hinton. Yes, sir.

Mr. Griffith. And then you report on up the line?

Admiral Hinton. Yes. I do.

Mr. Griffith. So why did FDA reverse course in less than a year and decide to have the OLSS revert back to reporting to the chief scientist?

Admiral Hinton. Well, sir, since that was announced, we have had the chance over the past year to observe and to see where it might be best fit for the alignment within the office.

Within the office of the chief scientist, which reports into the office of the commissioner and to the commissioner, we work on cross cutting cross-scientific issues to include those within laboratory science space.

So we thought that the OLSS would be best aligned there under my direct supervision on their day-to-day activities. The commissioner will be fully apprised of those activities.

Mr. Griffith. Well, and I certainly mean no disrespect to you, but that was the same setup we had when there were problems being reported and we had the expert

panel come in and give us recommendations, which FDA agreed to, and now you all are backtracking.

I understand different -- some different personnel, but it seems to me we're just creating the same problem we had before.

I see my time is up, and I have to yield back. Thank you, Mr. Chairman.

Mr. Harper. The gentleman yields back.

The chair will now recognize the gentlewoman from California, Ms. Walters, for 5 minutes.

Ms. Walters. Thank you, Mr. Chairman.

Dr. Bright and Dr. Schuchat, either through stockpile procurement or through other means, how do your agencies ensure we have sufficient diagnostic test capacity to identify cases of pandemic influenza or other infectious diseases?

Mr. Bright. In terms of development, so we have worked with a number of different manufacturers through the last 10 years to develop diagnostics for influenza, not only laboratory-based diagnostics, but to standardize and update the point-of-care diagnostics for influenza to make sure those are available and in the marketplace for use for pandemic and seasonal influenza detection.

Dr. Schuchat. Yeah. And I would say that CDC both develops assays and helps with validation.

You know, a number of years ago, there were quite a few point-of-care tests for influenza detection, and some of them didn't perform as well in the field as we had hoped. So we did quite an effort of validation comparison, shared the data with FDA,

and new labeling and improvements in the tests followed from that.

So we will develop tests against, you know, pandemic or avian flu and other high-threat concerns, develop them through to emergency use authorization when appropriate, 501(k) when possible.

The 501(k) final process is very labor intensive, very expensive, and there's a limited number of our tests that we are able to put through to that level. But we do work closely with FDA and BARDA on a number of the priority ones.

Ms. Walters. Thank you.

Dr. Fauci, you mentioned work by the National Institute of Allergy and Infection Diseases to support research involving diagnostic testing.

From a Homeland Security and public health perspective, multiplex point-of-care technologies are beneficial because they can be used to simultaneously test for multiple infectious disease pathogens with a single blood or urine sample.

Can you tell us about the research NIAID is doing with respect to multiplex point-of-care technologies and how these technologies enhance our ability to detect material threats and infectious diseases?

Dr. Fauci. Thank you very much for that question.

Yes. We are very heavily involved in that, both with our grantees to get concept to develop into something that's translatable, as well as contract.

There's multiplex, as you mentioned in your statement, is a very important tool of the future now for detecting outbreaks. For example, we have multiplex assays involving a whole series of particular types of viruses. For example, the flaviviruses, which are many of them that we have, particularly in the Western Hemisphere, that we

are involved right now in research for the development of a multiplex that would essentially cover all of the associated flaviviruses, and we're doing that with a number of other viruses.

So there's really a very important, I believe, and aggressive ongoing research program at the NIH, mostly through our grantees and contractors.

Ms. Walters. Okay.

Mr. Bright. If I can jump in, the challenge with the beauty of multiplex assays is that they can do a lot. And the challenge with them is they're very large instruments generally in centralized laboratories in a hospital or a public health laboratory.

The innovation that we're driving today with companies that move multiplex assays to point of care into a physician's office, and even to work with those multiplex technologies to push some of those now out into the home, one of our greatest challenges with our diagnostics for any disease is how long it takes for a patient to get to that system and into the system so they can get a sample drawn and can get a result.

Too much time elapses in that. So we're trying to also use this new technology for multiplex point of care to multiplex point of need into the home to get people earlier notification to empower patients to get treated sooner.

Ms. Walters. Okay. Thank you.

Rear Admiral Hinton, how many multiplex point-of-care diagnostic tests has the FDA approved for use?

Admiral Hinton. Thank you for your question, ma'am.

Work in this area is progressing well at FDA. We've cleared more than 25 multiplex tests that could be suitable for point-of-care tests.

Ms. Walters. Okay. And how many others are currently under assessment by the FDA?

Admiral Hinton. I'll have to get back to you. I don't have the exact number.

Ms. Walters. Okay. Can you describe the range of capabilities that these tests have? You know, how many diseases can one multiplex point-of-care diagnostic test detect?

Admiral Hinton. It can detect many. We can do up to 20, try to detect 20 up to -- and more than -- at one time, which is incredibly important, especially at the point of care so that we can help -- you know, help to easily detect in order to find the best treatment.

Ms. Walters. Okay. Thank you, and I yield back the balance of my time.

Mr. Harper. The gentlewoman yields back.

The chair will now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. Carter. Thank you, Mr. Chairman.

And, Mr. Chairman, I want to echo your comments earlier about what an outstanding panel this is. Thank you all for the very important work that you do. It is extremely important to our country, and we appreciate it very much.

Dr. Bright, I want to start with you. Being, of course, from Georgia, I am somewhat concerned, even still, about the move of the strategic National Stockpile and the management of that from the CDC to ASPR, and I just want to be assured again from you. I've met Dr. Redfield, and I think he's doing a great job. Dr. Schuchat and I have

worked together, and I just can't say enough good things about the CDC and the outstanding work that they do for our country.

And I just want to make sure that they're still going to have the opportunity to stay involved and to be involved in the medical counter-measurement development and everything else that goes along with the SNS.

Mr. Bright. Sir, you have my complete assurance. I echo your comments about the CDC and the great work they are doing. Many people don't know I got my first start in science at the CDC as an ORISE fellow coming from Emory University in Georgia.

I understand and appreciate the great scientific leadership of the CDC and their relationship with State and local and the value of that.

We plan to always include that in our assessment and our programs for the new strategic National Stockpile management.

Mr. Carter. We talked on it earlier. One of my colleagues had mentioned about the concern particularly for the -- that the transfer is not disruptive for the State and local agencies.

How can you assure us -- what would you suggest that we do to make that as least disruptive as we can?

Mr. Bright. Well, the most important thing is to recognize the value of their voice in the entire process, not just in the transition of the management of the SNS, but an entire end-to-end process of our efficient response to any emergency or public health emergency threat.

So we already have an intentional working group focusing on the State and local and Tribal and territory partners and their specific needs and their specific interests to

make sure those are encapsulated in our management of the SNS.

Mr. Carter. Great.

Dr. Schuchat, would you care to comment on that as well? How can well assure that this is not disruptive to our local and State communities?

Dr. Schuchat. I think that change is, by necessity, disruptive, and I think our job is to mitigate that disruption so that people aren't harmed. So I think it's on our radar. We're working really closely together. You know, the Association of State and Territorial Health Officers Board was just at CDC yesterday talking to us about how we can make sure this all goes as well as possible.

Mr. Carter. And let me ask you -- I run the risk of being a little self-serving here -- but wouldn't it make sense to look at perhaps just having ASPR co-locate down to Atlanta with the CDC? I mean, I recognize you're part of HHS, but, you know, we have to get out of the mindset that not everybody's got to be in Washington, D.C. I mean, we got a big country out here. Dr. Bright, I'm looking at you.

Mr. Bright. We have a big and beautiful country, sir, and I agree with you, and there is no intent to move the strategic National Stockpile from Atlanta to Washington, D.C. There might be one or two individuals who are located in our ASPR office to ensure we have smooth and efficient ongoing communication with the expert staff that is in Atlanta, Georgia.

Mr. Carter. Okay. Well, that might be a good compromise, and we appreciate that very much.

The Ebola crisis that we had, obviously it was -- you know, we learned a lot of lessons there, but I was so proud of the public/private partnership between Emory

University and the CDC, and all four patients recovered.

And I just wanted to know, will you be using that model in the future for other pandemics and other risks that we might run into? Because we're very proud of the work that was done at Emory University, and I think it's a great example of what we can do in the future.

Dr. Schuchat?

Dr. Schuchat. I would say that CDC benefits tremendously from being located right next to Emory, and there's a really close working relationship. We were fortunate that they such a terrific job in the Ebola -- in the care of the patients there.

There's ongoing collaboration and communication and support.

I think ASPR may have a more direct role in the hospitals and the care of such patients, and Dr. Bright might want to comment.

Mr. Bright. I also want to make sure that we capitalize and not lose that expert and lessons learned from Emory University.

As you may know, we stood up a National Ebola Training and Education Center. It's based in Nebraska as collaboration with Emory University, University of Nebraska, and Bellevue. It is an example of one the finest educational centers on Ebola and other epidemic treatments in the world now.

Mr. Carter. Okay. Again, I want to thank all of you for the work that you do. Extremely important, and especially shout out to CDC and the work that they do.

Thank you, and I yield back, Mr. Chairman.

Mr. Harper. The gentleman yields back.

The chair will now recognize the gentlewoman from California, Ms. Eshoo, for 5 minutes.

Ms. Eshoo. Thank you, Mr. Chairman, for extending the legislative courtesy to me, since I'm not a member of this subcommittee, but I have a great interest in the subject matter, since we're looking to reauthorize PAHPA and all of the listening to what's taken place in this hearing and the superb testimony from each one of you. We've made great progress since the legislation was first written in 2006.

So I'm pleased, but in America, we're never satisfied with exactly where we are. We always want to improve. And so there's been an important pathway of improvement, and I thank each one of you.

I'm very proud of the two women that are here. Rear Admiral Hinton, it's really a source of pride to me to hear you respond to the tough questions that have come your way. To Dr. Schuchat, it's always a pleasure to hear you. Dr. Bright, it's -- the partnership with BARDA has been a very important one, and I think that you're taking it to new places.

And to Dr. Fauci, I don't have any questions to ask you. I wish I could canonize you. You are such a gift to our country. Such a gift to our country. You could be in the private sector probably making millions of dollars. You've devoted your entire life to the people of our country, and you make the National Institutes of -- the NIH really stand for the National Institutes of Hope. You're a leader in that, and I just revere your record, your leadership, and what you've done and what you continue to do.

To Dr. Bright, how is restoring BARDA as a contracting authority led to increases in the efficiency and the certainty that surrounds the medical countermeasures at research

and development? That's my first question.

And my second one is, does your agency interpret your existing authority to allow the stockpile to invest in countermeasures other than those explicitly mentioned in the current statute?

Maybe start with the second question.

Mr. Bright. Thank you very much.

Ms. Eshoo. Do you need any additional authorities?

Mr. Bright. To be more effective, I believe we need to modify some of the authorities that we have to allow us to work more flexibly with our industry.

Ms. Eshoo. So you don't need additional authorities?

Mr. Bright. We don't need additional authorities. I believe we need to modify the authorities that we have.

Ms. Eshoo. What does that mean, modify the authorities?

Mr. Bright. Our other transactional authority, for example, does have limitations on how we can interface with our industry partners and how they might qualify for that type of partnership. So we have a draft of suggested language that might allow us that greater flexibility to do so.

Ms. Eshoo. And have you gotten that to us?

Mr. Bright. If it hasn't been sent to you yet, we will make sure that it is quickly.

Ms. Eshoo. Do BARDA's existing additional authorities promote work on the, and it's been brought up, not only at this subcommittee, but at others, of the antimicrobial resistance and the antibiotic development, or does your agency need additional authorities to engage in that work?

Mr. Bright. We've been working with the authorities we have since 2010 to address antimicrobial resistance.

One area of authority that is lacking, we believe, would be beneficial would be a specific authority for the appropriations for pandemic influenza, because there's a lot of critical work that needs to happen in pandemic --

Ms. Eshoo. Have you gotten that to us?

Mr. Bright. I do not have that authority yet.

Ms. Eshoo. Are you going to make that request of us?

Mr. Bright. I believe that request has been submitted. I hope so.

Ms. Eshoo. There was some mention earlier about how important the advanced -- I think you might have raised it in your opening statement, on advanced appropriations. I believe that, because the Senate has different rules on this, that we will meet the standard that needs to be met. That's probably the tidiest way for me to say it.

But it is critical, because if you don't have the advanced appropriations at BARDA, then our partners in the private sector are not going to be able to continue the important work that they're doing.

Mr. Bright. That's absolutely correct. They are business partners working in long-term cycles and forward-looking cycles, and the consistency and assurance of that advanced appropriations allows them to have that assurance that we will still be there doing our part so they can plan appropriately as well.

Ms. Eshoo. Thank you very much to each one of you for what you're doing for our country. You're all heroes of mine.

Thank you, Mr. Chairman. Yield back.

Mr. Harper. The gentlewoman yields back.

The chair will now recognize Ranking Member DeGette for concluding remarks.

Ms. DeGette. Thank you very much, Mr. Chairman, for the moment of personal privilege.

I wanted to bring up another issue that I think is a real crisis right now in this country.

I know we have a lot of HHS agency representatives here, and, of course, ASPR is under the purview of HHS.

Yesterday, our ranking member, Frank Pallone, wrote a letter to Secretary Azar about the HHS Office of Refugee Resettlement. And these kids who are being taken by their -- from their parents at the border, and then being put under the auspices of this agency, we have real concerns about what's happening to these children. And we have real concerns about their long-term prospects, being taken from their parents.

And, Mr. Chairman, I just wanted to bring this up, because you're going to be getting a request from the minority to have a hearing about this, and we would hope that you would seriously consider this, because we are quite concerned about the human aspects of this situation.

Thank you, and I yield back.

Mr. Harper. The gentlewoman yields back.

The chair will recognize Dr. Burgess for a concluding remark.

Mr. Burgess. Well, Mr. Chairman, thank you for the recognition.

I would just point out that this committee, and this subcommittee in particular, has a significant history of oversight on the ORR. I do feel obligated to point out this is not the agency that makes the decision about whether or not a family unit is kept together, but they are obligated to take care of -- whether a child arrives unaccompanied or is separated from their family at the DHS facility. But that is the responsibility of this -- in fact, the Health Subcommittee, and we do take that responsibility very seriously.

In fact, it was our work, our work, in July of 2014 that allowed them to acquire an actual physician to be in those facilities to assess those children as they were brought in.

And it was our committee that raised the question shouldn't we at least have some way of contacting the children after they have been placed with a family, at least on a voluntary basis.

So it was our committee that did that work, and that work will continue. I've been in contact with both Secretary Azar and with the gentleman that runs ORR, and I expect to have robust discussions with them going forward, and I yield back.

Ms. DeGette. If the gentleman will yield, thank you very much, and I look forward to working with you on this, because it's really a critical issue, and I'm on that subcommittee, too. Thank you.

Mr. Harper. I want to thank each of you for being here. Great insights and expertise, and I thank you for participating in today's hearing.

I remind Members that they have 10 business days to submit questions for the record, and I ask that the witnesses agree to respond promptly to any such questions.

With that, the subcommittee's adjourned.

[Whereupon, at 10:58 a.m., the subcommittee was adjourned.]