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EXAMINING THE REAUTHORIZATION OF THE

PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT

WEDNESDAY, JUNE 6, 2018

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123 Rayburn House Office Building, Hon. Michael Burgess [chairman of the subcommittee] presiding.

Members present: Representatives Burgess, Guthrie, Barton, Shimkus, Blackburn, Latta, Lance, Griffith, Long, Brooks, Mullin, Hudson, Collins, Carter, Walden (ex officio), Green, Engel, Schakowsky, Matsui, Castor, Eshoo, DeGette, and Pallone (ex officio).

Staff present: Karen Christian, General Counsel; Paul Eddatel, Chief Counsel, Health; Margaret Tucker Fogarty, Staff Assistant; Ali Fulling, Legislative Clerk, Oversight & Investigations, Digital Commerce and Consumer Protection; Ed Kim, Policy Coordinator, Health; Ryan Long, Deputy Staff Director; Kristen Shatynski, Professional Staff Member, Health; Alan Slobodin, Chief Investigative Counsel, Oversight & Investigations; Danielle Steele, Counsel, Health; John Stone, Senior Counsel, Health; Austin Stonebraker, Press Assistant; Josh Trent, Deputy Chief Health Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Jessica Wilkerson, Professional Staff, Oversight & Investigations; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Samantha Satchell, Minority Policy Analyst; Andrew Souvall, Minority Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

Mr. Burgess. Let me just ask all of our guests to please take their seats. The Subcommittee on Health will now come to order. The chair recognizes himself for five minutes for an opening statement.

But first, you know, as auspicious as we gather today it is a day that is so steeped in history. Last night was the California primary election. We all remember 50 years ago after the California elections when the country lost Senator Robert Kennedy.

This is also the 74th anniversary of the landing in Normandy and D-Day. This is the 100-year anniversary of the battle of Belleau Woods when the Marines basically initiated World War I for the United States of America, and it is 100 years since the Spanish Flu ravaged not just our country but the world.

So it's appropriate that we convene today to authorize the Pandemic All-Hazardous Preparedness Act. Again, a century ago, our country was in the worst pandemic in its history, claiming the lives of almost 700,000 Americans and killing more than 50 million people worldwide.

We have elicited testimony and we will discuss this critical legislation. It is paramount that we remember the significance of this centennial anniversary.

Sporadic flu activity has been spreading through the United

States, Europe, and Asia in the months following in the country and our soldiers faced an illness that we were not prepared to handle.

In that October over a hundred years ago, more than 100,000 Americans died as a result of the Spanish flu. It goes without saying that we have indeed come a long way. A century later we were substantially more prepared. As we consider this legislation we must remember that there is more to be done to support America's public health security.

The creation of the assistant secretary of preparedness and response under the original legislation in 2006 has helped us to make monumental strides in preparedness, coordination, and response.

Close collaboration and efforts between the Centers for Disease Control, the Food and Drug Administration, our local, state, and tribal and territorial health partners has been vital in making progress in this regard.

Much like politics, public health is local and it is executed on the ground by our hospitals, by our health departments, and our emergency responders who are our front lines addressing infectious diseases, disasters and threats.

I do want to thank my fellow Texan on our second panel, Dr. Umair Shah, for being here today and to share his testimony and

for his leadership in protecting the health of Harris County, Texas.

Recently, Dr. Shah and his team responded on the front lines for Hurricane Harvey, which caused such catastrophic damage in the Houston metropolitan area and did require a large coordinated response from all of the organizations that we had before us today.

You'll hear more about critical issues that must be addressed to continue and strengthen the nation's preparedness and response capabilities. We will talk about proposals to strengthen the Strategic National Stockpile, our cache of live saving medications and supplies for public health emergencies.

We also must address the policies that affect our regional disaster response system. It is essential the program continues to integrate and coordinate at the local level.

Additionally, we must provide assurances to protect those who respond to our health emergencies. We will also discuss sustaining the robust and reliable security capabilities such as disease surveillance, containment, risk, and countermeasure distribution.

We must evaluate the domestic biologic surveillance systems such as BioWatch, taking a closer look at what can be done to bring these programs up to date so that they are operating with

the most efficient technologies and capabilities.

I believe we must look for innovative ways to continue to advance medical countermeasures, ensuring that Americans can access medications that will provide critical protection in the future.

As we consider the problem of antimicrobial resistance in this country, we must address new methods to curb this growing problem.

Front line facilities and responders in Dallas, Texas experienced this first hand in 2014 when a patient presented with Ebola in a D/FW emergency department. We must remember that infectious diseases are a mere plane ride away and we must continue to ensure that we are prepared and ready to respond.

This pandemic all-hazards preparedness reauthorization is critical in protecting the lives of all Americans and providing the necessary tools and infrastructure to ensure that they are in place when disaster strikes.

I want to thank both Representative Susan Brooks and Anna Eshoo for working on this draft legislation which is being considered today.

Lastly, I want to thank all of our witnesses for testifying before us this morning. I do look forward to a productive discussion on a broad array of issues that will be the focus of

this authorization.

And will yield the balance of my time to the gentlelady from Tennessee, who I believe is celebrating a birthday on this day rich in history.

Mrs. Blackburn. I am, indeed, celebrating a birthday and I thank you for yielding.

Thank you all for being with us to discuss this. We have focused so on how the response ought to be to address our national disasters and our natural disasters, and this has been a process.

We have worked with our friends in the Senate, our friends here. As you know, this is something we have done in a bipartisan manner so we thank you for your time, and I yield back to the gentleman.

Mr. Burgess. Chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentleman from Texas, the ranking member of the subcommittee, Mr. Green, five minutes for an opening statement, please.

Mr. Green. Thank you, Mr. Chairman, and again I'd like to welcome the panels -- both the first panel and I particularly want to thank Umair Shah, the executive director of Harris County Public Health, for joining us this morning on the second panel.

They help keep my constituents healthy.

Events in recent years including natural disasters, cyber terrorism, influenza epidemic has posed a threat to our public health systems and our national security.

PAHPA provides a framework that allows us to address in a coordinated way various threats both natural and manmade. As a founding member of the Congressional Public Health Caucus and a long-time advocate for public health, I hope our committee will look at the very real threat that antimicrobial resistance poses.

Antibiotics and antimicrobial agents have been used for the last 70 years to treat patients who have infectious diseases. These drugs greatly reduce illnesses, death, and infectious -- from infectious diseases.

However, these drugs are being used so widely and for so long that the infectious organisms that the antibiotics are designed to kill have adapted to them and make the drugs less effective.

Each year in our country at least 2 million people become infected with bacterial that are resistant to antibiotics and at least 23,000 people die annually as a result of these infections.

In the past years, the Generating Antibiotic Incentives Act

-- GAIN -- and the Antibiotic Development of Advanced Patient treatment -- ADAPT -- have sought to address both the economic hurdles and the regulatory barriers to the development of new antibiotics.

Through the reauthorization of PAHPA we need to ensure that the proper incentives are in place that will lead to investment in the development of new antibiotics and antimicrobial agents.

I believe the creation of a market entry reward program that incentivize the manufacturers to develop novel antibiotics would provide the best bang for our buck in this space.

I'd like to work with my colleagues and I have over the years with Congressman Phil Gingrey recently on our committee and also currently with Congressman Shimkus. I'd like -- it's such a critical issue.

In addition to addressing antimicrobial resistance, we also need to further consider the proposal to move the Strategic National Stockpile -- SNS -- from CDC to the office of Assistant Secretary for Preparedness and Response.

My home state and our district has -- was heavily impacted by Hurricane Harvey last year in response to the flooding. The SNS was deployed to Houston and provided needed material to help local and state health departments respond to the overwhelming needs of the community.

SNS had been deployed countless times since its inception. It was placed in CDC over the years. CDC has worked closely with state and local health departments to respond to public health emergencies.

Before our committee codifies any change in the SNS, we must learn whether it's the best policy to advance human health. Additionally, as we have discussed the move of the stockpile from CDC to ASPR we have to ensure that the systems and networks which have been in place are not disrupted in order that the stockpile may be deployed successfully when needed.

Mr. Chairman, I yield the remainder of my time to my colleague from California and co-sponsor of the bill, Congresswoman Eshoo.

Ms. Eshoo. I thank the gentleman for yielding, and welcome to the witnesses. And Mr. Chairman, thank you for your opening remarks, especially about the 50th anniversary of Senator Robert Kennedy.

In 2001, our nation endured the attacks of September 11th and the anthrax attacks shortly after that. It was one of the most grueling times, I think, in the modern history of our country.

Congress realized that our country was not prepared to coordinate responses to mass casualty events or chemical attacks. I authored legislation with then Representative Richard Burr, who was a member of the committee, that established the Office

of the Assistant Secretary for Preparedness and Response -- we refer to it as ASPR -- to be responsible for coordinating federal responses and the Biomedical Advanced Research and Development Authority we call BARDA to be responsible for developing the needed medical countermeasures for chemical, biologic, radiological, and nuclear threats.

That important bipartisan legislation, the Pandemic All-Hazards Preparedness Act -- or PAHPA -- was signed into law in 2006.

The threats we faced in 2001 have not gone away. They have evolved and new threats have emerged and that's why it's important that this committee work to reauthorize PAHPA in a timely manner before it expires at the end of this fiscal year.

We need to give the agency the tools that they need and the resources they need to respond to the threats that confront us.

This is a discussion today and I think all members need to keep that in mind because stakeholders and others have not seen their suggestions come into a draft yet.

So I think all members need to keep that in mind and I'd like to compliment Congresswoman Brooks. I couldn't have a better partner in this.

So thank you, Mr. Chairman. I yield back.

Mr. Burgess. The chair thanks the gentlelady. The

gentlelady yields back.

The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, five minutes for an opening statement, please.

The Chairman. Well, thank you, Mr. Chairman. Thanks for your leadership on this issue and that of Ms. Eshoo and Mrs. Brooks as well. I know we will be hearing from both of them even more during this process.

I appreciate their work together on this. They've been the team leaders for this for our committee.

Since the terrorist attacks of September 11th, 2001, our country has taken important steps to fortify our health preparedness and response infrastructure.

The federal government has recognized that we must foster development of important medical countermeasures in the event of a potential chemical, biological, radioactive, or nuclear attack.

Preparing for and responding to these kinds of incidents and mass casualty events requires the collaboration of all levels of government with hospitals, biotech firms, community leaders, members, and other partners both public and private all across the country.

Recent diverse threats illustrate the importance of our

country having an effective and an efficient emergency preparedness system in place.

In the last few years alone, we have seen the arrival of the Zika virus, last year's devastating hurricane season, the WannaCry malware outbreak, and looking ahead, I can think about other prospects including the projected devastating earthquake of Cascade event that they predict could hit the Oregon coast as it has hundreds and hundreds of years ago.

In 2004, Congress authorized Project BioShield. I was here when that happened, and later in 2006 enacted the Pandemic and All-Hazards Preparedness Act.

In addition to establishing a strategic plan to direct research, development, and procurement of medical countermeasures, PAHPA also created the Assistant Secretary for Preparedness and Response -- ASPR -- and the Biodefense Advanced Research and Development Authority -- BARDA -- within the Department of Health and Human Services.

So today's hearing really will take a closer look at this bipartisan discussion draft led by our colleagues, Susan Brooks and Anna Eshoo. Thank you both for your leadership on this bill.

This bipartisan bill builds upon our previous work to modernize our health preparedness and response systems, ensuring that we are well equipped across all levels and government

agencies to handle current emergency -- emergent bio threats, chemical attacks, radiological emergencies, cybersecurity instances, and mass casualty events.

This is an important conversation. It's an important issue. We will move forward. We will move forward expeditiously.

We realize there is a deadline ahead for reauthorization and so we look forward to getting your feedback as we -- as we put this legislation into final form and move it through this committee.

With that, I'd yield the balance of my time to the gentlelady from Indiana, Mrs. Brooks.

Mrs. Brooks. Thank you, Mr. Chairman, and thank you for holding this hearing today to examine the issues surrounding the reauthorization of PAHPA.

I am proud to be working on this important bill with my good friend, Representative Eshoo, who was one of the authors of the first PAHPA bill in 2006 as well as the lead author of the last reauthorization in 2013.

As everyone here knows, this is not a question of if we will face a threat. It is more of a question of when we will face the threat. The threat of chemical, biological, radiological, or nuclear incidents continues to grow.

Every day our adversaries are looking for more effective

and faster ways to produce a threat. We have already faced threats from naturally occurring outbreaks such as Ebola and Zika as well as from hurricanes.

In addition, cyber-attacks like the WannaCry incident illustrate the vulnerability of our public health system. Reauthorizing PAHPA is an important public health and national security issue and I look forward to working with all members of the committee on this bipartisan effort.

The discussion draft bill that we have written creates a PAHPA -- a public health emergency respond fund for the HHS secretary to use as a funding bridge when we face an outbreak like Ebola so that immediate funding is available so that we can supplement them with an emergency appropriation bill.

The bill strengthens the hospital preparedness program to improve surge capacity by allowing grantees to use federal funding for health care surge capacity response activities in addition to the preparedness activities.

It establishes a pandemic influenza program as well as an emerging infectious disease program at BARDA. Our bill includes and this draft includes requests from CDC, ASPR, HHS, and FDA, and we look forward to working with everyone to improve the bill and ensure that it's ready for introduction later this month.

Thanks the PAHPA, already we have seen 14 products placed

in the Strategic National Stockpile to be used in an emergency. Our bill increases funding for the Strategic National Stockpile to $610 million per year in order to keep the authorized level consistent with what we have currently appropriated.

In addition, the bill codifies moving the SNS from the CDC to ASPR but, really, it's more an appropriate realignment of the responsibilities and it's a move that the administration is already making. And so it seems as members of Congress it's important that we provide that oversight and the guardrails for any move or any changes.

PAHPA reauthorization is a unique opportunity to examine our response to all threats and ensure we look forward to the future, that we have the procedures, the resources, and the support in place to protect ourselves and our citizens, and I look forward to hearing from our witnesses this morning.

I yield back.

Mr. Burgess. And the chair thanks the gentlelady. The gentlelady yields back.

The chair now would like to recognize the ranking member of the subcommittee -- ranking member of the full committee, Mr. Pallone of New Jersey, five minutes for an opening statement, please.

Mr. Pallone. Thank you, Mr. Chairman.

Today, we will examine the reauthorization of a critical law known as the Pandemic All-Hazards Preparedness Reauthorization Act, or PAHPA.

It's designed to prepare for and respond to health security events and emergencies that unfortunately are all too common, and these include bioterrorism acts, the spread of emerging infectious diseases, and natural disasters.

In order to effectively prepare for and respond to these types of events, we must have extensive coordination between federal, state, local, and tribal governments and the private sector organizations, and the critical programs included in this law help to accomplish that goal.

That's why I am disappointed that on a bill of such magnitude my staff and our witnesses including the administration did not receive the draft legislation until late last week.

This has been a very broken legislative process to date, and now the administration is limited in the feedback it can provide on the specific provisions of the bill.

And I hope, moving forward, we will work together to ensure that these policies are fully understood. Federal funding and support for local, state, and tribal public health activities is critical to saving lives.

This existing public health infrastructure is how we respond

to all types of hazards. Unfortunately, our public health capacity and infrastructure is not as strong as it could be.

Public dollars have been depleted and the workforce has shrunk. Public funding is also not stable or reliable from year to year, making planning across all levels of government difficult.

I am worried that there is a lack of public health funding at a time when communities are facing increased need. For example, climate change is creating conditions for increased extreme weather events.

Last year, hurricanes in Texas, Florida, Puerto Rico, and the U.S. Virgin Islands placed significant stress on our public health system and we need to increase public health funding including to programs authorized by this bill to bolster both our ability to prepare for and respond to these threats.

While I am generally supportive of the draft bill, I'd like to outline some specific concerns and questions. First, the public health emergency response fund is funded under transfer authority, and this is short-sighted.

We witnessed the downside of this approach firsthand during the Zika outbreak when the Republican Congress forced the administration to fund our initial Zika efforts through transfers of existing appropriations.

As a result, a state like Michigan, which was confronting its own public health emergency -- the Flint water crisis -- had some of its public health funding sent to states at high risk of local Zika transmission.

Michigan lost funding that it could have used to address its own crisis in Flint and we shouldn't have to pick one crisis over another. New real funding should be put in this fund.

Second, I have yet to hear a strong argument for moving the Strategic National Stockpile -- or SNS -- from the Centers for Disease Control and Prevention to the Assistant Secretary of Preparedness and Response -- or ASPR -- in statute.

The secretary of HHS has already started the process of moving the SNS under existing law and I see no reason to codify this move before we know the consequences.

We must make certain that placing the SNS in ASPR instead of CDC does not weaken our current preparedness and response capabilities before making such a move permanent. From what I can tell, we are trading some debatable improvements and procurement efficiency on the front end for the ability to more effectively reach communities and individuals with the materials they need in case of a public health emergency, and I would argue that ensuring that we can reach people with potentially lifesaving drugs and medical supplies in the event of a public health

emergency must be our top priority.

CDC has the relationships and expertise that make the most sense managing and operationalizing the stockpile as well as the record of successful stewardship of the SNS.

And third, I have numerous questions regarding the intent of the cybersecurity language in this draft. As many are aware, the Oversight and Investigations Subcommittee has been working on this issue and has discovered challenges regarding internal and external cybersecurity preparedness within HHS.

I agree we need to do more to protect our health system from cyber-attacks and the potential interruptions of care because of these attacks.

However, we need to make certain that placing increased cybersecurity authorities within ASPR as part of other emergency preparedness and response programs is the optimal solution, and if it is, that we authorize the resources to support any new authorities.

Simply adding the word cybersecurity to certain programs within the Public Health Service Act and FDA's emergency use authorities will do little to boost our preparedness and response for cybersecurity threats unless it is done thoughtfully and with consideration for the problems we are trying to solve.

So I look forward to learning what exactly the role of the

assistant secretary for preparedness and response would play under this legislation in the event of a cybersecurity attack on the health care system.

I believe we should evaluate this legislation, Mr. Chairman, based on whether Americans in all corners of the country will be safer or not, and I look forward to continuing our work on this bill.

So thank you, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back.

This concludes member opening statements and the chair would remind members that pursuant to committee rules all members' opening statements will be made part of the record.

And we do want to thank our witnesses for being here this morning and taking the time to testify before the subcommittee.

Each witness will have the opportunity to give an opening statement followed by questions from members.

Our first panel this morning we will hear from Dr. Robert Kadlec, assistant secretary for preparedness and response from the United States Department of Health and Human Services.

We will also hear from Rear Admiral Stephen Redd, director of the Office of Public Health Preparedness and Response, Center for Disease Control and Prevention, and Ms. Anna Abram, deputy

commissioner for policy planning, legislation, and analysis at the United States Food and Drug Administration.

We appreciate each of you being here today and, Dr. Kadlec, you're now recognized for five minutes to summarize your opening statement, please.

STATEMENTS OF DR. ROBERT KADLEC, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; REAR ADMIRAL UPPER HALF STEPHEN REDD, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; ANNA ABRAM, DEPUTY COMMISSIONER FOR POLICY, PLANNING, LEGISLATION, AND ANALYSIS, U.S. FOOD AND DRUG ADMINISTRATION

STATEMENT OF DR. KADLEC

Dr. Kadlec. Thank you. Good morning, Chairman Burgess, Ranking Member Green, and distinguished members of the committee.

I am Dr. Bob Kadlec, the Assistant Secretary for Preparedness and Response -- ASPR. Thank you for this opportunity to appear before you today as you consider the second reauthorization of the Pandemic All-Hazards Preparedness Act.

This committee championed the drafting and passage of PAHPA more than a decade ago and I want to acknowledge the original vision and leadership of Representative Mike Rogers and Anna Eshoo, now under the stewardship of Representative Brooks and Representative Eshoo as well. Thank you again for your hard efforts in this work.

One of our Constitution's sacred obligations to our citizens is to provide for the common defense, to protect the American

people, our homeland, and our way of life.

The ability of our nation's public health and medical infrastructure to quickly mobilize a coordinated national response to 21st century threats like pandemics, deliberate attacks, and natural disasters is a national security imperative and is at the heart of my efforts at the ASPR.

When ASPR was originally established by PAHPA, the objective was to answer a very simple question -- who's in charge of federal public health and medical preparedness and response functions.

The approach adopted was modeled on the Goldwater-Nichols Act that created the unity of effort at the Department of Defense. My goal is to ensure that we can mobilize the capabilities of the federal government to support state, local, tribal, and territorial health authorities to save lives and protect Americans.

I have four key priorities: provide strong leadership, develop a regional disaster health response system, advocate for CDC sustainment of robust responsive public health security capabilities and advance an innovative medical countermeasure enterprise.

I will elaborate on two of these. The importance of national health care readiness and medical surge capacity was highlighted

during the last hurricane season when ASPR led federal medical and public health response and recovery activities under the national response framework.

We worked closely with FEMA and state and territorial health officials to augment health care with HHS disaster medical assistant teams, many of whom are your constituents who are health care providers, and public health commission core officers as well as physicians and health care providers from the VA, Department of Homeland Security, and the Department of Defense.

As we speak, we are implementing many lessons learned from the hurricanes and from the 2014 Ebola outbreak two work with our colleagues across HHS and the federal interagency to better coordinate our national preparedness and response to the current Ebola outbreak in the Democratic Republic of Congo as well as actively monitoring the dynamic global national security landscape as well as the weather landscape.

As we look forward we are actively engaging our public and private partners in health care delivery to understand how we can most effectively improve their readiness for potential catastrophic threats.

I believe we need to modernize our existing programs to build a tiered regional system utilizing local health care coalitions and trauma center systems that integrates all medical response

capabilities, expands specialty care expertise in trauma and other related disciplines such as burn and radiation treatment, and incentivize the health care system to integrate measures of preparedness into daily standards of care. I call this the foundation of a regional disaster health response system.

The second area to highlight is our medical countermeasure enterprise. PAHPA established the Biomedical Advanced Research and Development Authority -- or BARDA -- which is the component of ASPR to bridge the so-called valley of death in the late stage of development of vaccines, drugs, and diagnostics where many products historically languished or failed.

By using flexible nimble authorities, multi-year advance funding, strong public-private partnerships, and cutting-edge expertise, BARDA has achieved a remarkable 35 FDA approvals.

Just yesterday, we announced an exciting new public-private engagement model called DRIVe -- the Division for Research, Innovation, and Ventures -- which is designed to accelerate innovation, address some of the nation's most pressing health security challenges and potentially affect major health care markets.

It is the brain child of this committee in the 21st Century Cures Act. At a time when synthetic biology and personalized medicine are not just conceivable but attainable, the time is

right to apply an innovative approach to some of the most daunting far-reaching health security problems such as sepsis and early diagnosis of infectious disease.

We are opening our doors to more innovators and, most importantly, investors to better leverage advances in science and technology.

Thank you again for your bipartisan commitment to this national security imperative. I am happy to answer any questions you may have.

Thank you.

[The prepared statement of Dr. Kadlec follows:]

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588 Mr. Burgess. The chair thanks the gentleman.

589 The chair now recognizes Rear Admiral Redd. Dr. Redd,

590 you're recognized for five minutes, please.

STATEMENT OF ADMIRAL REDD

Admiral Redd. Chairman Burgess, Ranking Member Green, and members of the subcommittee, I am Rear Admiral Stephen Redd, director of CDC's Office of Public Health Preparedness and Response.

Thank you for the opportunity to testify before you today to describe the role that CDC plays in public health preparedness and response including those responsibilities under the Pandemic and All-Hazards Preparedness Reauthorization Act.

Today, I will highlight CDC's role in protecting the nation against health threats and I will describe that in three areas -- preparedness, protection, and response.

Within that discussion, there are three themes that I would like you to appreciate -- first, the work that CDC does every day in public health lays the foundation for responding to emergencies; second, CDC's world-class scientific and medical expertise ensures we are 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 responses.

Let me first address the issue of preparing 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.

Our 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.

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

Turning now to detecting threats, CDC's laboratories and surveillance systems are able to detect and identify agents causing illness, whether that cause is microbial or from chemical or radiation exposure.

Every year, laboratories from all over the world send several hundred thousands of specimens to CDC because they know that we will be able to identify pathogens other laboratories cannot.

Rapid identification of disease permits intervention before a health threat becomes a crisis. CDC's laboratory response network maintains an integrated, scalable, and flexible system of 153 federal, state, and local laboratories.

The development of this network over the past 15 years has

provided a larger capacity to test and report more quickly than was possible before. For example, during the Zika outbreak, CDC and other laboratory response network laboratories processed over 207,000 specimens.

Now, turning to response, when there's a crisis, CDC responds. We are able to deploy scientific and medical experts anywhere in the world.

For example, by the end of the 21-month Ebola response, 3,700 CDC staff, more than a quarter of our workforce, shifted from their day-to-day duties to assist in the response.

Fifteen hundred staff deployed to West Africa, accounting for over 2,000 trips. Today, we are responding to the much smaller outbreak in the Democratic Republic of Congo.

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

Being able to prepare for, detect, and respond to public health threats is a top priority for CDC. Our preparedness and response capabilities are built on a broad and deep scientific medical and program expertise.

Our longstanding partnerships with state, local, and public health authorities assured an integrated approach wherever that approach is needed, resulting in better responses and better public health outcomes.

Thank you for the opportunity to testify here today. I look forward to answering your questions.

[The prepared statement of Admiral Redd follows:]

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669 Mr. Burgess. Thank you, Dr. Redd.

670 Ms. Abram, you're recognized for five minutes, please.

STATEMENT OF MS. ABRAM

Ms. Abram. Thank you.

Chairman Burgess, Ranking Member Green, and the other members of the committee, thank you for the opportunity to appear today and discuss reauthorization of the Pandemic and All-Hazards Act, or PAHPA.

Medical and public health preparedness and response is of critical importance to the health and security of our nation and I am pleased to be here today to share how FDA is working toward the shared goal of making sure we have the medical products we need to protect Americans from a range of public health threats, whether naturally occurring, like a pandemic, or the result of a deliberate attack.

We are reminded of the urgency and need to remain ever vigilant against identified and emerging public health threats as we carefully monitor the current outbreak of Ebola virus disease, this time in the Democratic Republic of Congo.

I can assure you that FDA is dedicated to helping end this outbreak as quickly as possible and we are actively engaged with our federal colleagues testifying here with me today, as well as with medical product developers, international organizations including the World Health Organization, to support international

response efforts.

This most recent Ebola outbreak accentuates the continuing threat posed by emerging infectious diseases, which can and often do emerge with little to no warning and the need for us to continue to optimize our preparedness and response capabilities.

PAHPA, which was passed in 2006 and reauthorized in 2013, in addition to other key pieces of legislation that has served to significantly strengthen our nation's preparedness and response capabilities to respond to public health emergencies involving chemical, biological, radiological and nuclear -- or CBRN -- threats as well as emerging infectious disease threats such as the Zika virus, Ebola virus, and pandemic influenza.

Prior to joining FDA, I worked for more than a decade on health care policy with your colleagues in the United States Senate, serving as a health policy director to U.S. Senator Richard Burr from North Carolina on the Health, Education, Labor, and Pensions Committee for many years.

In that capacity, I collaborated with colleagues serving in the United States House of Representatives, including this committee, and it's nice to see some of those colleagues here today.

I was actively involved in working on a range of health care issues and my tenure was very much highlighted by my work on

medical and public health preparedness and response issues including the bipartisan 2013 PAHPA Reauthorization ACT, or PAHPA, and more recently the 21st Century Cures Act.

PAHPA recognized the key role FDA plays in emergency preparedness and response and codified and built on FDA's ongoing efforts to augment our review processes and advance regulatory science to enable better response to public health emergencies and emerging health threats.

The provisions in PAHPRA have been critical to FDA's efforts to drive innovation in the medical countermeasure space and have provided FDA with essential tools that continue to support our mission to protect and promote public health.

At FDA we've made it a priority to utilize these 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 medical countermeasures as part of advancing public health and strengthening our national security.

We share Congress' goal to have safe and effective medical countermeasures available in the event they are needed and we have made key progress towards this important goal.

As of the end of fiscal year 2017, FDA has approved, licensed, or cleared 121 medical countermeasures including supplementals

to approvals, licensures, and cleared medical products.

We have issued more than 60 emergency-use authorizations since 2005 including about 40 since 2013, including for Ebola and Zika. Medical countermeasures can face unique development challenges that require medical product sponsors to rely on animal models because even efficacy trials would not be ethical.

PAHPRA required FDA to issue final guidance regarding the development of animal models to support the approval and clearance of medical countermeasures.

FDA finalized this guidance in October 2015 and to date, 13 medical countermeasures have been approved under the animal rule including the approval of a new indication for a medical countermeasure to increase survival of adult and pediatric patients acutely exposed to myeloid suppressive doses of radiation as could occur after a radiological or a nuclear event.

This is the third FDA-approved medical countermeasure that is indicated to increase survival in patients exposed to myeloid suppressive doses of radiation.

Other approvals under the animal rule include inhalational anthrax therapeutics of botulism anti-toxin, antibiotics for the treatment and prophylaxis of plague, prophylaxis against the lethal effects of some nerve agent poisoning and treatment of known or suspected cyanide poisoning.

We have been actively implementing the new authorities within our medical countermeasures initiative, specific to our engagements with the Department of Defense as well.

In January of 2018, the agency launched enhanced engagements with the Department of Defense under a joint program to prioritize the efficient development of safe and effective medical projects intended for our U.S. military personnel.

We are fully committed to working with our colleagues at the Department of Defense to support the needs of our U.S. military personnel and look forward to continue to enhance collaborations in these endeavors.

Finally, I am pleased to share that today we are releasing our medical countermeasures initiative program update which highlights the many notable achievements the agency has made to advance the development and availability of safe and effective medical countermeasures in fiscal year 2017.

This report provides an in-depth insight into the breadth of activities and the progress FDA has contributed to our nation's medical countermeasure assets.

FDA remains deeply committed to working closely with its partners and fully using the authorities and resources Congress provides us to advance this mission.

We look forward to partnering with this committee and the

Senate in the reauthorization of PAHPA. Thank you again for the opportunity to testify today and I would be happy to answer any questions.

[The prepared statement of Ms. Abram follows:]

**********INSERT 3**********

Mr. Burgess. Well, I thank you for your testimony. I thank all of our witnesses for their testimony. We will proceed to the question and answer portion of the hearing.

Let me recognize myself for five minutes for questions and, as always, I will run out of time before I finish questions. So we will be submitting some for the record.

Ms. Abram, let me just ask you, several years ago in the middle of a flu epidemic in Fort Worth, Texas, I came home one Thursday night to the Channel 8 news and they said the FDA was making available expired Tamiflu to the area hospitals.

So, as you can imagine, Dr. Hamburg and I had a call the next morning, and she assured me that expired Tamiflu would in fact be just as efficacious. But as far as the Strategic National Stockpile goes, do you try to rotate stock in and out so we don't end up with an expired national stockpile?

Ms. Abram. So FDA supports the Strategic National Stockpile very much from a technical and regulatory perspective. Congress has given us the authorities to help to extend the shelf life of products.

So we will look at products to see if -- even if they have a certain expiration date that they've been assigned whether or not it would be appropriate and they could still convey a therapeutic benefit if they were used.

And I don't know if my colleague would like to add anything further to that.

Admiral Redd. That's exactly right. The products are maybe labelled expired but they're tested to assure that they haven't expired.

Mr. Burgess. So, Dr. Kadlec, let me just ask you -- of course, we had Ebola in Dallas, Texas, a few years ago and recognized the unified response was certainly necessary in that public health emergency and all systems need to be able to coordinate their efforts at the federal, state, and local level.

So can you perhaps enlighten us further how ASPR would identify partners who would be involved in this collaboration and enhance our medical surge capacity?

Dr. Kadlec. Yes, sir. In fact, during this Ebola outbreak we've -- basically, the secretary asked me to basically lead the coordination across the department. So we've been holding regular conversations with HHS partners as well as other federal interagency partners to do two things.

One is establish whatever is needed to support the response overseas, keep the disease over there rather than over here, and the second one is making sure that our capabilities domestically are prepared.

We do have the National Ebola Treatment Network that was

created with supplemental funding that runs out in fiscal year 2019 that created three centers -- national centers for the treatment of Ebola patients as well as 10 regional centers in addition to the NIH clinical facility here in Bethesda. So it was basically assuring that the training, the equipping, and the requirements were all up to date in terms of if their case should show up on our soil how would we respond.

Second is mobilizing the assets that were -- that were funded largely by BARDA, though NIH had some significant capabilities to include diagnostics that were basically made available and donated by the company to DRC as well as vaccines that BARDA supported with Merck that was deployed and has immunized and the folks down there, the responders, have immunized 1,100 folks so far in vaccination.

So there have been a number of activities that we've kind of monitored, coordinated on, and just ensured that we had everything kind of ready to go should this outbreak kind of take a different turn than it has so far shown.

Mr. Burgess. What we discovered two and a half years ago, whenever the previous outbreak occurred, is a state like Texas, where you have got some big distances between communities, hospitals were -- did form networks and were agreeable to helping each other at the same time. If you had a car show up with a

group of folks where high index of suspicion for a problem, all of the assets in a local area could be consumed very quickly.

Are you looking at how to -- how to deal with that?

Dr. Kadlec. Yes, sir. And beyond those 10 regional treatment centers we've also had 60 designated state Ebola treatment centers and 178 Ebola assessment hospitals. So we've really focused on the concentration of those skills and supplies necessary for those front -- you know, if you will, leading edge hospitals or clinics to basically initially evaluate patients, safely do so for themselves and for their patients and then make the referrals up the chain to higher levels of care and treatment.

Mr. Burgess. Let me -- let me ask you this. You stressed strong leadership several times in your testimony. I am grateful that you are where you are. I want you to be there.

But just in general, as far as your position is concerned, I mean, there are some -- there are some jurisdictional issues.

There are some Interagency issues. There has been some discussion about designating the office of the vice president as part of that central command. What are your thoughts about that?

Dr. Kadlec. Sir, in an operational sense, I think the ASPR performs a function as part of the national response plan. In

terms of orchestrating probably beyond the operational levels of the strategic levels, particularly for resourcing, having a friend or an ally at senior levels in the White House is a good thing.

Having served as a special assistant to the president during the Bush administration -- the second tour -- I can only say that having support by the vice president or someone of stature like his would be exceptional and very force multiplying in terms of having the support to get the resources to support what we need to do at the operational or at the tactical level.

Mr. Burgess. Thank you, and my time expired. I will recognize the gentleman from Texas, Mr. Green, five minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

Dr. Kadlec, antibiotic resistance is a real and growing problem. I think we all agree to that, that in occurring pandemics, chemical, biological, radiological, and nuclear attack medical counter measures need to be able to treat the initial injury from these attacks.

But, as you know, these patients may be suffering from burns and wounds, for example, that are susceptible to secondary bacterial infections. Antibiotics are an integral part of that with the growing threat of antibiotic resistance in public health

as well as preparedness and response efforts.

Can you tell us what role you see BARDA playing in shoring up this pipeline of new antibiotics?

Dr. Kadlec. Well, thank you for the question, sir, and BARDA has been very active in this area. They set up a program called CARB-X which is an active program which is interesting because it really forms as a model for what we believe the DRIVe program will look like.

It's the idea of creating private -- public-private partnerships and in this case CARB-X and BARDA has basically interactions with 28 different companies who make novel anti-bacterial drugs, vaccines, or diagnostics, and as a result of that, there have been identified eight new classes of antibiotics.

So that's important. But, significantly, for the taxpayer, $70 million of federal investment by CARB-X has resulted in about $485 million in private equity following that investment.

So not only are we trying to create new avenues and interest in this area which, quite frankly doesn't have a large commercial market for the drug companies, but we've worked effectively with the private sector to kind of build, I think, the requisite investment to identify promising candidates that we can move through the developmental cycle and pathway to ultimate

licensure.

Mr. Green. There are not enough new antibiotics in the pipeline. Almost 75 percent of those products in clinical development are based on previously-approved classes of antibiotics. Novel structures and approaches are needed to state ahead of the resistance -- innovative preclinical antibiotic approaches.

CARB-X is a global public-private partnership with BARDA and NIAID and other global partners ensure that a robust pipeline of preclinical innovation candidates that a product protect human health from the most serious bacterial infection.

Can you describe how BARDA, CARB-X, and NIAID are working to ensure that there are enough preclinical products moving on the -- on to clinical trials?

Dr. Kadlec. Well, sir, they do so by a variety of methods. Part of it is active -- I want to say query which is part of it. And again, I will just use the example that we hope to do -- to build on is using innovation accelerators around the country to basically identify promising candidates that could be antibiotics or antimicrobials that would be part of this CARB-X program or part of the larger innovation program.

So the thing is is that we work closely with NIAID on this. We do work with the Wellcome Trust as other organizations as

well as with companies to basically identify these.

Obviously, it's going to take long-term constant vigilance and, again creating new drugs is just part of the challenge, as Dr. Burgess would identify. Part of it is basically monitoring the environment and I think Dr. Redd can highlight on those pieces as well as practices by physicians in prescribing antibiotics.

Dr. Redd.

Admiral Redd. Yes. First of all, I want to acknowledge the significance of the problem, that if we run out of antibiotics, not just treatment of infects but things like cancer therapy and surgery are going to be much more difficult than they are today.

In addition to developing new products, there are steps that need to be undertaken and are being undertaken in the public health domain. First is just preventing infections in hospitals -- that bacteria in hospitals are -- it's where real resistance is bred.

Secondly is tracking and identifying infections when they occur with resistant organisms so that intensive infection control measures can be undertaken to prevent the spread of those organisms to other individuals.

And then thirdly, improving the prescribing of antimicrobial -- that if these drugs can be limited to the people who really need them, that will also slow the development of resistance.

Mr. Green. Is there any overlap between the CDC's investment in antibiotic resistance laboratory network and what ASPR does?

Admiral Redd. There's not. We are funding laboratory testing as part of the surveillance system to identify resistant organisms so that those interventions can be undertaken to prevent their spread.

Mr. Green. Well, and I want to thank the CDC because in 2005, after Hurricane Katrina in Louisiana, Houston, Texas got about a quarter of a million people from south Louisiana, and CDC was there bringing in the medications and also the public health officers to help our local medical schools and our hospital system.

So CDC is very valuable, and I yield back my time, Mr. Chairman.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Tennessee, Mrs. Blackburn, five minutes for questions, please.

Mrs. Blackburn. Thank you, Mr. Chairman.

Ms. Abram, I want to come to you for just a minute and talk a little bit about the stockpile and the definition that is there. It is in statute, defined to include drugs, biological products,

or devices.

And until 2016, when we passed 21st Century Cures and included in that the software act, which deals with medical technology, medical software had been included in that definition of medical devices.

And what happened or what we did in that was to remove some classifications of medical software from FDA oversight, and I know that you're familiar with the legislation and familiar that FDA is still in the process of implementing that law and making those determinations which products are going to go where.

And we recently -- I think it was the end of December -- received more guidance documents to that fact. Would -- so what I wanted to know from you is are there any types of medical software or applications currently in the stockpile that no longer fall under the device definition?

Ms. Abram. Thank you so much for the question. You alluded to this and mentioned it in your remarks. Yes, we are actively implementing a number of the provisions that were enacted as part of Cures including delineating in a risk-based manner the regulation of various devices and the software kind of components that get into that.

You know, traditionally, much of what has been procured into the stockpile has focused more on vaccines, therapeutics,

diagnostics, and some of the other materiel -- for example, I believe, like, personal protective equipment would be something purchased there.

And I would like to acknowledge that one of the additions to the draft that was released over the past week includes the concept of cyber security, which is, of course, a very important matter.

Mrs. Blackburn. Okay. Let me ask you this. Would you recommend that we amend the definition of security countermeasures to include medical software in applications when there is a clear need that some of these products may need to be procured?

Ms. Abram. So the addition of the cybersecurity references and the context of where that may interface here with the software considerations and device considerations has raised some novel questions and considerations.

And having just recently received the text we are having our subject matter experts look at it quickly because we understand this is an area of interest for the committee and we want to make sure we are providing very thorough and thoughtful input on these points because, as I mentioned, cybersecurity is, obviously, a very serious concern and we want to be responsive to it.

We have looked at it in the context of devices form a total produce life cycle approach. At the same time, much of the framework that you're referencing has traditionally been looked at in a CBRN context.

So this does raise some new questions for us. But we look forward to working with the committee and providing technical assistance.

Mrs. Blackburn. Well, I think that -- and probably Ms. Eshoo and Mrs. Brooks would agree with me -- when you all conduct that oversight and look at this and formulate an opinion, I think we would like to have that --

Ms. Abram. Absolutely.

Mrs. Blackburn. -- and include it in the information from this hearing.

Ms. Abram. Absolutely. We'd be happy to follow up.

Mrs. Blackburn. Okay. That would be -- that would be great.

Kadlec, let me ask you a little bit about -- we've had a bill here, the Good Samaritan Act, and of course, there is part of the language included in the Senate HELP's version of PAHPA, and I have worked on this for several years and I am appreciate that it is included. Part of that language is included here.

But I am interested to hear your thoughts on how we can truly

harness the services of health care professionals who are willing to volunteer their skills during emergencies.

And, you know, after Katrina we saw the need to get people into the area. After the Boston Marathon bombing, we saw the need to get people in.

So I would love a quick response on that.

Dr. Kadlec. Well, thank you, ma'am, for the question. And, clearly, there's a real significant role for volunteers in this situation. I think the best case scenario is when they identify before the crisis or the disaster happens and there are two programs that allow that -- Medical Reserve Corps and ESAR-VHP, which is a volunteer program to allow people to enroll so they can be identified.

I think the key thing is is, as many know, that sometimes even though volunteers come forward, their ability to help is going to be based on their knowledge and training. And so we would prefer that those people would be identified before an event and then we have confidence, you know, what to do and the right things to do so they do not cause any further injury or harm.

We are very supportive of volunteers. They're a critical part of the response as we've seen historically and we know in the future they'll be there as we witnessed in the cases of several events recently. So very supportive of this notion.

Mrs. Blackburn. I yield back.

Mr. Burgess. The gentlelady's time has expired.

The chair now needs to recognize the gentleman from New York, Mr. Engel, five minutes for questions, please.

Mr. Engel. Thank you, Chairman Burgess and Ranking Member Green, for holding this very important hearing.

I don't think we'll have properly considered pandemic preparedness without discussing the threat of antimicrobial resistance, a serious international drug crisis wherein diseases are able to resist the very drugs meant to destroy them.

To underscore the seriousness of antimicrobial resistance, I want to talk about tuberculosis, or TB, not only because Ranking Member Green and I are two of the co-chairs of the House TB Elimination Caucus, because TB and airborne infection kills more people worldwide than any other infectious disease, and drug resistant TB is the most common and deadly airborne antimicrobial resistant disease.

Cases of anti-resistant TB cost much more to treat than drug-sensitive TB in cases of multi-drug resistant TB, and extensively drug-resistant TB unfortunately becoming much more frequent.

While we may typically think drug resistance is caused by inappropriate treatment, most drug resistant TB cases are now

caused by transmission from person to person, making it much easier for drug resistant TB to spread to new parts of the world.

History has shown us that we cannot stop infectious threats with isolationist policies. We need to invest in new tools to keep Americans safe and the growing threat of antimicrobial resistance and the very real possibility that one day, unfortunately, there might be a drug-resistant outbreak in the United States.

So Dr. Kadlec, let me ask you what more can BARDA do to spur the development of novel antimicrobials and ensure that we have the tools we need to address antimicrobial resistance and improve health security in this country?

Dr. Kadlec. Thank you, sir, for the question and, again, I would just, again, like to reemphasize the role that BARDA does have in this area, working closely with NIAID and with foreign activities Wellcome Trust to basically create CARB-X, which is really the opportunity to pool resources to promote research into a variety of different potential candidates.

I mentioned the possibility of eight new classes of antibiotics. Do this date, 30 potential high-quality antibacterial products have been identified and are being evaluated for this.

So I think part of this is is realizing that there is a --

there is an ongoing activity that BARDA is working with NIAID on.

It's informed by CDC in terms of its role subject to monitoring the environment and identifying those cases and evaluating the sensitivities of those organisms, whether it be TB or anything else, quite frankly, and the ability to evaluate what we can do to promote renewed interest and research and commitment not only by the government but also by the private sector into these areas.

Mr. Engel. Thank you very much.

Let me also say, to truly protect Americans from health threats I believe we, obviously, cannot limit our focus to threats within the United States itself.

So Dr. Redd, you know from your years of service, including during the 2009 H1N1 pandemic and the 2014 West Africa Ebola outbreak, the disease that knows no borders, do you think it's important for the U.S. to evaluate the global threats to health security to ensure that we are prepared to face these threats?

Admiral Redd. Yes, sir. The work that has been done to strengthen global health security since 2014 is very important and needs to continue.

I think our work in the Democratic Republic of Congo is emblematic of the kinds of threats that we need to be able to

detect and, working with host countries, contain at the source.

Mr. Engel. Thank you.

Ms. Abram, would you like to comment on any of the things that I've mentioned?

Ms. Abram. I would just further add to some of the comments that my colleagues have made is that FDA is also actively involved in helping to foster and bring forward next-generation of antibiotic products.

We've been implementing the GAIN Act provisions and we've also been actively implementing the break points provisions that were included as part of the Cures Act, which are very helpful in helping to inform providers of proper utilization of the antibiotics that are available to treat.

Mr. Engel. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. Burgess. Gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Illinois, Mr. Shimkus, five minutes for your questions, please.

Mr. Shimkus. Thank you, Mr. Chairman. It's great to have you all. Thanks for your work.

Anyone who's followed this committee knows that I've been working on the antimicrobial resistance front for many, many

years. Good to see folks who have been in this battle.

You probably heard me say that we need to develop products we hope we never has to use. The fact is we are in a race, you all know, against antibiotic resistance by bacterial and fungal pathogens and we are losing because these diseases are developing resistance faster than our efforts can develop new agents.

And BARDA is very valuable to these efforts, but it's clear that BARDA's work, even combined with commercial potential, isn't enough.

FDA Janet Woodcock, CDC's Tom Frieden, and the National Institute of Allergy and Infectious Diseases -- I hate these acronyms so I use -- and NIAID's director, Tony Fauci, have joined every major country's assessment, acknowledging that there is simply very little incentive for biopharma companies to do the necessary R&D.

I want to first go to Dr. Kadlec but others can chime in if they'd like. Can you comment on why antibiotics are a focal point of BARDA's work?

Dr. Kadlec. For two reasons. As you defined, it is a public health challenge but, quite frankly, it's inextricably linked to the issues that relate to the more -- to other threats that may happen -- emerging infectious disease as well as deliberate threats.

So it would be a circumstance that you could anticipate I think as highlighted before either in cases of radiation exposure where the immune system is depressed or burns where the immune system is compromised. Infection becomes a significant consideration as well as if you had the intentional use of infectious diseases.

Mr. Shimkus. Would you -- would you agree that the situation is dire?

Dr. Kadlec. Sir, it's difficult and, depending on the agent or organism you're talking about, it can be dire, and for the individual who's afflicted by it, it is dire, quite honestly.

Mr. Shimkus. Can you commit or will you work with my office and this committee on solutions that spur the proper level of critically-needed antimicrobial development?

Dr. Kadlec. Yes, sir.

Mr. Shimkus. Mr. Green and I have been trying to deal with this over the past couple years. He did touch on this issue and you mentioned the ongoing activities.

But it's my understanding that these efforts may fall short when it comes to incentivizing development. Anyone want to comment on that observation? Admiral.

Admiral Redd. I think the point I was going to make is that these products are used in a system and the detection and infection

control procedures and assessment of effectiveness are all part of to ensure that these products are used to obtain the greatest effect.

More products are, clearly, needed but we also need to do better in who is prescribed antimicrobials, making sure that there is -- have as narrow a spectrum as is possible and, hopefully, that race we can kind of slow down the spread and evolution of resistance so that as new products develop there will be a -- they'll be effective for longer periods of time.

Mr. Shimkus. Go ahead.

Ms. Abram. Yes, I was just going to add, there's another facet to this that I think is important and you actually touched upon this in the opening of your question, which is around the development of products that you hope to never have to use but you may need to use.

And so one of the aspects of actually being able to capture some of this data and real-world experience with the utilization of antibiotics and these other naturally occurring circumstances helps to add to our data set for understanding how these products might be used in the event of a bioterrorism event.

Mr. Shimkus. And I've always been concerned. We haven't worked -- there are some ongoing activities -- my observation is that they're too small. When you're doing the -- you need

to -- the companies need -- I mean, I always talk about raising capital, assuming risk and a return. Now you want to raise capital, assume risk, hoping never to get a return.

How do -- and even though there's attempts being made to encourage that we just -- I still think it's too small, based upon the risk out there.

So go ahead.

Dr. Kadlec. Sir, I think you're kind of highlighting the issue of kind of two kind of categories of incentives. One is the push -- what can we do to help companies be successful in their endeavor to bring new antibiotics or class of antibiotics to the table, and then what's the pull -- what's the incentive on the other side that would kind of somehow offset the cost, either opportunity or real, to execute that.

We are actively looking at that. I think in the past Congress has responded in terms of, like, the priority review vouchers, obviously, the incentives in terms of investments into this are.

But we are trying to evaluate what is -- what is the road to success and what's a sustainable road to success, which is another story here in terms of looking at incentives over time that make sense as well as are affordable.

Mr. Shimkus. Excellent. Thank you very much.

Yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentlelady from Illinois, Ms. Schakowsky, five minutes.

Ms. Schakowsky. Thank you, Mr. Chairman, and I want to thank our panellists all for being here.

One absolutely essentially part of disaster preparedness is having the workforce in place to respond to public health emergencies and the workforce is, of course, the backbone of disaster preparedness, in my view, and that's why I am proud I've introduced H.R. 5998, which is the Securing Experts to Control, Understand, and Respond to Emergencies -- or the SECURE Act -- to support and build a robust disaster preparedness workforce and the bill would actually simply reauthorize the education loan repayment program for the Epidemic Intelligence Service -- EIS -- at the Centers for Disease Control.

So I am hopefully that this program can be reauthorized and make it a part of the underlying bill. EIS officers are health professionals who serve on the front lines of public health emergencies as boots on the ground, disaster detectives who investigate outbreaks and assist during natural disasters.

And since its creation in 1951, the EIS program has trained

more than 3,600 officers and based in state and local public health departments across the country.

EIS officers deploy more than 200 times -- are deployed more than 200 times every year, responding to public health emergencies at home and abroad.

So Dr. Redd, I wanted to ask you how important in our ability to recruit this workforce is this program, the loan repayment program?

Admiral Redd. So I agree with you that the Epidemic Intelligence Service, or the EIS, is a major asset for CDC and the country. It's a major vehicle to recruit health professionals and, in particular, physicians to public service.

I was actually an EIS officer quite a few years ago. The proportion of physicians that have been included has decreased over the years and I think that probably -- that is a part of that.

I am not going to specifically address your bill but I can say that for myself when I came to the EIS program I did have student loans and it would have been -- it would have been an incentive to have some method to have those loans repaid.

I think it is really critical that we continue and strengthen the EIS program.

Ms. Schakowsky. So why don't you tell us all what EIS

officers -- how they protect the public's health, what kind of events do they respond to, and what role do they play in responding to those events?

Admiral Redd. Sure. So Epidemic Intelligence Service officers are either -- have doctorate degrees in public health sciences or in medicine, generally finish their training, come to CDC for post-graduate training. So the EIS program is a two-year experiential training program.

Officers are assigned either within CDC or with state and local health departments and the experience part is investigating outbreaks. So when -- for example, I investigated a Legionnaire's disease outbreak in California as part of my EIS experience, working with state health departments and local health departments to identify risk factors and implement control measures.

It's really -- it's a great lead-in to public service and to public health --

Ms. Schakowsky. That's really what I wanted to get at. After the EIS two-year training period, 85 percent of EIS graduates enter the public health workforce.

So I think what I am hearing you say and I would agree that EIS acts as a pipeline for the next generation of health care leaders and contributes to a strong workforce. Would you agree?

Admiral Redd. Absolutely. I am just -- as a personal matter, I am pretty sure I wouldn't be here today if I hadn't done the EIS program a number of years ago.

Ms. Schakowsky. Well, thank you. I know you can't comment on the legislation but I am going to really try and make sure that this incentive to get more people into this program is part of the legislation.

Thank you so much for your service.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady.

The chair recognizes the gentleman from New Jersey, Mr. Lance, for five minutes.

Mr. Lance. Thank you, Mr. Chairman.

Good morning to the distinguished panel. Dr. Kadlec, scientists and drug companies are looking to discover and develop approaches other than traditional antibiotics to combat bacterial infections and these can range from using viruses to attack the bacteria, creating vaccines to prevent hospital-acquired infections, applying known successful interventions in treating cancer by changing the way the human immune system responds to infections.

Scientists harness cutting-edge science that will combat bacteria in new ways and potentially reduce risk of resistance.

Would you please talk about BARDA's role in fostering the discovery and development of non-traditional approaches?

Dr. Kadlec. Sir, BARDA is very interested in those kinds of approaches and, quite frankly, I think it's part of the innovation side that was required through 21st Century Cures Act is now building a program to actually look for those kind of innovative ideas.

To your point about viruses to beat bacteria that's phage technology, which BARDA is actively investigating and actually looking at different programs that exist that could be relevant in terms of addressing -- again, a novel way of addressing antimicrobial resistance.

Every bacteria has a counter virus that effectively can either disarm it, kill it, or potentially change its antibiotic resistance patterns.

And so those are things that are actively being investigated right now. It is, I think, one of the areas that probably deserves more consideration. We welcome the opportunity through the 21st Century Cures Act to kind of open these new doors to innovative approaches and to maybe non-traditional approaches and we look forward to Congress' continued support to do more of that, going forward.

Mr. Lance. Thank you very much, Doctor.

To the panel in general, the Presidential Advisory Council on combatting antibiotic-resistant bacteria was created under an executive order in 2014 and has twice been continued, most recently in 2017.

The Advisory Council is set to expire on September 20th, 2019, unless there is another continuation by executive order. Considering the danger posed by antibiotic-resistant bacterial infections, the fact that this remains quite high, is there any reason why the Advisory Council should not be extended to continue its mission to produce reports and recommendations that influence federal combatting antibiotic-resistant bacteria activities both here and abroad?

Admiral Redd. Well, I think this problem is going to be with us for the foreseeable future. So I think that, regardless of the exact structure used to organize our response to that, this will be a problem that we'll be -- we'll be facing for years and years to come.

Mr. Lance. So that means, I assume, that looking in the future we probably should extend this beyond the current deadline?

Admiral Redd. I think that's a -- that's a decision that won't be mind to make. I think we'll have to look at what progress we've made and how that panel had encouraged that -- encouraged that progress.

Mr. Lance. Thank you.

Would anyone else on the panel like to comment?

Yes. Go ahead.

Ms. Abram. I was just going to add, there's, understandably, a considerable amount of interest in the antimicrobial-resistant issues and one point I haven't made be remiss if I didn't is also the importance of regulatory certainty when it comes to bringing forward the next generation of antibiotics products and they, like other medical countermeasures, can face unique development challenges.

And so one thing that FDA has also been very focused on is putting out product-specific guidance. For example, we've issued guidance on the clinical trial design for specific diseases including prophylaxis of inhalational anthrax.

And so we are trying to do our part, what we can to help make the pathway as clear as possible, recognizing that there are some inherent challenges that have been discussed at length at the hearing.

Mr. Lance. Thank you very much, and please keep up the good work -- a very distinguished panel.

I yield back 37 seconds, Mr. Chairman.

Mr. Burgess. The chair is overjoyed and thanks the gentleman for yielding back.

The chair now recognizes the ranking member of the full committee, Mr. Pallone, five minutes for questions, please.

Mr. Pallone. Thank you, Mr. Chairman. I am trying to get in some questions about the Strategic National Stockpile and also the priority review vouchers. So I am going to ask -- try to be quick in answering the questions.

Dr. Redd, I am interested in learning more about CDC's past work in leading the Strategic National Stockpile. Can you describe the range and type of deployments as well as the types of products CDC has delivered through the SNS program?

Admiral Redd. Thank you for that question.

There have been in the neighborhood of a hundred deployments since the formation of the Strategic National Stockpile. Many of these are very small deployments, for example, for treatment of adverse reaction to smallpox vaccine -- vaccinia immune globulin -- also for containing or for treating people who've been involved in a botulism outbreak with the antitoxin.

The largest deployment of the stockpile was during the H1N1 pandemic. A quarter of the stockpile of antiviral drugs -- about 12 million treatment courses -- were distributed to states. Also, personal protective equipment was distributed.

Another product that is frequently distributed -- it's called federal medical stations. These are basically hospitals

but without the building. They are -- they've been deployed for the hurricanes.

About every other year there's a significant deployment of federal medical stations.

Mr. Pallone. Okay. How does CDC help ensure that state and local health departments are ready for the last-mile deployment of the SNS in which items are dispensed to the public in the event of a public health emergency?

Admiral Redd. Well, the state and locals have a very important responsibility to assure that products are dispensed quickly and in accordance with guidelines.

So we've been working through really two different parts of our state and local program. The Cities Readiness Initiate funds states to develop those systems.

We also have an assessment process called the medical countermeasure operational readiness review where we have worked with each of the grantees and, in fact, the grantees have worked with their subgrantees and local departments -- around 500 assessments of state and local capability. The things that we found in that are that there are some areas where we need to improve.

The capability to dispense from a manpower standpoint, the staffing and then also staffing for security areas that are not

universally but pretty general challenges that state and local health departments face.

Mr. Pallone. All right. Thanks.

I understand that some of these training activities are funded through the SNS program appropriations. So, Dr. Kadlec, will SNS funding continue to be used to pay for these important training activities?

Dr. Kadlec. Yes, sir. I think the key thing is understanding in this transition of oversight that nothing, and nobody's moving, if you want to call it that, and we are leveraging all the resources and expertise that CDC has offered in the past.

And, again, to highlight one thing that Dr. Redd talked about is in a recent preparedness summit that was held in Atlanta, we did an informal survey of state and local authorities about what kind of help they need.

And so what we found out is true to his characterization they need more people to help deploy and dispense these kinds of things, particularly if they were interested in the opportunity for residential delivery or potentially capitalizing on retail distributors that could be used to distribute some of these products in the event of an emergency and that's maybe the one, if you will, new area that we are hoping to work with CDC, going forward, is using our state representatives from ASPR to basically

work together to help more on the sense of what can we do nationally to help state and local authorities do that. Part of it may be mobilizing the federal workforce, which has been considered before. Part of it may be looking at alternative means to help with residential delivery. People have suggested even Amazon.

And then the third area is really about what can we do with retail outlets that could basically facilitate for this. And so in the end, I think what we hope to build is a stronger partnership with our state and local authorities, realizing if they're not successful, no one is successful, and that is our intent is to basically build on the past success of the programs and basically further extend them to support state and local authorities.

Mr. Pallone. All right. Thank you. I wanted to ask about priority review voucher but I think I've run out of time. So I will have to get back to you on that. Thank you.

Mr. Burgess. Gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentleman from Ohio, Mr. Latta, five minutes for your questions, please.

Will the gentleman suspend? I didn't realize Mr. Barton had come on the end of the dais. The gentleman --

Mr. Barton. I will only take two or three minutes.

Mr. Burgess. The gentleman is recognized for five minutes.

Mr. Barton. Normally, I would yield to Mr. Latta but I've got to leave and go to another meeting. So I am just going to be real quick.

First, thank our panel, especially Dr. Kadlec. It says that you used to work for Senator Burr and Senator Kennedy. The senator doesn't talk about it but he used to be a congressman on this committee and he and I worked on what's now Medicare Part D, the prescription drug benefit, way back when and, of course, Senator Kennedy helped me tremendously on what was the reauthorization of the National Institute of Health.

So they were both good -- you know, Senator Kennedy has passed away but, you know, Senator Burr is still over there and they're both good men.

So you were trained right, or maybe you trained them right. I don't know.

Dr. Kadlec. Well, sir, Anna Abram was also trained by him so you got a pair of us here, bookends.

Mr. Barton. Oh, well, that's good. Well, apparently, the big controversy in the pending reauthorization is the transfer of the stockpile from CDC to APR whatever.

I am going to start with you, Admiral. You're the one who

controls it now. Why should we keep it with you?

Admiral Redd. Well, we are implementing the transfer and so that is a process that's underway. We've worked -- been working closely with ASPR. We've actually formed a number of committees to make sure that the transition doesn't result in any degradation --

Mr. Barton. So you don't oppose the transfer?

Admiral Redd. Well, I will say that we are -- we are working to make sure that we -- that when we make the transfer it doesn't result in any loss of capability.

Mr. Barton. It's obvious your Navy training is kicking in. You have been giving a directive and you're -- I thought I would get a little different answer.

Well, I will go to you, Dr. --

Admiral Redd. Let me mention a couple of areas that are -- that we are working closely with -- that in these five committees the two areas that I think are really essential to sustain are the linkage with subject matter expertise at CDC in the stockpile and in the decision making process, and the other was the question earlier about the state and local capabilities in our work to strengthen or assure that the state health departments are able to dispense.

That's something that we are working very closely on, I would

say, on a more than weekly basis.

Mr. Barton. Okay. Well, that's a great answer.

Dr. Kadlec, why should we transfer it to your agency?

Dr. Kadlec. Well, sir, we are in the business -- all in the business about preparedness and response. I think the secretary, when he made his decisions, thought about three things in particular -- integrating with the operation -- other operational assets that exist within the national medical system.

There's another logistics system within HHS that supports disaster response. The second thing is is how do we streamline the medical countermeasure enterprise to make sure what we have in it can be sustained and replenished over time efficiently as well.

And then the last thing is, is to this point is how can we better support state and local authorities in the last mile.

Mr. Barton. It sounds like your two groups are working well together. Would you both agree with that?

Dr. Kadlec. Yes, sir.

Mr. Barton. Okay. And Ms. Abram, since you don't have a dog in this hunt, does the FDA have a position on where it should go and if so, what is it?

Ms. Abram. The FDA stands ready to support the Strategic

National Stockpile wherever it ends up being housed.

Mr. Barton. It's a very political correct answer.

With that, Mr. Chairman. I yield back.

Mr. Burgess. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentlelady from California, Ms. Matsui, five minutes for questions, please.

Ms. Matsui. Thank you, Mr. Chairman. I want to thank the witnesses for being with us today.

Some of the scariest potential attacks that the world is vulnerable to today are now posed by chemical and biological weapons as well as cyber-attacks.

We made so much progress with the innovation of new drugs and treatments as well as technology. But those new advancements come with new vulnerabilities.

We also continue to see damage from ever-increasing natural disasters. We want our health system to be prepared to respond to hurricanes, fires, and earthquakes as well as things like Ebola and anthrax.

PAHPA is critical to our success in both responding to public health emergencies including minimizing harm of any attacks and this field is constantly changing. So we need to keep up. I am pleased that we are working on the reauthorization in a

bipartisan manner on this committee. I look forward to working with my colleagues, Representatives Eshoo and Brooks, to advance their legislation.

One of the main issues that we are discussing today is the Strategic National Stockpile supplies that can be deployed in case of a variety of types of emergencies under discussions which you have all been talking about with your last -- in the last witness here is the -- whether it's appropriate and necessary to transfer some SNS functions from CDC to assistant secretary.

I am interested in hearing more of your thoughts on this. But I want to ask a specific question related to safety of products stored in a stockpile.

I understand that vaccines and other injectable drugs can be contaminated by glass because the glass containers may break, crack, delaminate, or contain glass particles.

In some cases, glass failure is a result of recalls because they pose a potential threat to patient safety. Dr. Redd, do you have any concerns about the impact of glass failures on the safety, security, or sterility of counter measures in the stockpile?

Admiral Redd. So I think the issue of assuring the safety of the material that is stored in the stockpile is a very important

issue. The products are stored at undisclosed locations.

There is a standard monitoring of those materials. As Ms. Abram noted earlier, there's a process for products for which the shelf life extension program is appropriate to test them and make sure that they retain their capability. For products that need to be stored at certain temperatures there is quite a system --

Ms. Matsui. Right. How about glass in particular? Dr. Kadlec or Ms. Abram, would you like to comment on the issue of glass contamination?

Ms. Abram. Yes. I would be -- I would be happy to take that one and thank you for the question.

We recently put out -- the agency, FDA, did put out information specific to some of the analysis we have been looking at in recent years. You're touching upon the phenomenon that can occur with glass vials.

Glass affords many advantages as a packaging. However, there can be this phenomenon where you have these thin flexible fragments that break off.

Ms. Matsui. Right.

Ms. Abram. -- and that's something that we've been studying to look at.

We issued an advisory in 2011 and went back and did some

pretty extensive surveillance of products on market that had these type of vials, going back to fiscal year 2008 through fiscal year 2017.

We've actually seen a decrease in the number of recalls associated with particulates and so we recently shared. Based on that analysis, we didn't see a new or emerging safety signal or trend. We chose not to update the analysis at that time.

There's been particular interest around kind of new glass design and how that compares to the more traditional borosilicate glass vials, and in that regard our studies demonstrated that the novel glass vials exhibited improved performance in terms of withstanding mechanical stress and scratching relative to type one borosilicate glass vials in the study.

But we also looked at this from the standpoint of chemical durability because, under certain stress conditions such as a more basic environment, the novel glass vials exhibited an improvement over one of the borosilicate glass vials. But there was no definitive difference in performance relative to the other borosilicate vials.

Ms. Matsui. So are you continuing to follow up on this to ensure that, you know, you look at the glass, ensure --

Ms. Abram. Yes.

Ms. Matsui. Okay.

Ms. Abram. Absolutely.

Ms. Matsui. Okay. Thank you, and I am running out of time already. I have further questions and I will submit them.

Thank you. I yield back.

Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady.

The chair now recognizes the gentleman from Ohio five minutes for questions, please.

Mr. Latta. I thank the chairman very much and I also want to thank our witnesses for being with us today on this very important topic.

And Dr. Kadlec, if I could pose my questions to you right off the bat, first of all, I want to thank you very much for your service to our country in the Air Force for your 20 years of service.

And as we talk about cybersecurity, I think it's really important because this committee has been involved in very -- not only involved but concerned about what's going on out there, and I've served on a cybersecurity task force in the past and in the hearings that we've had so it's a very -- it's huge issue.

I represent a very unique district -- that I have more community hospitals than anybody else in the state of Ohio, and when I am out one of the things I hear from my community hospitals

is to -- on the cybersecurity and cybersecurity threats that they're under.

In the last Congress, Mr. Welch from this committee -- from Vermont -- and I did the Internet of Things Working Group and we heard from folks, especially when we are dealing with telehealth and when you look at electronic medical records and the Internet of Things what's happening on the great things there. But then, again, on the cyber side it's always a concern.

So the question I have is as I've seen in your testimony that the healthcare sector very nearly suffered a severe cyber-attack last year due to the -- because of WannaCry.

In fact, while the United States was spared the worst of the damage, the U.K. had 34 percent of its hospitals affected and there are numerous other examples of recent and growing cybersecurity threats to the healthcare sector.

All that being said, I notice that cybersecurity isn't listed in one of the key -- of your key priorities. Does this mean that cybersecurity isn't a key priority at ASPR and, if not, is there a part of HHS that does consider healthcare cybersecurity be a priority?

Dr. Kadlec. Thank you for your question, sir, and I just want to reiterate the importance of this issue as it relates to our health care systems because they can range from hospitals

to actually individual devices that may be at risk and I think it's important to note that in the Department of HHS that the deputy secretary basically manages the overall cybersecurity of the department.

And so from that standpoint, each operation and staff division has its own cybersecurity piece of this but it's managed and if you will -- overseen at that level to ensure that there is uniformity of policy as well as oversight and capabilities.

Mr. Latta. Well, let me follow up then because you say the deputy secretary is there, because in their report from -- to this committee last spring the previous HHS secretary had designated your office as the health care sector specific agency to lead the health care cybersecurity.

Did you agree with that designation?

Dr. Kadlec. Sir, I don't disagree with it. I think one of the things that happened as a result of the WannaCry event is that because the potential impacts are much greater than just simply ASPR that they can affect CMS, FDA, CDC, all of OpDivs and StaffDivs that I think it was the decision at that point in time.

But to be fair to your question, sir, I will be very happy to provide an answer for the record, if you'd like.

Mr. Latta. Okay. Let me just follow up, though.

So the -- with the deputy secretary then because would you -- are you saying then that you think that that -- the specific and the proper position would be having that cybersecurity control for the -- for the agency -- for the HHS, then?

Dr. Kadlec. Sir, I think the fact is is that the only person higher than the deputy secretary is the secretary to manage the issue and I think the issue here is is that the deputy secretary I think performs a vital function to ensure that it remains on the forefront of everyone's consideration for the different staff and operational divisions of HHS.

Mr. Latta. Well, if you could follow up again on that with me I would greatly appreciate it.

Dr. Kadlec. I would be happy to, sir.

Mr. Latta. And we look forward to that.

Mr. Chairman, I am going to yield back the balance of my time.

Mr. Guthrie. [Presiding.] The gentleman yields back his time.

The chair recognizes the gentlelady from California, Ms. Eshoo, five minutes for questions.

Ms. Eshoo. Thank you, Mr. Chairman, and thank you to the witnesses for your testimony.

Just a couple of comments before I get to my questions.

I wish Dr. Bright were here today, who heads up BARDA. He couldn't. I think there was a conflict relative to his schedule.

But I want the members to have a deep appreciation of what BARDA has accomplished -- 35 approved measures in 10 years. I don't know of a pharmaceutical company that has produced 10 major drugs in a decade.

And so that really is a -- it's an outstanding record. Many members have raised the issue of anti -- the whole issue of antimicrobial infections. Now, God forbid there's an anthrax attack and we have something for that but you're in the hospital and you have -- you know, you contract a terrible infection and I think that we are all worried about that. I mean, I don't know of conversation with friends of mine where someone doesn't mention someone having been in the hospital and contracted an infection.

So I want members to know that Dr. Bright is all over this. I mean, he truly is, even in the meeting that Congresswoman Brooks and I had just recently over at BARDA.

Questions -- Admiral, you described in detail how the CDC is responding today, and I know that we just heard Congressman Barton raise the issue of CDC, the stockpile.

I think it's important for all members to know that the stockpile isn't moving anywhere. It's going to remain with the

CDC.

There is an administrative change here. With the shift from -- in that -- what's in the legislation from CDC to ASPR, what actually changes for you? Do you have to get permission from ASPR to do something?

Is it that you and ASPR are going to coordinate? In a very clear way, can you just set down in a sentence or two what is going to change?

Admiral Redd. So thanks for that question, and you're correct. The people --

Ms. Eshoo. Well, I know that. But just tell us what it is.

Admiral Redd. The -- sure.

[Laughter.]

Ms. Eshoo. You don't have to thank me.

Admiral Redd. The stockpile provides funding within CDC and that's one of the things that we are talking about with ASPR is what things in that mission --

Ms. Eshoo. So it's not decided yet, you're saying?

Admiral Redd. Well, some areas are, some aren't. But we are still working on the details.

Ms. Eshoo. Well, that's interesting. All right. Thank you.

To Dr. Kadlec, always good to see you. In your opening statement, you used the term in terms of responsibilities, one of them territorial responsibility. It's very important.

The official government death count for Hurricane Maria, relative to Puerto Rico, was 64. Now the New England Journal of Medicine last week, one of the most prestigious publications in our country, they concluded that the death toll was 70 -- seven oh times higher than the official estimate.

What is ASPR doing in Puerto Rico? I think that even in the meeting that we had we came over to the agency, I think you sensed my lack of confidence in what ASPR is doing.

Dr. Kadlec. Yes, ma'am.

Let me first just comment on the New England Journal article because I think it's important to realize --

Ms. Eshoo. Well, do you accept that?

Dr. Kadlec. I accept it that it's an estimate. I accept it that --

Ms. Eshoo. Well, there's -- look, there are two and there's a chasm between the two. So tell the committee what you're doing on the --

Dr. Kadlec. Sure, ma'am.

On the issue of the mortality rates, I've been working this --

Ms. Eshoo. Tell us what you're doing in Puerto Rico right now. Who's on the ground, what's being used, are people being inoculated?

Dr. Kadlec. I just wanted to differentiate between mortality for sure. We have 40 personnel down in Puerto Rico right now working with the Puerto Rican Department of Health looking how to basically make their system more resilient and that goes to the issue of not only the hospitals, which are both private and public, as well as federally qualified health --

Ms. Eshoo. So you're having discussions with their public health people, with their -- do you have people that are administering anything to the Puerto Rican people?

Dr. Kadlec. Based on the requests from the Puerto Rican Department of Health, no, ma'am, at this point in time. We basically extended our emergency prescription assistance program that was basically providing 30 days of prescriptions free to people.

We've left 13 DMAT caches there, which is a host of medical supplies that we --

Ms. Eshoo. Well, my time is -- my time has --

Dr. Kadlec. Sure, ma'am.

Ms. Eshoo. -- run out. But I --

Dr. Kadlec. And we also --

Ms. Eshoo. -- I really would like a full report from you on it.

Dr. Kadlec. Sure. Be happy to. We can do that, ma'am.

Ms. Eshoo. Yes.

Dr. Kadlec. I would just also add we are also maintaining or taking care of about a hundred or so people who were evacuated from the Virgin Islands and Puerto Rico who are dialysis dependent until they can go home and receive their care at home. But we'll be happy to provide a more fulsome picture for you and for the record.

Ms. Eshoo. Thank you. Yield back.

Mr. Burgess. [Presiding.] The gentlelady's time has expired.

The chair is pleased to recognize the gentleman from Virginia, Mr. Griffith, five minutes for your questions, please.

Mr. Griffith. Thank you very much.

Let's continue with Puerto Rico for a minute, and I appreciate what you all are doing down there. But Dr. Kadlec, did -- or Dr. Redd -- Admiral Redd -- were any of the stockpiles that we've talked about today used in Puerto Rico?

Dr. Kadlec. Yes, sir. We deployed both our DMAT, or disaster medical assistant team caches, actually 13 of them, as well as field medical stations, which are these kind of like

hospitals in a box kind of thing.

Mr. Griffith. Right. So here's my question. Back to you, Ms. Abram.

When we start talking about the vials and the delamination and whether or not there's a better product, you indicated that the new novel product does better under stress but it was -- one product was better than the other in chemical situations or more normal situations it was pretty much the same.

My question is, though, isn't the stockpile for emergency situations and wouldn't the stress be greater if you're sending something in either before or immediately after a hurricane or other natural disaster and so wouldn't we want to have the better product in those situations?

Ms. Abram. We want to make sure that we have high quality safe and effective medical countermeasures in the event they need to be used and there's a number of steps that go into making sure that the products that we have are what we are expecting them to do in terms of safety efficacy and being effective.

Mr. Griffith. And my concern is just this.

Ms. Abram. Yes.

Mr. Griffith. If they're just sitting on the shelf and we go in one day into the back storage room and say we need these, I get it. The current glass works.

But if there's a risk of delamination, which we've see in the past, and there's a product that takes care of that, with the stockpile wouldn't -- at least with the stockpile wouldn't we better off using the glass that's less likely to have glass fragments floating around in what we are trying to then use in an emergency situation?

Because when people are trying to get something in there in a hurry, whether before or after the storm, they're not necessarily handling it with kid gloves. Wouldn't you agree they're not handling it with kid gloves under those circumstances?

Ms. Abram. The handling is a matter like -- of importance to the product, depending upon if it's something that has to be temperature controlled. That's one of the issues that is at play with the Ebola response efforts right now.

So depending upon the counter measure, depending upon how it's going to be used, it could bring unique handling and care instructions.

Mr. Griffith. I appreciate that. Thank you.

I do want to ask about and I've heard a lot and I am stepping a little bit outside of my comfort zone. I've heard a lot about the antimicrobials and the antibiotics and the concerns there. I am just wondering is BARDA looking at some interesting and new novel approaches?

I recently toured a facility in my district -- a very small start-up group, Techulon, and they have a platform technology for gene targeting. So I asked my team to find out what that is and here's what I got back, so I don't get it wrong.

It is an anti-sense approach. It knocks down gene expressions. That kills the pathogen -- basically, disrupts gene functions, which means there's no way for the pathogen to adapt because basically you're going in and knocking out part of their genes and they die. Are we looking at some of that kind of new novel approach?

Dr. Kadlec. Sir, I would like to hear more about it, quite frankly. I haven't heard of that particular approach but I would be welcome to the idea that we would hear about it and understanding how we could learn more and potentially see it in the future of our efforts.

Mr. Griffith. But it's fair to say for both you and the rear admiral that there's a -- there's a lot of interesting things going on out there and it's hard to keep track of it. I will make sure you get some of the info on this.

Dr. Kadlec. Sir, and again, you know, compliments to the committee with the creation of the Medical Countermeasure Innovation Partnership because that's one of the things we hope to do with this program called DRIVe is to basically set up the

opportunity for great ideas to come in.

We've identified so far as of yesterday eight accelerators around the country in your states -- different states around the country to basically be these receptive points for these great ideas so that we can make sure kind of sweep them up and don't miss them.

Mr. Griffith. Thank you. I appreciate that.

I would be remiss -- and I appreciate the chairman bringing this up in his opening remarks -- if I didn't mention the historic nature of today's date.

Being the representative on this committee from Virginia, we have a national D-Day memorial in Bedford because, per capita, they lost more boys on D-Day than any other part of the country, and I had the opportunity to know the sister -- meet the sister of one of the boys who was part of the D-Day boys of Bedford and knew Bob Slaughter, who pushed for the memorial and had the great thrill about 12 years ago before he passed away to introduce my daughter to him at a -- in a local cafeteria.

He was just there, as humble as he could be, but these were true heroes and they really did save the possibility of a vibrant world with democratic principles in place and it all came down to that one morning on this day 74 years ago.

So I yield back.

Mr. Burgess. Gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentlelady from Colorado, Ms. DeGette, five minutes for questions, please.

Ms. DeGette. Thank you, Mr, Chairman.

I want to thank Representatives Eshoo and Brooks for their leadership on this important draft that we are discussing today. Medical countermeasures are really an important element of preparing for pandemics.

Several of our witnesses have mentioned the 21st Century Cures Act, which Fred Upton and I authored but which everybody on this committee had input into, and Representatives Eshoo and Brooks were really instrumental in helping us put some of the medical countermeasures into that bill.

They included encouragement of complex, adaptive, and other novel trial and medical advice designs, fostering potential use of real-world evidence for the development of drugs, and harmonizing FDA human subject protections with the common rule, otherwise known as the federal policy for protection of human subjects.

And in addition, Cures including provisions that would waive certain paperwork requirements during a public health emergency along with streamlining BARDA procurement process and allowing

BARDA to enter into agreements with independent non-profit entities to support medical countermeasure development.

Now, Commissioner Abram, you spoke a little bit earlier about the recent Ebola outbreak in the Democratic Republic of the Congo. I am wondering if you can talk for a minute about exactly how the lessons learned in the 2014 Ebola outbreak are being used to help contain the recent outbreak.

Ms. Abram. Absolutely, and I will likely ask my colleague from CDC to join as well.

Ms. DeGette. Great.

Ms. Abram. We've been very much supporting the efforts and helping to facilitate the export of vaccine that's being used overseas as part of the outbreak control measures.

We've also continued to engage with our international collaborators and conversations with developers around diagnostics and therapeutics.

And so I think one of the continual lessons learned and actually that PAHPRA was very effective in doing is helping to make some accommodations and adjustments in our authorities so that we can be even better prepared in prepositioning which helps us then when we do have these emergent situations to be even more timely in the response effort.

Ms. DeGette. That's good to hear. Yes?

Admiral Redd. So I think one of the lessons of 2014 is that when an outbreak like what is happening in the Democratic Republic of Congo occurs you really have to pursue it until there are no more cases.

Ms. DeGette. That's right.

Admiral Redd. There was an opportunity to do that in West Africa in the spring and that opportunity was lost, resulting in the outbreak over the summer and fall.

In the Democratic Republic of Congo, CDC has had a long-standing presence. There are actually 33 staff there --

Ms. DeGette. Excuse me. I don't have a lot of time and so my question really was what did -- what, from the 2014 outbreak, helped us now. If you can address that.

Admiral Redd. Sure. I think there is a much more intense focus on contact tracing, making sure that our partnership with WHO and the country ministry of health is solid and that things are slipping through the cracks.

So there's much more intense follow-up, identification of cases. Laboratory testing is in place now. We are working on measures of exit screening with the ministry. So all the things that we should have done in 2014 are happening now.

Ms. DeGette. Mr. Kadlec, do you want to add on?

Dr. Kadlec. Yes, ma'am. May I just insert that we have

two candidate vaccines, one that's actually being used for ring vaccination.

We have a point of care diagnostic that has been deployed, donated by the companies, as well as those vaccines as well as three different monoclonal antibody therapies that could be used. The one from NIH is actually deployed down there right now.

Ms. DeGette. Right. Okay. Thank you.

While I've got you on the hot seat, you talked about -- you indicate that increasing BARDA's authorization levels would increase BARDA to implement new innovation authorities that the 21st Century Cures Act provided.

Can you talk about those new authorities and how additional funding would actually help increase the goals of BARDA?

Dr. Kadlec. Yes, ma'am. We announced yesterday, with the creation of DRIVE -- the Division for Research, Innovation, and Ventures -- with the intent that right now $25 million will be spent on two areas, which will be one is on the treatment of sepsis.

Sepsis basically afflicts 1.5 million Americans a year, kills 250,000, costs the health care system $24 billion, and so we think that's an area ripe for an opportunity to find things that could either prevent or mitigate that.

The second area is actually identifying or finding

diagnostics that would identify people who are -- who have been exposed who are not yet sick so that you can institute treatment or therapies to actually prevent them becoming ill or potentially dying.

Ms. DeGette. Thank you.

Thank you very much, Mr. Chairman.

Mr. Burgess. Gentlelady yields back. The chair thanks the gentlelady.

The chair recognizes the gentlelady from Indiana, Mrs. Brooks, five minutes for your questions, please.

Mrs. Brooks. Thank you, Mr. Chairman, and thank you all so very much for your testimony and for your important work.

I think there continues to be a little bit of confusion that has come up with the various members regarding what I think the word that might be causing confusion is the word moving the Strategic National Stockpile, which is in our draft text of the bill from CDC to ASPR.

But as I understand it, discussions and things are still taking place relative to what the roles will be and I think we all have the same goal and that is to ensure that all medical countermeasures get to our citizens in the appropriate time and as fast and as efficient as possible.

And so for our sake, maybe starting with Dr. Kadlec and then

going to Admiral Redd, if we could please talk about what -- where that stands right now and are there tools or resources you need to effectively carry out the execution of the Strategic National Stockpile for our citizens who expect it to work.

Dr. Kadlec and then Admiral Redd.

Dr. Kadlec. Yes, ma'am. Thank you, ma'am. I need --

Mrs. Brooks. We just need to clarify and make sure we understand.

Dr. Kadlec. Sure. Sure. As Dr. Redd identified earlier, there are a number of working groups. I think the key thing is some of them dealt with contracts and particularly how would the contracts that have been previously administered by CDC be administered by ASPR.

And so part of that is kind of -- I think the word is novate -- contracts to ASPR so that in terms of replenishing the stockpile in the future so you'd have single oversight of how you would basically procure -- develop, procure, and resupply this -- the Strategic National Stockpile.

There are issues around personnel, how many people would be, basically, transferred to the ASPR and would be the responsibility of ASPR to basically pay for or provide services to.

And then, lastly, one of the areas that's still under

negotiation is what percentage, if any, of those people who are working with the state and locals would be transferred to ASPR as well.

And so that is an area that is further under discussion. The intent is to meet with senior CDC officials later this month to basically hopefully finalize that.

But as to this date, there has been no requirement for any legislative language -- the facility to transfer is within the secretary's purview and authorities to do so.

Mrs. Brooks. And I think that's what the greatest concern is is that local and state authorities -- and one of our next witnesses in the next panel expresses that as well and so we need to make sure that that relationship with whomever is responsible.

And I think what I am hearing you say, though, and I would like, Admiral Redd, you to talk about what you believe the role is -- and is going to be because we want to make sure that there is no problem working with state and local officials that actually do the work on the ground.

Admiral Redd. Yes, ma'am. I think actually Dr. Kadlec summarized the current situation quite well. The areas that I think are critical to just make sure we've got really clear -- good clarity on are the role that subject matter experts at CDC will have both whether or not they're funded by the stockpile

now or not -- that that linkage with the stockpile and with planning, for example, in clinical guidance, how the product should be used, under what circumstances to control or to respond to emerging events, that we've got that part nailed down and then similarly work that we have been doing partly funded by the stockpile, partly by the state and local program that we've got very good agreement on the work that we are going to continue in that domain to make sure that state and locals are able to dispense products.

I think the overall medical countermeasure structure is now more completely under the ASPR but that state and local role -- we think we have a role to support both state and locals and the mission of the ASPR.

Mrs. Brooks. And would you agree with that, Dr. Kadlec?

Dr. Kadlec. Yes, ma'am, and we also have a role at the state and local level and we look to figure out how we can best integrate that to provide the best support in state and locals.

Mrs. Brooks. Well, and I think integration is the key here and it is trying to ensure that everyone is clear as to what CDC's role is with state and local partnership and what ASPR's role is. But it sounds as if the contracting piece and the management of the product, so to speak, and mostly the vaccines, the diagnostic testing, is what would move to ASPR but yet there will

be -- both agencies will be or both parts of -- will be working with state and local health officials. Is that correct? Fair to say?

Dr. Kadlec. That's -- I think that's the overall intent.

Mrs. Brooks. And very briefly, Ms. Abram, a very quick question relative to diagnostic tests and so forth, and can you speak to the role of diagnostic tests including point of care tests and influence in infectious disease detection and management and how FDA ensures that we have what we need for diagnostic testing because it's not just about vaccines. It's also about the diagnostic.

Ms. Abram. Right. When we think about medical countermeasures it runs the full gamut of medical products from vaccines, therapeutics, and, of course, diagnostics, and rapid point of care of diagnostics is something that also colleagues at BARDA and ASPR are working on.

It's absolutely critical and it's not just critical in the context of emergency response as a public health emergency. It's critical as part of good routine care. The sooner you can pinpoint what a patient is dealing with the faster you can provide optimal care.

Mrs. Brooks. Thank you. My time is up. I yield back.

Mr. Burgess. The gentlelady yields back. The chair thanks

the gentlelady.

The chair recognizes the gentlelady from Florida five minutes for questions, please.

Ms. Castor. Thank you, and thank you to the witnesses for everything you do to strengthen America's public health infrastructure, especially when we are talking about medical emergencies and preparedness and response.

And I want to thank the authors for their bipartisan work on PAHPA. I am very pleased that we are going to codify what CDC is doing relating to the children's preparedness unit into this bill because when we are talking about public health emergencies, children have very special needs and we have to ensure that they're not overlooked, and for many years CDC has had a group of experts working through their children's preparedness unit.

I mean, just think about the Zika emergency. Child development was the issue. Think about Flint and the water crisis -- lead in the water. That had a direct impact on babies and children. So it's very important that we do.

So, Dr. Redd, does this codification language -- does it do what we need to do? Is there anything that's left out here?

Admiral Redd. I think we recognize the importance of children in emergencies and we'll work on that. Whether or not

--

Ms. Castor. Yes. So this is actually Senate language that we need to bring into this version because this version just has kind of the national advisory committee.

Admiral Redd. Well, I think -- I think that both in preparing for and then responding to almost any emergency, children are going to be an important part of that and there are particular considerations that need to be taken into account.

And as you noted, we have, within CDC, a children's preparedness unit. That unit mobilizes when we -- when we have a response. For example, in the Ebola response there was work on reopening schools that unit played an important -- in West Africa -- that that unit played an important role in.

Ms. Castor. So I hope the authors can look at what the Senate language is and make sure that we are carrying over this very important initiative where they bring in the pediatricians, the psychologists, everyone, at the table to make sure that it's properly recognized, funded, and structured.

Dr. Redd, the draft legislation also would allow the secretary to transfer 1 percent of any appropriation to the public health emergency response fund. The emergency response fund would supplement the response of local and state authorities during any number of public health emergencies.

Previously, this has been an issue and it's been a problem because transfers during emergency situations resulted in automatic cuts elsewhere in funding in critical areas for state and local governments. They were kind of left in the lurch -- created a lot of uncertainty for communities back home.

For example, during the height of the Zika crisis in 2016 funds were pulled from emergency preparedness and public health grants across the country, despite the fact that those communities needed to prepare, they needed to respond, and they were hamstrung at that time.

Probably the most troubling example -- and I am glad Mrs. Dingell is here because she worked so hard on this -- was the fact that during that Zika crisis we had a terrible crisis in Flint, Michigan, and when we -- when they had to go take funds to address Zika, they swept some of the grants back in Flint and in Michigan that they needed for their public health emergency.

In a Washington Post article, the president of the Association of State and Territorial Health Officials said it is short-sighted to fund the Zika response by weakening all states' ability to respond to future public health crises.

So based on your experience with the Zika response, could you describe how state and local public health departments were impacted when the funds were taken and drained from the public

health emergency prepared cooperative agreement?

Admiral Redd. Yes, ma'am.

Ms. Castor. Go into a little detail for us on that.

Admiral Redd. So, first of all, this is a real problem. In the H1N1 response there was a 54-day interval between the request for funding and the appropriation. For Ebola there was a four-month interval and for Zika 190 days. So this is -- this is a significant problem that is inhibiting the best response.

I am not going to speak directly to the bill but I will say that during the -- during the Zika response the PHEP award overall was cut by about 8 percent and we heard from states that that was causing problems with staffing.

That money was -- there was sort of a payback about six months later but there was a period of uncertainty and I think that uncertainty really is not helpful to the preparedness interval.

Ms. Castor. And I think congressional members have a lot of responsibility for those. When you get into government shutdowns and you can't work together when we are talking about emergency situations in Flint, Michigan, or Zika or flu we simply cannot be caught up in these partisan fights. There has to be a fund -- a pot of money where we can adequately respond to public health emergencies without getting into the partisan food fights, not in times of emergency.

So I would hope that the authors would work on that with all of us as we move forward. Thank you, and I yield back.

Mr. Burgess. The gentlelady's time has expired.

The chair recognizes the gentleman from North Carolina, Mr. Hudson, five minutes for questions, please.

Mr. Hudson. Thank you, Mr. Chairman, and thank you to each members of the panel for what you do on behalf of our country. Thank you for being here with us today.

Every time there is a disaster or an infectious disease outbreak I hear from my constituents back home. Hurricane Matthew, Zika, and Ebola outbreaks are all recent events that have quickened the pulses of my constituents.

Understandably, they're concerned and want to know what we are doing to ensure their communities have the resources they need and these outbreaks are contained.

One thing I've heard from physicians, medical -- emergency medical responders, and hospitals is that there are continuing drug shortages, particularly essential emergency medications. These providers are concerned that they're not prepared to respond to a massive public health emergency.

Dr. Kadlec, you mentioned in your testimony that the strength of our nation's public health and medical infrastructure and the capabilities necessary to respond to emergencies and disasters

are foundational to the quality of life of our citizens and I completely agree with you.

But I believe these drug shortages hamstring our ability to properly respond. So I want to see how we can work tighter to best fix these problems.

So, Dr. Kadlec and Ms. Abram, can you share your thoughts from both the FDA and ASPR's perspective on assuring the availability of emergency medications in a public health emergency and are there options Congress should be considering as part of PAHPA and beyond?

Ms. Abram. I will go head and jump in and take it first and then turn it over to my colleague. Drug shortages is a serious concern.

It's a serious concern not just in routine everyday clinical care but also in the context of what a particularly lifesaving product -- the shortage of a lifesaving product at a time of a public health emergency might mean. We've got medical countermeasures and we've also got other products that would certainly go towards patients and be part of care, perhaps supportive care.

And we've also recognized that even though we have a very dedicated team that is focussed on this at the agency amongst our CDER colleagues, we continue to see some challenges persist.

The agency is doing everything that we can to mitigate and prevent. Particularly, we've been very forthcoming about some of our work in the IV saline solution shortages and our work to work with developers.

We encourage manufacturers to try to build in capacity. It's not something that we can require. But we do encourage that they try to do that to help to mitigate.

We've also worked in a discreet manner to help to import product to supplement where there have been shortages. But it's a continual challenge and it's something we continue to look at and would welcome the opportunity to have dialogue with the committee around what other solutions might be brought to bear as part of this.

Mr. Hudson. Thank you.

Dr. Kadlec. Sir, for the purposes of time, I would probably want to get back to you on the record on this. But I just want to highlight as -- I think it was alluded to by Ms. Abram and that is the subject to the events in Puerto Rico and how that impacted on several critical supplies of critical medicines -- not only saline solution but also pediatric oncology drugs and the like.

And we have an interest in that in terms of how do you basically make sure that that critical infrastructure is more

resilient. I will just highlight that there is some interesting legislation in the House subject to the Disaster Recovery Reform Act of 2017. I think it's being considered with the FAA Act as well, and that is subject to how we can use some of our disaster relief funding in advance of an event to basically make things more resilient.

So there -- I think there's a couple of pieces here as how can you make your production supply chain more resilient before a disaster and then what to do with the events, as Ms. Abram had mentioned about what can we do to make sure that there is an uninterrupted supply of these critical supplies.

But we'll be happy to get back to you with further details.

Mr. Hudson. Great. Well, I appreciate that and appreciate the commitment to work with us on it.

Just changing topics, Dr. Kadlec, I have become aware of the time-intensive process involved in producing a vaccine through egg-based production. Oftentimes, this manufacturing can take up to six months, which is a lifetime in the ever-changing world of infectious disease.

I've recently become aware of the new flexible platform techniques -- technologies that have the potential to reduce production time for vaccines from months to weeks.

I understand BARDA's primary mission is to support products

that are being tested in clinical trials of which I know of one product in phase three. But there are also products in preclinical testing. I understand ASPR and BARDA are examining these innovative platform technologies. But I want to get some clarification from you.

How would these rapid response platform technologies benefit BARDA and its mission and can BARDA play a more proactive role in fostering the plug-and-play platforms that are beyond basic research but not yet at the clinical trial stage?

Dr. Kadlec. Sir, I think just two things to echo what your comments are, our dependence on egg production, which provides more than 70 percent of our vaccine for flu, and eggs are not very flexible and they're not very fast. The only other vaccine you can produce from an egg is yellow fever. So the idea of having flexible and fast capabilities which are platform technologies is either cell or recombinant production that is going to be critical, going forward.

So we see that as an essence and there's also been the situation we experienced this past seasonal flu season where some of the vaccine strains drifted a little bit from the -- from egg production and so that's another liability.

So there's several reasons why we are relooking what we are doing. But we really owe you and this committee probably a

detailed brief on not only the situation we experienced in the past but what may be a strategy to address how to avoid those limitations and get us the most flexibility and speed in the future. I will turn to Anna.

Ms. Abram. Yes. I was just going to quickly add we'd be happy to follow up with some of the work that we've been doing to advance continuing manufacturing and innovations. We think that this could be responsive in terms of helping to foster a more nimble flexible responsive framework.

Mr. Hudson. I agree. Thank you, Chair.

Mr. Burgess. And the gentleman's time has expired.

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, five minutes for questions.

Mr. Guthrie. Thank you, Mr. Chairman. I thank the panel for being here today.

And so this kind of follows on what he's saying about new platforms. There's a company in my district, Kentucky BioProcessing, in Owensboro that actually uses a plant-based platform to more efficiently produce recombinant protein products.

In fact, applying their platform technology they rapidly developed an experimental antibody and use it to successfully treat an American doctor who contracted Ebola while treating

patients in Africa.

I understand a major goal of BARDA is to identify new approaches and capabilities that allow for better preparedness and response to multiple public threats by serving as platform technologies.

So, Dr. Kadlec, how can BARDA interact with and support companies which have developed such technologies but do not have a specific medical countermeasure in clinical development?

Dr. Kadlec. Well, I think -- I think that's an issue that we probably need to follow up with on the notion of this flexible and agile kind of production capacity and how do we basically nurture that and promote that in a way that to this date hasn't been fully actualized.

So I think it's an area that I think we'd be very welcome to work with you and our colleagues at FDA who are also evaluating these kinds of innovative ideas and how do we do that.

We think that the DRIVe program that was -- we just announced yesterday could be one of those venues to basically evaluate that as well as promote those kinds of concepts.

Mr. Guthrie. Thank you. I would encourage BARDA to use its current authorities to support preclinical platform technologies -- planned technology which has demonstrated its ability to deliver BARDA's needs in one-third of the time of

traditional platforms.

So that follows up what he just said so I appreciate that. Matter of fact, the plant they used for Ebola was tobacco. So it's nice that we have a use for our plant -- for our -- one of our plants that's positive in that direction. So we appreciate that very much.

And also, Dr. Kadlec, kind of switching gears a little bit, could you speak to the how the discussion draft can further empower ASPR to be the vital coordinating agency for both planning and responding to a biological threat?

Dr. Kadlec. Well, sir, I think just reauthorizing the language that already exists is critical. I think there's some areas in there in terms of effectively improving our ability to respond in terms of direct hiring for national disaster medical personnel will be very important. That was one of the critical shortfalls during the last hurricane season. We only had less than half of the number of intermittent federal employees who basically service our disaster medical assistant teams.

We also believe that what you have in your discussion draft is so important in terms of providing, if you will, life benefits to those people who would lose their lives in an event of a response to make sure that they get the equal consideration as to public safety officers.

So there's several areas. There's also mention about in your draft about the PHEMCE, or the Public Health Emergency Medical Countermeasure Enterprise.

We think the idea of basically having that role to ensure that, as Dr. Redd said, that we use the expertise within the department and CDC, FDA, NIH to basically ensure that whatever we are trying to develop and produce is not only useable but safe and efficacious to use in our population, both children and adults and elderly.

So those are all positive things that I think just off -- in the little time that I have. I would be happy to follow up on the record if you'd like.

Mr. Guthrie. Thank you very much. We appreciate that and look forward to, hopefully, a briefing as you talked about and schedule that sometime in the future.

That concludes my questions and I yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back.

The chair recognizes the gentleman from Missouri, Mr. Long, five minutes for questions, please.

Mr. Long. Thank you, Mr. Chairman, and Dr. Kadlec, as you may be aware, I've introduced legislation along with Ms. Matsui to allow the HHS secretary to reorganize HHS cybersecurity offices

as the secretary thinks best.

One of the motivations for this legislation is the recognition that many organizations including HHS are using the cybersecurity organizational strategies that were originally designed in the early 2000s and my not be suited for modern-day threats.

I think you would agree with me -- I will ask you if you do -- that the nature and severity of cybersecurity threats to healthcare have significantly changed over the last 20 years. I don't think your mic is on.

Dr. Kadlec. Yes, sir. They have.

Mr. Long. Do you think the evolution of cybersecurity threats may require organizations like HHS to evolve their cybersecurity strategies including the way they organize their cybersecurity offices and channels -- or offices and officials to manage?

Dr. Kadlec. Sir, I believe giving the secretary that flexibility and the authority would be appropriate.

Mr. Long. And how has HHS addressed its cybersecurity strategies to confront the changing cyber threats and what more needs to be done, in your recommendations?

Dr. Kadlec. Sir, thank you for that question. As I outlined earlier, there is -- the center of gravity for the

department is in the deputy secretary's office at the present time.

I think we probably owe you a full and fulsome response to that question. If you don't mind I will take it for the record and provide you a complete outline of what is ongoing and anticipated for the department in these areas that could help guide your future actions.

Mr. Long. Okay. Thank you.

And Mr. Chairman, I yield back.

Mr. Burgess. The chair thanks the gentleman. The gentleman yields back and the chair is aware that Dr. Kadlec has another engagement at HHS. But we'll now recognize the gentlelady from Michigan, who's not on the subcommittee, five minutes for questions, please.

Mrs. Dingell. I will be brief. Thank you, Mr. Chairman and Mr. Green, for holding this hearing.

I do have a concern, like everybody else has. We've asked a lot of questions but not gotten as much into the long-term care and hospital preparation when we have these hurricane emergencies.

So, Dr. Kadlec, I am going to go right to you and ask you. You have said that a regional disaster health response system would incentivize the health care system to integrate measures

of preparedness into daily standards of care.

Would this include an important sector of the health care system, the long-term care facilities, which in these most recent hurricanes have really suffered some tragedies?

Dr. Kadlec. Yes, ma'am, and I just want to annotate two things really quickly. In Puerto Rico, we evaluated in an acute situation about 1,900 adult senior living facilities of varying different types in terms of their resilience and their functioning during that terrible period of time there, and certainly we know the events in Florida and I just acknowledge that Florida has established new guidelines for its hospitals and skilled nursing facilities. So I think we have to have greater sensitivity to these areas as they take care of some of the most vulnerable populations in our society.

Mrs. Dingell. Thank you.

In an effort to improve our understanding involved with threats hospitals and long-term care facilities face I have a bipartisan bill that directs HHS to engage with the National Academy of Medicine to conduct a comprehensive study into the assessment of future threats impacting emergency preparedness policies and procedures across the health care system.

In your opinion, would a study of this kind be helpful as you establish a regional disaster health response system?

Dr. Kadlec. I am always having very bright and experienced people consider these efforts and to do a deep study would always be beneficial and, obviously, the National Academy of Sciences is the place to do it.

Mrs. Dingell. Thank you.

So we talked briefly a minute ago about the tragedies in Florida where one home lost 12 residents who eventually died. Following the disaster of this kind, how do we best ensure that long-term care facilities that lose power are prioritized as hospitals are and back up and running fast? Because that was part of the problem.

Dr. Kadlec. Part of the practical situation is is that in terms of our approach to these events, a pre-event to identify those facilities -- I don't know if you're familiar with the Empower program that we have in the department, but I think it's the idea of identifying those places where people of particular vulnerability are housed and how quickly you can make sure that they have the capacity and capabilities and are identified early so that you can connect with them and that was an issue that, quite frankly, in Puerto Rico we did on foot, place by place, because their -- the nature of their facilities was very different than what you'd find in places like Florida.

Mrs. Dingell. We do need to worry about it.

My colleagues, Debbie Wasserman Shultz, Ms. Eshoo, and I have a bill that would, among other things, require states to prioritize nursing homes in the same manner as hospitals are prioritized in all-hazards public health emergency preparedness and response plans and would include in those plans information on how utilities plan to ensure that nursing homes return to operating as soon as practical following a disaster.

I would urge all of my colleagues to support that. We are down to one minute so, Deputy Commissioner Abram, some have advocated that as a part of the reauthorization of PAHPA that we should make the MCM PRV program permanent.

Can you comment on FDA's viewpoint regarding whether or not this program should be permanent at this time?

Ms. Abram. We think it's premature to determine how effective the program has been. I think Congress had good foresight when enacting the MCM PRV program and reauthorizing the pediatric PRV program to charge GAO with looking at this.

One of the dynamics with the priority review voucher programs -- and we now have three programs: one for neglected tropical diseases, one focused on peds, one focused on security medical countermeasures, which I would point out are those which are linked to material threat determinations.

So these are pretty serious -- is the more vouchers you have,

it diminishes then the incentive and the value of the voucher. And so I think Congress had good foresight to consider that this would need to be looked at as how many vouchers are out there -- is the program having the intended effect.

There has always, throughout the journey of these issues, been a consistent threshold question, which is have we optimized the incentives for bringing forward the medical countermeasures we need to protect the American people and I think if you look at the bipartisan history of these issues from BioShield to the creation of BARDA to the innovation collaboration that Dr. Kadlec has talked about today to the MCM PRV, this continues to be a threshold question.

Mrs. Dingell. Thank you.

Mr. Burgess. The gentlelady's time has expired.

Dr. Kadlec, we know you're needing to depart and I think all the members now asked questions. I do want to just note for the record that you were part of a bipartisan Energy and Commerce delegation to the island of Puerto Rico last -- late last year and were very much a part of our work in assessing the damage there.

Also, you mentioned in your prepared testimony about the BioWatch program and I will note that the Shattuck Lecture that was published in this week's New England Journal of Medicine given

by Bill Gates, the subject innovation for pandemics also talks about an early detection system. I will probably be submitting a question for the record for you on that because I believe that should be part of our work here.

Dr. Kadlec. Thank you, sir. I look forward to it.

Mr. Burgess. And seeing no other -- Mr. Green, any parting comments?

Mr. Green. No.

Mr. Burgess. Bye. All right. We will excuse this panel and Dr. Kadlec, again, thank you for your forbearance and we appreciate all of you being here today.

And we will transition immediately to our second panel.

[Pause.]

I will ask all of our participants to take their seats and the subcommittee will continue. We are pleased to have our second panel here today.

Just as a housekeeping detail there is likely to be a series of votes on the floor. If that does occur we will adjourn briefly to -- I mean recess briefly to attend to those votes and then immediately resume activities here.

But I do want to thank our second panel of witnesses for being here today. You each have a chance to give an opening statement followed by questions from members.

We are pleased today to welcome Dr. Umair Shah, executive director of Harris County Public Health; Dr. Michelle Berrey, president and CEO, Chimerix, Incorporated; and Mr. Erik Decker, chief security and privacy officer, University of Chicago School of Medicine.

We appreciate each of you being here today and we appreciate you sticking with us through the first panel.

Dr. Shah, you are now recognized five minutes for an opening statement.

STATEMENTS OF DR. UMAIR SHAH, EXECUTIVE DIRECTOR, HARRIS COUNTY PUBLIC HEALTH; DR. MICHELLE BERREY, PRESIDENT AND CEO, CHIMERIX, INC.; ERIK DECKER, CHIEF SECURITY AND PRIVACY OFFICER, UNIVERSITY OF CHICAGO MEDICINE

STATEMENT OF DR. SHAH

Dr. Shah. Thank you, Chairman Burgess and Ranking Member Green. A pleasure to see you, Representative Barton. As fellow Texans, it's always great to have a conversation with you as well.

To members of the House Energy and Commerce Health Subcommittee, thank you for inviting me to testify this morning on this very important topic.

My name is Dr. Umair Shah. I am the executive director of Harris County Public Health, the county health department in Houston, Texas, the third largest county in the U.S. with 4.7 million people.

I am also the local health authority of Harris County, Texas. I am also here as the president of NACCHO, the National Association of County and City Health Officials, representing the nation's nearly 3,000 local health departments.

I refer you to my full written testimony today. In the interest of time, I will touch on three main points -- one, that

public health truly matters, especially at the local level and in emergencies. The PAHPA reauthorization, number two, is extremely important to support our work. Number three, CDC and ASPR must appropriately be funded and getting dollars to local communities.

So public health is vital to the health of our communities. This is especially true in emergencies. Public health does all the behind-the-scenes work and is truly boots on the ground, performing disease surveillance, ensuring the safety of our environment, spraying for mosquitoes, providing immunizations, picking up dangerous animals, supporting chronic disease and mental health efforts. These are just some of what public health departments do to keep our communities healthy, protected, and safe.

I can tell you firsthand how important these roles are because I am from an impacted community. Dating back to Tropical Storm Allison in 2001, the nation's first BioWatch had Hurricanes Katrina, Rita, and Ike, H1N1 pandemic, Ebola, and Zika and, most recently, 300-plus year floods in three years including Hurricane Harvey with its 1 trillion gallons of water that were dumped on Harris County.

Emergencies abound. But our story is one of a community of resilience, one that has invested in our health and response

systems and understands the importance of working together to prepare, respond, and recover and that's what Texans do.

Truly, our strong response to Harvey was built on the responses to Tropical Storm Allison on forward. Indeed, you can learn from previous emergencies and investments can and do pay off. Harvey was just one storm, though.

In the last year, our nation has seen severe weather events, ice storms, floods, hurricanes, wildfires, acts of violence, a severe flu season. This doesn't even include the issue of opioids or global health challenges that impact domestic health.

Truly, two things are certain. Emergencies can and will be lurking around the next corner and public health agencies will be there to respond in kind.

But we cannot do our job without the adequate resourcing and support that both public health emergency preparedness and the hospital preparedness program funding streams -- PHEP and HPP -- provide.

That's why, number two, the PAHPA reauthorization bill is so critically important for our work. Let me now speak briefly to some of the proposed provisions.

First, we strongly support the reauthorization of the PHEP and HPP programs through 2023. These are complementary programs that work hand in hand to enable health departments and health

care systems alike to prepare and respond to emergencies.

Secondly, the Medical Reserve Corps program strengthens our ability to respond by deploying an army of volunteers. We urge you to maintain the authorization level under the current law.

Thirdly, with respect to the public health emergency fund, we are concerned about the 1 percent transfer authority to infuse the fund when a public health emergency is declared. The transfer authority would take vital dollars away from other public health programs in the midst of a funding cycle and we recognize that multiple emergencies can be happening at one time.

Finally, the SNS plays a critical role in preparedness regardless of its structure or location. With the proposed of authority from CDC to ASPR legislative language must assure maintenance of appropriate coordination and support of state and local health departments.

Public health response capabilities cannot get lost in the sea of other health care system capability needs.

Number three, we feel strongly that CDC and ASPR are agencies that are critical to support what we do on the ground. The provide not just funding and resources, technical expertise, and advice, but they often are the response agencies that deploy at a moment's notice when necessary.

We must ensure that the authorization levels of both agencies are maintained.

Truly, as we do our work in public health we remain hidden from the public's eye. We have a visibility crisis in public health and it impacts our ability to be appropriately resourced.

I think of public health as the offensive line of a football team. Of course, it is Texas so I must say football. Whether it is Tom Brady or Aaron Rodgers, everyone knows the quarterback but very few know members of the offensive line, yet they are critical to the success of that line.

Just that -- just like that we are that -- the behind-the-scenes offensive line absolutely critical to the wellbeing of our communities. Since we don't invest appropriately in public health capacity, we find ourselves reactively scrambling to act when the next emergency is upon us.

Decreased investment in public health leaves us more vulnerable and forces us to rob Peter to pay Paul by taking from elsewhere, and funding fluctuations also take a toll.

If funding for public health is cut by 10 percent, for example, the expectations of our communities do not decrease by 10 percent in kind. We must have adequate resources to do our job appropriately.

Let me close by saying I am honored to represent the strong

dedicated public health workforce that give it their all as first responders in emergencies just like fire, EMS, law enforcement, et cetera, even when themselves personally impacted.

This proposed bill helps support our work. More is needed, of course, especially to support the values of innovation, engagement, equity of collaborative multi-disciplinary linking of one health, global domestic health, and all-hazards preparedness with ongoing public health capacity building, ensuring funds get equitably to jurisdictions based on both need and risk. This reauthorization is an important step in that direction.

Thank you, and I look forward to taking your questions.

[The prepared statement of Dr. Shah follows:]

**********INSERT 4**********

Mr. Burgess. Thank you, Dr. Shah.

Dr. Berrey, you're recognized for five minutes, please.

STATEMENT OF DR. BERREY

Dr. Berrey. Good morning. My name is Michelle Berrey. I would like to thank Chairman Burgess and Ranking Member Green, other members of the committee, for the opportunity to speak to you today.

I am here in support of reauthorization of PAHPA and to highlight the important components of successful public-private relationships to develop medical countermeasures from the perspective of a small biotechnology company.

I am a board-certified infectious disease and public health physician. I spent the last 20 years developing new drugs for viral diseases.

I currently serve as CEO of Chimerix, a small publicly-traded biotech of 85 employees in Durham, North Carolina. We are one of many companies currently collaborating with BARDA in development of medical countermeasures against CBRN threats.

We are here today as members of the Alliance for Biosecurity as a strong supporter of reauthorization of PAHPA.

Our lead candidate, brincidofovir, or brinci for short, is an anti-viral with activity against a broad range of viruses. It is in late stage development for treatment of small pox.

Brinci is one of a handful of dual-use agents, meaning it

is in development both as a medical countermeasure for protection of the public health and to address some of the most common viruses in patients with urgent needs for new treatments.

For brinci, this is for children undergoing bone marrow transplants. It was federal funding that allowed us to jumpstart our smallpox program and to progress to full development and our currently collaboration with BARDA.

When smallpox was eradicated in the 1970s, routine vaccinations ceased. Without broad immunity, weaponized smallpox could be devastating to the global population and thus it became an appealing potential biological weapon.

It is a highly infectious easily transmitted airborne virus with at least a 30 percent mortality date. As the first lien of defence for smallpox exposure, vaccines are stockpiled by BARDA for every American including the one in five Americans who would require a next-generation or attenuated vaccine.

So why did the Institute of Medicine also recommend that the U.S. stockpile two different smallpox antivirals with different mechanisms of action?

The reason that antivirals are critical is for three separate populations -- one, those who remain ineligible for vaccine; two, patients with severe side effects from the vaccine; and three, those with symptomatic smallpox.

Like the flu, once symptoms begin it is too late for a vaccine. Specifically for brinci, we have completed over a dozen efficacy studies for the treatment of smallpox under the FDA's animal rule. In our largest rabbit pox study, we demonstrated 100 percent survival in animals that we began dosing at the time we confirmed infection.

Our studies have also shown that brinci may also reduce transmission of smallpox by accelerating clearance of virus. This point could be critical in stopping an outbreak.

Chimerix has worked closely with our colleagues at the Division of Antivirals at the FDA to progress this challenging program. Just this morning, we received orphan drug designation from the FDA, which provides a waiver for FDUFA fees and will thus provide further savings for BARDA.

Developing countermeasures as dual-use compounds allows us to stretch precious federal resources and to ensure sustainability of the enterprise.

We've also seen that brinci's development for the treatment of life-threatening antivirus infections has provided innovations for drug formulations that are paid for fully by private sector dollars and this has reaped additional benefits for compounds that are included in the medical countermeasures and the stockpile.

The passage of Project BioShield and PAHPA created a market for medical countermeasures where one did not previously exist. Knowing that there is a fund dedicated to support stockpiling provides for our common defense. This is critical. We are developing a solution for a problem that we all hope never presents itself.

But not being prepared for a smallpox event is not an option. We commend the committee for the bipartisan collaboration on PAHPA reauthorization and in particular for the 10-year advance appropriation for the Project BioShield special reserve fund.

Companies like Chimerix rely on the existence of a government market for medical countermeasures in order to sustain the long-term investment in research and development for these critical.

I will be happy to welcome any your questions.

[The prepared statement of Dr. Berrey follows:]

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

Mr. Burgess. Thank you, Dr. Berrey.

Mr. Decker, you're recognized for five minutes, please.

STATEMENT OF MR. DECKER

Mr. Decker. Thank you, Chairman Burgess, Ranking Member Green, and members of the subcommittee. It's an honor to testify concerning the reauthorization of PAHPA.

I am the chief security and privacy officer for the University of Chicago Medicine. I also serve as the chairman of the advisory board for the Associations of Executives and Health Care Information Security, otherwise known as AHIS.

AHIS is an association that represents more than 850 senior security leaders within health care. Lastly, I serve as the industry lead and co-chair of a public private partnership task group sponsored by the Department of Health and Human Services for establishing cybersecurity best practices within the health care sector.

This group is the result of a legislative imperative of the Cybersecurity Act of 2015, Section 405(d) and authorized under the National Infrastructure Protection Plan.

We are organized under the joint cybersecurity working group within the Healthcare Sector Coordinating Council and the Government Coordinating Council.

We support the reauthorization of PAHPA. Specifically, we support the inclusion of cybersecurity as an identified hazard

and the need to designate a sector-specific agency such as ASPR to interface with the health care industry.

Over the last decade, the health care sector has witnessed the evolution of cyber-attacks against our health systems. Today's cyber-attacks have become more numerous and sophisticated from the establishment of underground markets for the exchange of stolen sensitive information to the creation of a "hacking as a service industry."

In the hyper connected world of health care, the digital footprint has exploded, creating more points of entry than ever for attacks to be successful.

As was evidenced by the WannaCry ransomware attack that was launched in May of 2017, we must recognize that cyber-attacks are a real and present danger. With the recent WannaCry incident has signalled to the industry that attacks are no longer localized to one particular health system or another but can impact us locally, regionally, and nationally.

We need a system of prevention and response that is similar to the disease prevention and infection control practices within the health care industry.

This system should encourage and incentivize the adoption of standard cyber hygiene practices, as our clinicians do with washing their hands, and that is capable of coordinating

large-scale emergency response to cyber threats as HHS has done with the Ebola and Zika outbreaks.

We feel that this is the perfect moment to introduce the inclusion of cybersecurity to PAHPA and strengthen the partnership with the federal government. Specifically, we feel that ASPR, in combination with the right cybersecurity expertise, capabilities, and funding will serve as an impartial partner to help bolster the industry's cyber capabilities.

I would like to offer a few methods that ASPR could deploy to achieve these outcomes. Number one, encourage the adoption of a cybersecurity framework and a soon to be released top ten cybersecurity best practices within health care.

Number two, bolster the importance of cybersecurity technical -- of sharing technical cybersecurity threat intelligence information through the use of a national healthcare ISAC, otherwise called NHISAC. Ensure that this information is protected from regulators.

Number three, offer enforcement relief for organizations that demonstrate the adoption of the cyber framework -- the aforementioned best practices and participation within NHISAC.

And number four, establish a national response program in partnership with NHISAC and potentially DHS that is capable of facilitating a response to the national threat.

I sincerely thank the committee for allowing me to speak on this important topic and I look forward to answering your questions.

[The prepared statement of Mr. Decker follows:]

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

Mr. Burgess. And I thank all of our witnesses for their testimony. We will proceed into the question and answer portion of the hearing. I will recognize myself five minutes for questions.

And Dr. Shah, again, thank you. Before I go to you, Dr. Shah, I wanted to introduce the Shattuck Lecture that was printed in the New England Journal of Medicine given by Bill Gates, specifically the comments about the early detection system and BioWatch.

So I will be asking unanimous consent to make that as part of the record. Without objection, so ordered.

[The information follows:]

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

So now, Dr. Shah, again, I appreciate you being here today. Appreciate all the work that you have done for the county of Harris where I lived for a while while I was in medical school. So I am very familiar with the issues that you -- that you elucidated in your testimony.

We talked a little bit about BioWatch. I think Dr. Kadlec mentioned that in his testimony. So do you see a need to update the technology currently used in the BioWatch program and is the guidance provided by Health and Human Services and Department of Homeland Security appropriate for our local responses?

Dr. Shah. Thank you, Mr. Chairman.

So let me answer that with going back a little bit in the history. So as the first BioWatch hit that we had in Houston in our community and then over the years having multiple BioWatch actionable results at the bars. What we've seen over the years is that there has been a shift in the way BioWatch was actually looked at.

Initially, it was you have a hit, it is an act of intent and you have to launch an all public health response to it. That has now shifted, fortunately, in a way that it is a laboratory confirmation -- a sensor positive that doesn't necessarily mean that it's a public health positive, and this is the difference between the science of public health and the art of public health

where we have to put all the other epidemiologic data, all the other environmental health data, all of the other factors in so we can make a determination whether this is truly a terrorist attack or a terrorist threat, and that, I think, is the way to go.

But what that really implies is that we have to make sure that the technology is as strong as it can be, it's as certain as possible to give us the right result.

And so we, certainly at the local level and even really thinking about this more from a physician standpoint, we really want to make sure that if you ask for a test that you know what you're going to do with the result and that's the first thing -- the first adage in medicine and that's what applies for here is that we want to make sure that the technology is certain, gives us the right results, and then we can use all of the other information that we have at our disposal to make a determination. So we support better technology. We also support better guidance because continuation of changing shifting guidance over the years means that we have to relook at what kind of guidance has been given to local health departments and state health departments so we could relook at this program and make sure that it really meets the needs of today and not just yesterday.

Mr. Burgess. So what is -- if I could ask, what is the state

of the art? The level of precision that is now technically available is -- obviously, you can work with that at the local level?

Dr. Shah. Yes, we can. There are -- there are some challenges with the, you know, proposed some technologies that were there.

The initial technology would allow for more information about what the results were and how there was some move towards saying it was more or less, for all intents and purposes, a positive or a negative and not giving you all the factors that were in play.

And, fortunately, DHS has moved away from that. But that was a challenge and so we are really recognizing that it's really important to work with federal, state, and local partners in a transparent way so that we can actually understand the science because we too can interpret information and we are partners as part of that system.

Mr. Burgess. Thank you for that answer.

Dr. Berrey, I referenced I went to medical school in Houston. It was a number of years ago. The New England Journal of Medicine back in 1974 or 1975 or 1976 talked about the fact that smallpox was going to be eradicated from the face of the earth.

As I sat in my study cubicle that day in the mid-1970s I

thought it was until I arrived here a number of years later as a member of Congress and found out that it wasn't.

But I just want to mention that as a thanks to you and your company for working on those agents. Right after 9/11 when people were concerned about biologic agents there was really an open question as to whether or not we were prepared because of the nonvaccination of the population and the lack of a substantial stockpile to deal with a -- what could have been a significant attack.

So you're welcome to respond to that but I just wanted to thank you for the work that your company has done.

Dr. Berrey. Thank you, Chairman Burgess, and we appreciate the opportunity to speak here today. We do believe the eradication of naturally-occurring smallpox remains probably the greatest contribution of medicine to humankind on the planet.

It is unfortunate that the technologies available to would-be attackers have kept a step ahead and we are hoping that we are keeping on lockstep with them.

I really commend BARDA for their foresight in moving forward not just with vaccination and being at the ready but their close work with CDC to be prepared to implement ring vaccination, to be able to control another outbreak that could begin from either naturally occurring or more likely from an attack of smallpox.

Some of the more recent information available about the likelihood of being able to implement synthetic smallpox is something we've had a lot of discussions about with our colleagues at BARDA and really hope to, by having multiple therapeutics available within the stockpile, to be prepared in the event to face whatever form that that smallpox could take.

Mr. Burgess. Thank you for that.

My time has expired. I will recognize the gentleman from Texas, Mr. Green, five minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman, and again, Dr. Shah, and our whole panel, thank you for being here.

I know in the Houston areas that I represent we have a coordinated effort. Both our county judge, Ed Emmett in the city of Houston and Harris County and some of the responses that we've had necessitate the deployment of the national strategic stockpile.

In your statement, you made reference, Dr. Shah, to the fact that the response to Hurricane Harvey was more than an acute response but was instead the result of years of planning and coordination.

With the likely transfer of SNS from CDC to ASPR, do you foresee any possible disruptions to the planning, coordination, and development of the SNS in future events, given that

predictable -- that frequency, intensity of weather-related events will only increase?

Dr. Shah. First of all, Congressman Green, thank you so much for your service and for the continued partnership that you have given to our health department and our community in general.

What I would say is that Hurricane Harvey was the culmination and the continuation of a lot of the lessons that we have learned over the decade plus since Tropical Storm Allison.

And, fortunately, we have learned those lessons and there has been incredible amount of investment in both public health and health care. With respect to the SNS, as you heard from the earlier panel, there -- you know, there certainly are challenges as we think about a transfer and there's some uncertainty at least at the local level of what exactly this means when they say it's being moved from the CDC to ASPR.

The biggest concern that I would -- I would put out there is the fact that we know that ASPR is responsible for hospital readiness and health care readiness, and we also know that oftentimes public health gets drowned out by the hospitals and healthcare system.

And so one of the biggest challenges we would have as moving SNS over to ASPR is to ensure that it does not get lost in all the public health activities that we at the local level and the

state level, that we require from an SNS as well -- from our federal partners.

And so ensuring that the legislation has that built in is absolutely critical. The other aspect of this is the federal medical station that was deployed during SNS for Hurricane Harvey response was very much about really having a field hospital that we were able to rely on.

Unfortunately, Florida and Hurricane Irma happened right afterwards and it started to move. And so one of our big challenges is to ensure that when we have multiple emergencies happening how do we really try to figure out what those federal assets are and how we can use them locally as well as across the system. I think that's another challenge.

Mr. Green. Well, I appreciate it, because I know the response with Hurricane Harvey and Katrina -- when the CDC came in we were treating a lot of our visitors, who are now Texans, from Louisiana. CDC can bring other resources including the public health service and I just didn't want to disrupt some of the good things we had.

If you have any suggestions on how we may make sure that that process will not lose the success we have now, I would be glad to see what we can do when we are marking up the bill, because that's my concern -- the change from CDC to ASPR, which is a great

agency, but I don't want to lose that effort.

The -- one of the -- Dr. Shah, one of the other concerns I have is we spent some today discussing the importance of well-funded public health infrastructure for preparedness and response.

A related discussion in the provision of the bill would allow the secretary to transfer 1 percent of any appropriation to the public health emergency response fund. The intent of the fund is to provide a source of extra funding for responding to public emergencies like Katrina or Harvey -- in extra funding.

However, in your written testimony, you indicated that you had significant concerns about the transfer authority. Specifically, you mentioned that the authority will take away vital dollars from other public health programs.

And my question is from the perspective of the local public health officials on the ground can you describe the challenges that would occur from allowing the secretary to transfer 1 percent of HHS funding to the public health emergency response in case of a public health emergency declaration?

Dr. Shah. Thank you again for that question.

What I would say is that we recognize the importance of having a fund because in the midst of an emergency you have to have that funding ready right then. You cannot waits months or some period

of time to get those dollars back into the system.

The challenge that we have is that while we were looking at what happened during Zika, we started to go back and pull dollars from Ebola. But Ebola was still a threat while we were also trying to find the dollars over to Zika.

And at our own health department, for example, we had hired a physician for chronic disease prevention for diabetes and high blood pressure and immediately because we did not have those funds we had to move that physician over to be the response -- part of the response system for Zika.

And so I think it's a real challenge that we have to remember that there are multiple challenges and issues the public health departments at the local level are facing all the time.

What we don't want to have happen is in mid-cycle dollars are shifted from one place to another and you now start to lose infrastructure in that existing area that is equally important.

And we also have to remember that multiple emergencies can happen at the same time. So yes, those are our concerns, Congressman, that we are interested in discussing.

Mr. Green. Thank you. I know I am out of time but that's another issue we'll look at because I still have my constituents waiting for FEMA assistance 10 months now since Harvey and I would not like to have our public health have to wait that long because

then we could end up with epidemics.

Thank you, Mr. Chairman.

Dr. Shah. When you wait for dollars that can cost lives, and so that's very important. Thank you.

Mr. Burgess. The chair thanks the gentleman.

The chair recognizes the gentlelady from Indiana five minutes for questions, please.

Mrs. Brooks. Thank you, Mr. Chairman.

Dr. Berrey, in 2004 Congress passed the Project BioShield Act, which created the special reserve fund of $5.6 billion made available over a 10-year period to help create stability and ease concerns from companies about the likelihood of, you know, help them decide about whether or not to get into the market for medical countermeasures. That has traditionally been unprofitable, and once this initial funding expired, Congress reverted to appropriating for the program on an annual basis, which I understand has created less long-term certainty.

Do you agree that recommitting to a multi-year funding approach for medical countermeasures development and procurement would help strengthen our nation against biological threats and could you please talk about whether or not it's incentives or how can we better prioritize our existing funding for medical countermeasures?

Dr. Berrey. Absolutely. Thank you, Congresswoman Brooks, and I want to thank both you and Congresswoman Eshoo for sponsoring this bill.

I will say without question that having federal moneys available for support of these long-term research and development projects is absolutely critical.

We know that the private sector does not establish the same value -- does not support those programs, especially these longer-term programs, and thus it is critical that we have federal moneys available.

We've seen the impact in other small and large companies that are committed to this space. But without a multi-year authorization have seen the dollar value and the size of those procurement contracts decrease because BARDA does not have that capability of having the security of a longer-term multi-year commitment there.

Having that dedicated fund is absolutely critical. We believe in dual use and the -- both the economic and the medical benefits that dual-use compounds can bring.

We've seen benefits to our medical countermeasure program that have been exclusively paid for through our private sector dollars.

One specific example is optimization of our pediatric

suspension. We now have a suspension that is -- has no need for refrigeration, which is ideal for the SNS, and because we are treating children through our clinical program for adenovirus, we have real-world data that can support the dosing information specific for pediatric use in the event of a smallpox outbreak.

I believe that both the long-term funding and continued support through PAHPA reauthorization are critical for that but, secondly, I wanted to make the point that I do believe dual-use compounds, even though they do bring additional challenges, have additional economic benefits.

Mrs. Brooks. Thank you.

Mr. Decker, the Blue Ribbon Study Panel on Biodefense called for the development and implementation of a government-wide security strategy for stored pathogen data that incorporates deterrent and enforcement measures, oversight, and inspection.

Would you be willing or interested in contributing to such a process and do you believe a strategy like this would improve the security of sensitive public health information?

Mr. Decker. Well, certainly, I think that focusing any amount of preparation and effort on securing sensitive information is going to be -- is going to be important.

I am not familiar with that particular provision so I am

happy to take that back and provide an answer to you, if you'd like.

Mrs. Brooks. Are you familiar with the Blue Ribbon Study Panel on Biodefense and recommendations they made?

Mr. Decker. No, I am not.

Mrs. Brooks. Okay. Well, we would welcome the opportunity to work with you on that and to get your further thoughts on what they recommended.

And finally, Dr. Shah, if we could just go in a little bit with respect -- can you help us understand the role that CDC -- we've certainly had quite a debate and discussion this morning about CDC's role and what would you say?

Are there any additional tools CDC needs that -- or resources that they need that we ought to be providing as we explore what their role is, going forward, relative to ASPR's?

Dr. Shah. Yes, that's a -- that's a tough one. Thank you for that question.

That's a tough one only because we -- there are a number of needs that public health in general has at the federal, state, and local level. And so I could really, you know, have a nice --

Mrs. Brooks. That's a huge lecture. I understand that.

Dr. Shah. Yes. Yes. Exactly. Exactly.

That said, I do think that, you know, outside of supply chain logistics and those kinds of things that, obviously, and ASPR would be -- would be very good at doing, there would be an opportunity really to be looking at the real consultation and the technical assistance --

Mrs. Brooks. Right.

Dr. Shah. -- and the support that's given to local and state health departments. Really, that's what CDC is really, really good at -- technical assistance and really being able to, you know, pick up a phone and call and/or even deploy in if you need help and assistance and want to make sure that that consultation piece is available.

But also the real piece about the support that is given to local health departments as they're doing their work. If this shifts over to ASPR and that piece is not so strong then at the end of the day the last mile is really the most important piece about SNS is how do you get medications into the -- you know, into the mouths of people and you want to make sure that local health departments have the support to be able to get that done well and that, obviously, would mean that we would continue to have that support from whomever is going to be providing it.

So those guardrails really need to be in place.

Mrs. Brooks. Thank you. I agree. I yield back.

Mr. Guthrie. [Presiding.] The gentlelady yields back and I will recognize myself for five minutes to ask questions, and thank you all for being here today.

And Dr. Shah, this is for you. During an Ebola outbreak in West Africa -- the Ebola outbreak in 2014, much was made about the lack of standards and guidelines for the use of personal protective equipment in hospitals that were treating infected patients.

What are your thoughts on establishing reasonable personal protective equipment guidelines and requirements for emergency medical service personnel in advance of a biological event based on existing research and lessons learned?

Dr. Shah. Thank you for that question.

I would say, first of all, there a few things about Ebola. I think Ebola and Zika and H1N1, the pandemic, teach us that global health is very much connected with domestic health and we have to keep that in mind.

So, really, the way to be able to interrupt the transmission or get to zero risk for the American people is to be able to interrupt transmission in global communities, for example, in West Africa in 2014 or in the case of Zika in Latin American and Caribbean countries.

That also, obviously, is a concern now with the Democratic

Republic of Congo with DRC because the concern now is does this get into an urban environment that potentially you could get spread and get on a plane and you can now get to North America and here we are, we are back and playing for years later a very similar situation.

So we work very closely with our environmental health folks. I mean, the environmental health field is amazing when it comes to really helping us as well as the occupational health field when it comes to those personal protective equipment and those environment changes that need to be made and we really believe with a disease like Ebola, because it's so meticulous that you have to use personal protective equipment every single time, we have to recognize the absolute importance of ensuring that we are working with our private sector that are designing these suits, designing those gloves, designing those masks, designing all those -- all those materials but we also train local practitioners so they know what they're doing, how they're doing it, how they're putting it on, how they're using it so they are meticulous.

One example I will give you is from Hurricane Harvey. We have J.R. Atkins, who was an EMS responder, who volunteered. In the middle of -- he was meticulous about using personal protective equipment except one time where he was bitten by a

mosquito -- it was a spider, most likely, and he wound up having necrotizing fasciitis, a flesh-eating bacteria, and we wound up going to the operating room three to five times.

So we have to be meticulous when it comes to infectious disease control and we certainly support that.

Mr. Guthrie. Okay. Thank you very much.

And also -- and this for you but anybody on the panel that would like to address it -- the public health emergency preparedness cooperative agreement is an annual source of direct funding for state and local public health systems.

Can you speak about the importance of these agreements in terms of capability to address biological threats and how do state, local, and territorial public officials leverage the federal support and how does it help prepare the country for the next outbreak?

Dr. Shah. Thank you again for that question.

What I would say is that we recognize that there is a lot of capacity already at the local and state level. There is a lot that's already being done with the resources that we have in state and local communities.

But it would be important to say that public health emergency preparedness funding -- that 55 percent of local health departments are actually relying on those dollars for their

preparedness work.

It is so critical to many of our local health departments, especially the smaller local health departments, the more frontier local health departments. We have to make sure that those dollars are available and that they can support and really augment what's already happening at the local level.

The other piece around the biologics is that we want to make sure that there is improved recognition of quicker digital systems and recognition of surveillance systems that really allow us to do disease pattern recognition.

The final point that I would make in the interest of time is the fact that we have to really be thinking about where the risk is, where the threats are, and really ensuring that those dollars are going not just to certain areas of a community but all of a community to make sure that those dollars are really reaching those local health agencies that are boots on the ground to ensure that they can do the work that they're doing.

Mr. Guthrie. Thank you.

Anybody comment? I know that's more his area but anybody want to comment on that as well?

Dr. Berrey. The only additional point that I would make is as we look back on smallpox and as Chairman Burgess noted earlier that we haven't seen smallpox since the 1970s. So when

you think about the physicians that are currently staffing emergency rooms, it's very unlikely that any of the physicians who are currently serving in those first response settings have actually seen smallpox.

So a big component not just in diagnosis is first to think about this could be a bioweapon, could be a chemical weapon, reflect recently on coverage of the nurses who was treating the Russian spy and his daughter who, when they first were -- entered into the emergency room considered it was mostly likely an opioid overdose, and only an hour later as the physically -- the police officer was brought in with similar symptoms did they realize that this was not in fact an opioid overdose.

So we really have to go back to thinking about those zebras. When you hear hoof beats, don't always think of zebras, but today might be the day for us to begin remembering those zebras. We can be educating our physicians to think about early diagnosis and give them the tools to make sure that diagnosis can occur rapidly.

Mr. Guthrie. Thank you. My time is expired.

I will recognize the gentleman from Missouri, Mr. Long, for five minutes for questions.

Mr. Long. Thank you, Mr. Chairman.

Doctor -- Mr. Decker, did you participate in the industry

calls that HHS led during the WannaCry cyber-attack?

Mr. Decker. Yes, I did.

Mr. Long. Did you find them valuable?

Mr. Decker. Yes, I did. I mean, what was -- what was valuable was getting the information out to all the health systems so that we could understand what was happening -- if we were being impacted. There was also -- having a sort of a pulse on what was going on in Europe and the U.K. at the time and if that was coming over across the pond was important.

There was some confusion on some of the calls -- some information that came out of those calls that was technical in nature and it was not necessarily related to the actual technical nature of the attack that was occurring. But the coordinated and facilitation effort of what those calls were doing was highly useful.

Mr. Long. So I am assuming that you did find it valuable to interact with HHS in real time?

Mr. Decker. Absolutely.

Mr. Long. Do you think that if another WannaCry attack took place today HHS would be able to serve a similar kind of function?

Mr. Decker. I think they would stand up a similar type of activity -- an incident response function like that. I think it would be beneficial for the preparedness of that response to

be a little more coordinated.

The means by which HHS is facilitating the process versus the means by which information sharing and analysis centers facilitate technical and distribute technical information down to the health systems, I think there's some better coordination that could occur there as well as some further monitoring of the other critical infrastructures that's occurring.

But, ultimately, you know, having HHS serve as the focal point and facilitation point and the coordination point for a national response so that we can have an open line of communication with them in case we need help is, I think, incredibly important.

Mr. Long. If another cybersecurity incident like WannaCry were to take place, would you want to contact HHS for guidance and additional information?

Mr. Decker. We would -- personally, yes. I think there's also a bit of hesitancy from some of our constituents on HHS being a regulator as well as an office that provides support and resources.

I think there's a hesitancy for some to not open up the lines of communication. So I think that further bolstering the knowledge of who that sector-specific agency is, what the protection is --

Mr. Long. Knowledge of what? I am sorry.

Mr. Decker. Of who the sector-specific agency is and how we can communicate with them under protection is something that would help with disseminating that information.

Mr. Long. If it did happen again, who would you want to contact at HHS and how do you know that that would be the right person to contact?

Mr. Decker. Yes. So contacting ASPR would be on the list as well -- now, ASPR would probably be the main focus point, or the MCIC within the Department of Health and Human -- or DHS.

Mr. Long. You mentioned some people might have concerns about sharing information with HHS since HHS is your regulator --

Mr. Decker. Yes.

Mr. Long. -- in addition to your sector-specific agency. You said other people had that concern. Do you share that concern?

Mr. Decker. Do I share that concern?

I think there is a clear line between which operating division is responsible for interfacing with industry and which is responsible for regulating the industry.

But I don't think that is common knowledge throughout all the healthcare industry. I think people see HHS as the regulator. They don't understand the intricacies inside of HHS.

So though I understand the difference between what ASPR is, what OCR, what ONC, CMS, et cetera, are, I think that's -- it's not a common knowledge.

Mr. Long. What steps could HHS take to address some of the concerns that you detail?

Mr. Decker. A lot of focused education and awareness I think would be important. Designating a very specific agency that's going to be responsible for coordinating with the sector -- with the industry is, I think, very important.

Being able to facilitate the various guidance between OCR, FDA, ONC, CMS, et cetera, because all of those operating divisions produce guidance for cybersecurity for the health care industry.

But it's potentially in conflicting matters and so deconflicting the guidance that comes out and being able to really lower the barrier of entry to, you know, to the cyber space I think is going to be important, especially for the smaller practice organizations like small practice -- small practices, one- or two-physician practices, critical access hospitals, community hospitals where they're resource strapped and every dollar that they have, if they spend it on cyber or if they spend it on public health, or they spend it on something is something they have to consider.

Mr. Long. With all the players involved in the soup it sounds like acronymology to me.

Mr. Decker. It is a little bit.

[Laughter.]

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

Mr. Burgess. [Presiding.] The chair thanks the gentleman. The gentleman yields back. We are just about to have votes on the floor so it looks like there are no further members wishing to ask questions.

So I want to thank our witnesses for being here with us today. Pursuant to committee rules, I will remind members they have 10 business days to submit additional questions for the record.

I am going to ask witnesses to submit their response within 10 business days upon receipt of those questions.

I would also like to submit documents from the following, for the record: American Academy of Pediatrics, the American Hospital Association, the American Society for Microbiology, America's Essential Hospitals, Global Health Technologies Coalition, Healthcare Leadership Council, Infectious Disease Society of America, International Safety Equipment Association, and the Trust for America's Health statement.

Again, members have 10 business days to submit additional

questions. I ask the witnesses to submit their responses within 10 business days of the receipt of those questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:13 p.m., the committee was adjourned.]