

**FACING 21ST CENTURY PUBLIC
HEALTH THREATS:
OUR NATION'S PREPAREDNESS
AND RESPONSE CAPABILITIES, PART I**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING FACING 21ST CENTURY PUBLIC HEALTH THREATS, FOCUS-
ING ON OUR NATION'S PREPAREDNESS AND RESPONSE CAPABILITIES

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JANUARY 17, 2018
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C O N T E N T S

STATEMENTS

WEDNESDAY, JANUARY 17, 2018

	Page
Alexander, Hon. Lamar, Chairman, Committee on Health, Education, Labor, and Pensions, Opening Statement	5
Murray, Hon. Patty, a U.S. Senator from the State of Washington	2
Burr, Hon. Richard, a U.S. Senator from the State of North Carolina	1
Casey, Hon. Robert P. Jr., a U.S. Senator from the State of Pennsylvania	6

WITNESSES

Kadlec, Robert, M.D., Assistant Secretary for Preparedness and Response, Department of Health and Human Services, Washington, DC.	8
Prepared statement	10
Gottlieb, Scott, M.D., Commissioner, U.S. Food and Drug Administration, Silver Spring, MD	14
Prepared statement	15
Redd, Stephen C., M.D., RADM, Director, Office of Public Health Prepared- ness Response, Centers for Disease Control and Prevention, Atlanta, GA	20
Prepared statement	21

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WEDNESDAY, JANUARY 17, 2018

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:04 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Richard Burr, presiding.

Present: Senators Alexander, Burr [presiding], Isakson, Collins, Cassidy, Young, Murkowski, Murray, Casey, Bennet, Murphy, Warren, Kaine, Hassan, Smith, and Jones.

OPENING STATEMENT OF SENATOR BURR

Senator Burr [presiding]. I would like to call this hearing to order, the Senate Health, Education, Labor, and Pensions Committee.

This morning, we are holding a hearing titled, "Facing the 21st Century Public Health Threats: Our Nation's Preparedness and Response Capabilities." We will hear from Dr. Robert Kadlec, the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services; Dr. Stephen Redd, Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention; and Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration.

This is the first of two hearings we plan to have on this topic. The second will be noticed for Tuesday, January 23.

Senator Murray and I each have an opening statement, then I am going to turn to Senator Alexander and Senator Casey for any opening remarks they might have. After that, we will introduce our panel of witnesses and hear their testimonies. And then each Member will have up to 5 minutes for any remarks and questions.

First, I would like to welcome the Chairman and thank him for giving me the opportunity to hold the gavel today. This hearing discusses a topic that is critical to our national security and has seen many years of bipartisan work in this Committee and in this Congress.

Together, we have developed and strengthened the framework to ensure we are prepared for chemical, biologic, radiological, and other nuclear threats with the potential to jeopardize the health of all Americans.

The Pandemic and All-Hazards Preparedness Act of 2006 created a framework which has grown and changed as we have learned from each public health experience we have been through. We should be proud of the accomplishments under PAHPA and the progress made over the last decade.

Our work has resulted in strong partnerships with our states and local counterparts, created greater certainty and accountability to bring forward medical countermeasures, and established a clear strategy with which we can combat the full range of public health threats we face today and those we may encounter in the future.

Despite this progress, we are not fully prepared and more work remains to accomplish our goals. The Blue Ribbon Study Panel on Biodefense stated in their 2015 report that there are, and I quote, “Serious gaps and inadequacies that continue to leave the Nation vulnerable to threats from nature and terrorists alike.”

As we move forward in revisiting this successful and bipartisan law, I want to make it very clear to my colleagues that this is a reauthorization of a national security bill, and I look forward to working with each of you on this important issue.

The threats we face continue to evolve and it is critical that we bring, with this discussion, the vigilance, urgency, and resolve this mission demands. We are in an unprecedented era of technological and biomedical innovation and advancement.

In November 2016, the President’s Advisory Council on Science and Technology warned that, and I quote, “While the ongoing growth of biotechnology is a great boon for society, it also holds serious potential for destructive use by both states and technically competent individuals.”

I urge the U.S. Government’s past ways of thinking and organizing to meet biological threats needs to change to reflect and address this rapidly developing landscape. For this reason, it is critical that fostering and advancing innovation, particularly in the development of medical countermeasures, is top of mind and that we work through this reauthorization process to ensure CDC, FDA, ASPR, BARDA have what they need to keep pace with these rapidly changing and evolving threats.

This Committee has worked to push the Federal Government, and HHS in particular, to meet these challenges. An HHS that fosters innovation in the development of medical countermeasures and across PAHPA’s framework provides the greatest hope to ensure the safety of the American people. The witnesses we have before us today will be able to provide insight into the urgency of this mission and the promise innovation holds if properly leveraged.

I look forward to hearing from each of you about the progress that we have made, and where we can continue to improve policies and programs to realize their full potential to save Americans’ lives.

Now, I would like to turn to Senator Murray for any comments she might have.

STATEMENT OF SENATOR MURRAY

Senator MURRAY. Thank you very much.

And thank you, to all of you, for joining this hearing on our Nation’s preparedness to combat public health threats as we look to-

ward now reauthorizing the Pandemic and All-Hazards Preparedness Act later this year.

I especially want to thank Senator Casey and Senator Burr for their bipartisan work and leadership on this really important issue.

Local Washington state papers show why today's discussion is so important to families across this country. We have headlines like, "Flu Deaths And Cases Increasing In Pierce County." And, "Flu Outbreak In Snohomish County Kills Five; 50 Hospitalized."

A bad flu season can be a nightmare for families and too often ends in horrible tragedy. Just as we must continue to improve our public health response across the board to prevent those tragedies on the local level, we have to also make sure we are vigilant against pandemics of a global scale.

A pandemic could affect half a billion people, more than the entire population of the United States; and that is not speculation. It happened 100 years ago. The 1918 influenza epidemic was a tragedy more deadly to the human race than World War I. And today, the threat of pandemic flu is joined by new threats.

What have we learned in the last century? Are we better prepared for the next catastrophe?

When we consider Ebola and how the Centers for Disease Control and Prevention, and so many partners, supported Nigeria as they instituted evidence-based policies and tracked the path of that disease, and contained it when the outbreak reached Lagos, the answer is clearly, yes.

When you consider our Strategic National Stockpile which can deliver 50 tons of emergency medical supplies anywhere in the U.S. in 12 hours, the answer is clearly, yes.

When you consider the FDA's approval of new medical countermeasures to combat anthrax, and flu, and radiation, and plague, the answer is clearly, yes.

However, our track record is far from perfect. We still can do better.

We can do better than the President's way too slow response in Puerto Rico and the U.S. Virgin Islands after Hurricane Maria. The storm left many Americans without access to clean water, and electricity, and healthcare for months.

We can do better than the Administration's response to the opioid epidemic. President Trump declared the crisis a public health emergency 83 days ago and has taken little meaningful action since.

So I am glad this Committee will continue its bipartisan work to address the opioid crisis in another hearing soon.

We can also do better than our slow response in approving funding to combat Zika in 2016. The World Health Organization declared Zika a global health emergency in February. Instead of a fast response with needed funding, the response got politicized around some Republicans who pushed to undermine women's healthcare and access to contraception, which was a key requirement to prevent the virus from causing devastating birth defects.

As a result, that took Congress 9 months to pass emergency funding for a public health crisis that endangered mothers, and babies, and families across the world. That delay hurt people and it

harmed families in ways they are going to carry for the rest of their lives. So we have to do better.

We are most successful at protecting our families against pandemic threats when we respond with quick, bipartisan action.

We need decisions based in science and expert medical opinion, not ideology, especially when it comes to women's health.

We need Federal, state, and local agencies to hire the people, and capacity, and have the funding they need to protect communities. Hiring freezes and funding cuts make us less prepared, not more.

We need to plan for everyone. We cannot overlook the young or the elderly. We cannot forget pregnant women, or individuals with disabilities, or those fighting chronic diseases like diabetes.

We need innovative medical countermeasures to protect us from today's threats like a universal flu vaccine and antibiotics to combat resistant bacteria. And we must continue strong partnerships with industry that will allow us to rapidly respond to new threats.

We need to stop fear and uncertainty before they create panic by getting families helpful and accurate information from sources that they trust. We cannot allow anyone to undermine the science of proven solutions like vaccines.

We need to respond to global health crises abroad before they travel here to home. Diseases are not stopped by borders, or walls, or bans. This is a place where the United States can, and should, lead.

We should continue to show our international partners that we are focused on these issues and will be their ally in preparing for, and addressing, public health threats.

Congress has a strong, bipartisan track record of addressing these challenges through the PAHPA, which strengthened our Nation's public health preparedness and created new roles, and programs, and authorities for public health emergency response.

Reauthorizing the Act in 2013, we built on that record and enhanced medical surge capacity. We modernized biosurveillance capabilities and increased our focus on at-risk individuals.

I am hopeful we can continue that progress with legislation that focuses on the science and evidence based policies we know work to mitigate public health crises, that considers the needs of everyone, and puts families and women before politics, supports state and local public health officials, ensures communities do not spend months waiting for emergency resources, and enables us to respond to the next crisis with foresight rather than learn from the next tragedy with hindsight.

We do not know what the next public health threat will be. We do not know where, or when, or even how it will start. But we do know that being prepared starts now.

All of you here today have a critical role to play in keeping our communities healthy and safe. The Food and Drug Administration helps facilitate the development and review of medical countermeasures and grants emergency use authorizations for products that are needed on the frontlines.

The Assistant Secretary of Preparedness and Response guides our Nation's preparedness planning. They help ensure our healthcare system is ready to face any emergency. And it invests

in the medical countermeasures pipeline through biomedical advanced research and development authority.

The Centers for Disease Control and Prevention is on the frontlines supporting state and local public health departments, overseeing the Strategic National Stockpile, gathering and analyzing key data, and serving as a trusted source of information to the public.

I am interested to hear from all of you today about your work to fulfill these important roles and keep our country safe.

Mr. Chairman, I do want to say I am frustrated that Director Fitzgerald is, once again, unable to join us here today. Due to conflicts of interest presented by investments, our CDC Director still has to recuse herself on some of the important health issues that we face, including issues related to data collection and information sharing, which are very relevant to the conversation that we are having today. I am concerned that she still cannot give her full attention to all the pressing health threats we face and hope that these conflicts of interest will be resolved soon.

Thank you, Dr. Redd, for joining us in her place and I look forward to hearing from you.

Thank you, Mr. Chairman.

Senator BURR. Thanks, Senator Murray.

Senator Alexander.

STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Thank you, Senator Burr.

Senator Burr, thank you for your willingness to chair this hearing.

In March 2013, President Obama signed into law the bipartisan Pandemic and All-Hazards Preparedness Reauthorization Act. Senator Burr was the author of that reauthorization and the original legislation, which became law in 2006. He worked with many Senators on this Committee, both Democratic and Republican, and I thank them all for that. Senator Murray, Senator Casey, and others, Senator Isakson was another of those. So Senator Burr is chairing the hearing and I thank him for that.

I would also like to welcome Senator Smith from Minnesota, who is joining our Committee and replacing Senator Franken, who was a valuable Member of the Committee.

Senator Jones, from Alabama, is also a new Member of the Committee. We welcome him. He replaced Senator Whitehouse, who was a very valuable Member of the Committee, and who has taken a lesser assignment on the Finance Committee for some reason.

[Laughter.]

The CHAIRMAN. But we will miss Sheldon and his work on this Committee.

Mr. Chairman, I am going to withhold my comments, although what I would like to do is call on Senator Isakson for 1 minute, just to make some comments, and then we will go to Senator Casey.

Senator BURR. Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman.

I just wanted to, in reference to the statements made by the ranking Member, Senator Murray, whom I have talked to about Dr. Fitzgerald. I talked with Dr. Fitzgerald yesterday.

As chairman of the Ethics Committee, I have gotten her in touch with the appropriate people to deal with the issue. She is forthrightly dealing with it to the best I can determine and I am working expeditiously to see we get it done as quickly as possible, so she will not have any conflict to testify whatsoever. And that is her desire as well.

Thank you.

Senator BURR. Senator Casey.

STATEMENT OF SENATOR CASEY

Senator CASEY. Thank you very much, Senator Burr.

I am grateful for this hearing, and grateful to be working with you again on this reauthorization, and commend your work on this for many, many years.

I also want to thank, of course, the Chairman, Chairman Alexander and Ranking Member Murray for this bipartisan hearing on the Nation's preparedness and response capabilities in advance of the reauthorization of the Pandemic and All-Hazards Preparedness Act known as PAHPA.

I will give you one story, one brief story, but I think, instructive about how important preparation is. This is a good example of preparedness infrastructure that PAHPA supports, in this case, in the aftermath of a tragedy, a train derailment that occurred in Philadelphia in May 2015.

The train was carrying 238 passengers. When it derailed, eight people lost their lives. Over 200 were injured in that derailment.

Fortunately, through funding from PAHPA's Hospital Preparedness Program, which we know by the acronym HPP, the Pennsylvania Department of Health and a regional healthcare coalition had long been working together to prepare local healthcare systems for emergencies that could cause a surge in patients.

When the train derailed, HPP funded systems were tracking bed availability in local hospitals and providing that information in real time to emergency responders who were at the scene, helping them to effectively triage patients, send them to hospitals that had the capacity to accept additional patients so they could begin to receive the care they needed.

Because these systems were in place before the train derailed, they were ready to protect both health and to save lives when seconds, literally seconds, counted.

Yet, health security threats are increasing in frequency and intensity due to a combination of factors including newly emerging infectious diseases, extreme weather events, and our aging infrastructure.

So now, more than ever, we must continue to build our Nation's resiliency by investing in countermeasure development, surveillance, and supporting state and local partners to reduce the impact of health events in the country.

So I would like to thank today's witnesses for their service. It is important to mention your service to the country, as well as your commitment to protecting America's public health.

We look forward to the hearing and grateful for the work that we can do today at this hearing.

Thank you, Mr. Chairman.

Senator BURR. Senator Casey, thank you.

Thank you for your continued help and work on this issue.

Let me just remind Members that this is the start of the reauthorization of PAHPA. Now, having been in Congress for 24 years, I realize that when you get involved in HHS legislation and FDA legislation, there is always a temptation to fix other things.

I want to encourage you to fight the urge. Let us keep this focused on perfecting PAHPA. It has been successful. We still have work to do, but if we become distracted and create a fight over changes within the FDA that have nothing related to this, or HHS, or somewhere else because the sheer geography that just PAHPA allows us to get into, we will lose the focus of what we are doing, and that is trying to make PAHPA even more effective in the future.

So with that, I would like to introduce our witnesses, which each have up to 5 minutes to give their testimony.

I am pleased to welcome today Dr. Robert Kadlec. Dr. Kadlec is the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. If he does not like the title, he was the one that created it.

It was with Dr. Kadlec's help that we created the ASPR position as part of PAHPA to establish a clear line of authority in the event of a public health emergency. The APSR is the person at HHS solely responsible for leading and coordinating the Federal medical and public health preparedness and response effort across all the agencies within HHS including FDA and CDC.

Dr. Bob, delighted to have you back today.

Next, we will hear from Dr. Scott Gottlieb. Dr. Gottlieb is the Commissioner of the Food and Drug Administration.

The FDA plays a critical role in our emergency preparedness and response capabilities through its review of medical countermeasures, including drugs, vaccines, diagnostic tests, and by ensuring these countermeasures are safe and effective.

Further, the 2013 reauthorization of PAHPA aimed to improve regulatory certainty and predictability for medical countermeasures under review at the FDA, while also providing the agency with the additional authorities to support rapid response to public health emergencies.

Scott, we are delighted to have you here and delighted to have you in that position at FDA.

Finally, we will hear from Dr. Stephen Redd. Dr. Redd is the Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention.

The CDC serves a number of roles under the PAHPA framework and has built strong relationships with state and local public health departments, an important aspect of preparing for, and responding to, emergency public health threats.

The CDC also works to make sure we have the information we need in advance of and during a public health emergency. As part of this effort, the CDC houses an expansive epidemiology laboratory capacity and is responsible for biosurveillance and public health data collection activities.

Again, we welcome all of you.

Let me just say at the beginning, I believe the hurdle that is in our way is not available innovation. I believe the hurdle that is in our way is government. Clearly defining what it is that our need is, and the certainty of a pathway for getting the approvals that we need for those to actually be deployed.

So I hope you will keep those in mind as you go through, not just your testimony, your questions, but more importantly in the roles that you carry out after leaving. Understand that you are on the frontlines at making this happen.

Dr. Bob, the floor is yours.

STATEMENT OF ROBERT KADLEC, M.D., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. KADLEC. Well, thank you, sir. Sorry for the false start there. I was excited to be here, sir. I was ready to go.

Good morning, Mr. Chairman, both of you, sirs and Senator Murray, and distinguished Members of the Committee.

I assumed this role 5 months ago just a week before Hurricane Harvey struck Texas. It has been an interesting experience so far and I have much to share from that experience.

I appreciate the opportunity to appear before you today as you prepare to consider the second reauthorization of PAHPA. This Committee championed the bipartisan effort to draft and pass this groundbreaking legislation and I want to thank you for your continuing commitment to this endeavor.

I am proud to have played a part in the original legislative process during my tenure with this Committee, and acknowledge the vision and leadership of Senator Burr and the late Senator Ted Kennedy.

This morning, I will share with you my perspective on the national security imperative of PAHPA, the mission and duties of ASPR, and my vision for areas of improvement.

The Constitution states that one of the Federal Government's fundamental obligations is to provide for the common defense, to protect the American people, our homeland, and our way of life. The strength of our Nation's public health and medical infrastructure, as well as the capabilities to quickly mobilize a coordinated national response to pandemics, attacks, and disasters are essential to save lives and protect all Americans.

Therefore, improving national readiness and response capabilities for 21st century threats is a national security imperative, as Senator Burr outlined earlier, and is the crux of my efforts as the ASPR.

The 21st century health security environment is increasingly complex and dangerous. It demands that we react with urgency. Having recently left my job with the Senate Select Committee on Intelligence, I know these threats all too well.

Terrorist organizations remain determined to attack the United States. State actors now directly threaten our homeland with nuclear weapons and have the means to employ both chemical and biological weapons.

Further, we have witnessed the increased frequency of naturally occurring disasters as well as disease outbreaks and are currently

monitoring potential emerging infectious diseases that could cause a pandemic such as the H7N9 influenza strain circulating in China.

The bottom line is whatever happens, your constituents, the American people, expect our Federal Government to be ready to respond to save lives.

When APSR was originally established by PAHPA a decade ago, the objective was to answer a simple question: who is in charge of all Federal public health and medical preparedness and response functions? The approach adopted was based on the Goldwater-Nichols Act that created the Unified Combatant Commands at the Department of Defense.

APSR's mission is to save lives and protect Americans from these threats by recruiting the entire weight of the federal, medical, and public health assets and recruit support of the public health sector to support state and local activities and responses to help Americans in distress.

As APSR, I have four key priorities.

First, provide strong leadership. Focus on coordination, planning, and preparing for events that threaten the national health security. Second, develop the national disaster healthcare system.

Third, advocate for CDC's sustainment of a robust and reliable public health security capabilities.

Last, but certainly not least, advance an innovative medical countermeasure enterprise.

Two areas of progress and opportunity I will elaborate on are operational healthcare readiness capacity and the medical countermeasures enterprise.

The importance of the national healthcare readiness and medical surge capacity was highlighted during this hurricane season. After Hurricanes Harvey, Irma, and Maria, 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 healthcare with HHS disaster medical assistance teams, as well as V.A. and DOD assets.

We learned from these disasters that ASPR needs to update its incident command and deployable medical capabilities, as well as enhance our support for the healthcare infrastructure across the country.

As with medical countermeasures, the Nation's healthcare delivery infrastructure is mostly a private sector enterprise that must be effectively engaged in improving readiness.

To address the potential catastrophic medical consequences of the 21st century threats, we need a tiered regional system that is based on existing local healthcare coalitions and trauma centers that integrates all medical response capabilities, including Federal assets, as well as emergency medical services, the frontline of our response capabilities.

We must expand specialty care expertise and trauma, behavioral healthcare and chemical, biological, radiological nuclear response. And certainly, but not least, incentivize the healthcare system to integrate measures of preparedness into daily standards of care. I call this the foundation of a national disaster healthcare system.

The second area is our medical countermeasure enterprise, and I am grateful that Dr. Rick Bright behind me—Rick, why do you not wave to the crowd—who is the Director of BARDA, is joining me today.

BARDA was established as part of PAHPA and is a component of ASPR to bridge the so-called “valley of death” in the late stage development of vaccine, drug, and diagnostic development when many products historically languished or failed.

By using flexible, nimble authorities, multiyear advanced funding, strong public-private partnerships, and cutting edge expertise BARDA has successfully pushed many innovative products from advanced development to stockpiling FDA approval. To this date, 34 products have been approved by the FDA for the purposes of responding to disasters to the credit of Dr. Bright and his predecessor, Dr. Robin Robinson and the team at BARDA.

We have opportunities to further improve this enterprise by streamlining our internal decisionmaking processes, finding new ways to support innovation, promoting flexible, fast response capabilities, and increasing our collaboration with Federal interagency partners.

We also must work closely with our state and local partners, as well as the private sector to enhance the capability to quickly distribute and dispense medical countermeasures in an emergency.

In times of great challenge, we have the opportunity to build on the great progress made and further improve our national readiness and response capabilities.

I look forward to working with you and your staff. And thank you, again, for your bipartisan support and commitment to national security.

I am happy to answer any questions you have.

[The prepared statement of Dr. Kadlec follows:]

PREPARED STATEMENT OF ROBERT KADLEC

Good morning Mr. Chairman, Senator Murray, and other distinguished Members of the Committee. I am Dr. Bob Kadlec, the Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services (HHS). I assumed this role 5 months ago, a week before hurricane Harvey struck Texas. I appreciate the opportunity to appear before you today as you prepare to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), which expires at the end of this fiscal year.

Building upon years of incremental legislative changes in the prior decade, this seminal legislation transformed the Federal Government’s medical and public health preparedness for threats to our national security. This Committee championed the bipartisan oversight and analysis that led to the drafting and passage of this groundbreaking legislation. I want to thank you for continuing that commitment here today.

I am proud to have played a part in that original legislative process, when during the 109th Congress, I was Staff Director of this Committee’s Subcommittee on Biodefense and Public Health Preparedness, led by Senators Burr and Kennedy. In the decades before and after PAHPA was passed, I worked in various government capacities focused on biodefense and national security. I spent more than 20 years in the United States Air Force as an officer and physician, and served as Special Advisor for Counter Proliferation Policy within the Office of the Secretary of Defense during 9/11 and the 2001 anthrax attacks. I served two tours of duty at the White House Homeland Security Council, first as the Director for Biodefense then as Special Assistant to President Bush for Biodefense Policy from 2007 to 2009. Most recently before taking my current position, I served as the Deputy Staff Director for the Senate Select Committee on Intelligence.

This morning, I will share with you my perspective on the national security imperative of PAHPA, the mission and duties of ASPR, the status of our Department

and our Nation's public health and medical preparedness and response capabilities, and my vision for areas of improvement. I welcome the opportunity to engage with you and your staff in the months ahead as you continue your oversight and legislative drafting.

The National Security Imperative

The Constitution states that one of the Federal Government's fundamental responsibilities is to provide for the common defense—to protect the American people, our homeland, and our way of life. The strength of our Nation's public health and medical infrastructure, and the capabilities necessary to quickly mobilize a coordinated national response to emergencies and disasters, are foundational for the quality of life of our citizens and vital to our national security. Therefore, improving national readiness and response capabilities for 21st century health security threats is a national security imperative and is my singular focus as the ASPR.

The 21st century health security environment is increasingly complex and dangerous; it demands that we act with urgency and singular effort: to save lives and protect Americans. Terrorist organizations such as ISIS and al-Qaida remain determined to attack the United States as we experienced first-hand in 2001. ISIS has demonstrated no compunction about using chemical and other unconventional weapons in attacks overseas. State actors, such as North Korea, have already threatened our homeland with nuclear weapons, and have the means to employ both chemical and biological weapons; the Syrian regime has already used chemical weapons against its own citizens.

Furthermore, we have witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola, and SARS, and we are monitoring other potential emerging infectious diseases that could cause a pandemic, such as the H7N9 influenza strain circulating in China. 2018 marks the 100 year anniversary of the 1918 influenza pandemic, which killed more people than World War I. During that pandemic, more than 25 percent of the U.S. population became sick and 675,000 Americans, many of them young, healthy adults, died from the highly virulent influenza virus.

Cyber-attacks like the WannaCry incident remind us that technological advancements have tradeoffs in the form of new vulnerabilities and risks, as our health delivery systems become more networked.

Finally, we face extreme weather events, such as the recent 2017 hurricane season in which Hurricanes Harvey, Irma, and Maria caused an unprecedented amount of damage, reminding us of the awesome destructive power of nature.

These are threats that most of us would rather not think about. However, when natural disasters, disease outbreaks, or attacks occur, the people expect our government to be ready to respond to save lives and protect Americans.

The ASPR Mission & Duties

When ASPR was originally established by PAHPA a decade ago, the objective was to create "unity of command" by consolidating all Federal nonmilitary public health and medical preparedness and response functions under the ASPR. This approach was modeled on the Goldwater-Nichols Act that created the Department of Defense (DoD) combatant commands; the impetus was the disorganized and fragmented response to Hurricane Katrina in 2005.

ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR is, in effect, the national security mission manager for HHS. As such, on behalf of the Secretary of HHS, ASPR leads the public health and medical, preparedness, response and recovery to disasters and public health emergencies, in accordance with the National Response Framework (NRF) and Emergency Support Function No. 8 (Public Health and Medical Services). It is my responsibility to coordinate the Nation's medical and public health capabilities to help Americans during such events, whatever their cause. ASPR also coordinates with other components of HHS with respect to HHS's role in ESF No. 6 (Mass Care, Housing, and Human Services) and HHS's lead role as the coordinating agency with respect to the Health and Social Services Recovery Support Function.

ASPR coordinates across HHS, the Federal interagency, and supports state, local, territorial, and tribal health partners in preparing for and responding to emergencies and disasters. ASPR, in partnership with HHS agencies, works to enhance medical surge capacity by organizing, training, equipping, and deploying Federal public health and medical personnel and providing logistical support for Federal responses to public health emergencies. ASPR supports readiness at the state and local level by coordinating Federal grants and cooperative agreements and carrying out drills and operational exercises. ASPR oversees advanced research, development, and procurement of medical countermeasures (e.g., vaccines, medicines, diagnostics,

and other necessary medical supplies), and coordinates the stockpiling of such countermeasures. ASPR manages the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, and the Public Health Emergency Medical Countermeasures Enterprise.

HHS and ASPR have made significant progress since PAHPA was enacted in 2006 and was reauthorized in 2013, which I will discuss shortly. The ASPR organization is filled with very capable, committed, and mission-driven staff; I am proud to lead them. It is my goal to further improve national public health and medical readiness and response capabilities, which have been developed by my predecessors who worked long hours to establish ASPR and build the capabilities that exist today. I aim to do that through four key priority areas:

- First, provide strong leadership, including clear policy direction, improved threat awareness, and secure adequate resources.
- Second, seek the creation of a “national disaster healthcare system” by better leveraging and enhancing existing programs—such as the Hospital Preparedness Program (HPP) and the National Disaster Medical System (NDMS)—to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery.
- Third, advocate for the sustainment of robust and reliable public health security capabilities, primarily through the Centers for Disease Control and Prevention (CDC), but also through other components of HHS, including an improved ability to detect and diagnose infectious diseases and other threats, as well as the capability to rapidly dispense medical countermeasures in an emergency.
- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on additional authorities provided in the 21st Century Cures Act, as well as advances in biotechnology and science, in order to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, and supplies to respond to emerging disease outbreaks, pandemics, and chemical, biological, radiological, and nuclear incidents and attacks.

The State of Public Health and Medical Preparedness and Response Capabilities

In 2006, when then-Secretary of Health and Human Services Michael Leavitt testified before this Committee in advance of PAHPA’s passage, he told Senators that we had the ability to “become the first generation in history to be prepared for a possible pandemic.” At that time, HHS was closely watching the H5N1 influenza virus, and was concerned about the potential for another human influenza pandemic. Congress invested heavily by passing emergency supplemental appropriations bills, which were used to greatly expand our domestic vaccine manufacturing infrastructure, invest in new vaccine development, and provide funding to state and local governments to enhance medical and public health readiness.

Today, our capabilities are far greater than they were then; for example, we have sufficient domestic vaccine manufacturing capacity to produce bulk vaccine for every American within 6 months. However, we have exhausted the emergency supplemental funding balances at a time when we are now closely watching the H7N9 influenza virus circulating in China, and we are concerned with the ominous trends that we are seeing. While building domestic manufacturing capacity may be a one-time expenditure, maintaining that capacity as well as sustaining, testing, and strengthening the readiness of our medical and public health infrastructure at the state and local level requires continuous support and an enduring commitment to the Public Health Emergency Medical Countermeasures Enterprise.

Last month, a report by the public health organization Trust for America’s Health found that half of states scored five or lower out of 10 on health emergency preparedness. Earlier in 2016, the National Health Security Preparedness Index from the Robert Wood Johnson Foundation found that health security metrics showed modest 1.5 percent improvement overall during 2016, reaching the highest level of 6.8 out of 10 total; however, levels of readiness varied significantly across the country. So, while we have made progress in the last decade, we still have work to do.

Two areas of progress and opportunities I would like to highlight are our medical countermeasures enterprise, specifically BARDA, and our healthcare readiness capacity.

Medical Countermeasures Enterprise—BARDA

PAHPA established BARDA to bridge the so-called “valley of death” in late stage development of medical countermeasures where many products historically languished or failed. By using flexible, nimble authorities, multi-year advanced funding, strong public-private partnerships, and cutting edge expertise, BARDA has suc-

cessfully pushed innovative medical countermeasures, such as vaccines, drugs, and diagnostics, through advanced development to stockpiling and FDA approval or licensing.

In the last decade, BARDA's strong partnerships with the National Institutes of Health, other HHS components, and biotechnology and pharmaceutical companies have led to 34 medical countermeasures approved or licensed by the FDA, which is a staggering accomplishment. BARDA has supported the development of 27 medical countermeasures against Department of Homeland Security (DHS)-identified national security threats through Project BioShield, including products for smallpox, anthrax, botulinum, radiologic/nuclear emergencies, and chemical events. Fourteen of these products have been placed in the Strategic National Stockpile and are ready to be used in an emergency. BARDA also has supported the development of 23 influenza vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza. As a result of this progress, more medical countermeasures than ever before are eligible to be acquired for the SNS, thereby creating new challenges in terms of acquiring and maintaining sufficient quantities of medical countermeasures for identified threats.

We are supporting the development and stockpiling of many more novel medical countermeasures within the next few years, such as H7N9 influenza vaccines, next generation anthrax vaccines, enhanced smallpox vaccines, biodosimetry diagnostic devices, thermal burn radiation drug and skin replacement therapies, radiation cell therapies, new antibiotics, and new chemical antidotes.

We also have opportunities to further improve our national security medical countermeasures enterprise by streamlining our internal decisionmaking processes, finding new ways to support innovation, promoting flexible, fast response capabilities, and increasing our collaboration with Federal interagency partners, such as DoD and Department of Veterans Affairs (VA). We also must work closely with our state, local, territorial, and tribal partners, as well as the private sector to enhance the capability to quickly distribute and dispense medical countermeasures in an emergency—if we can't get these products to the right place, at the right time, then the enterprise has failed.

Healthcare Readiness to Respond

The 2017 hurricane season highlighted the importance of national healthcare readiness and medical surge capacity. ASPR led the public health and medical responses to Hurricanes Harvey, Irma, and Maria under the National Response Framework Emergency Support Function No. 8 mission. We worked closely with state and territory health officials in affected areas to augment care with NDMS teams, VA personnel and facility support, and DoD transportation, facilities, and clinicians. Personnel under the supervision of HHS treated over 36,000 patients, and HHS deployed over 4,500 personnel, evacuated nearly 800 patients, awarded over 200 contracts, and provided nearly 950 tons of equipment.

During the response, due to the combined efforts of ASPR and the Centers for Medicare & Medicaid Services (CMS), we utilized the innovative HHS emPOWER program to identify and treat at-risk individuals requiring electricity-dependent medical and assistive equipment (e.g., ventilators, oxygen concentrators, feeding machines, intravenous infusion pumps, suction pumps, dialysis machines, wheelchairs). In one instance, ASPR teams used this data and worked with Urban Search and Rescue teams to identify all of the dialysis patients in the U.S. Virgin Islands and evacuate those patients for treatment since the local dialysis centers were destroyed.

Despite our successes, we also learned that ASPR needs to improve its internal capabilities as well as enhance our support for the healthcare infrastructure across the country. As with medical countermeasures, the Nation's healthcare delivery infrastructure is mostly a private sector enterprise. We must better leverage and enhance existing Federal programs—such as the Hospital Preparedness Program and NDMS—to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery I call this the foundation of a “national disaster healthcare system.”

Conclusion

Through this second reauthorization of PAHPA, we have the opportunity to build on the great progress made and further improve our national readiness and response capabilities for 21st century health security threats. The Department looks forward to working with you in the months ahead to consider any legislative changes needed to achieve this objective. I am committing the entire ASPR team's grit, ingenuity, expertise, and perseverance to this mission. Thank you, again, for your bipartisan commitment to this national security imperative, and I look forward

to continuing to work together to enhance our Nation's health security. I am happy to answer any questions you may have.

Senator BURR. Thank you, Dr. Bob.
Dr. Gottlieb.

**STATEMENT OF SCOTT GOTTLIEB, M.D., COMMISSIONER, U.S.
FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD**

Dr. GOTTLIEB. Senator Burr, Ranking Member Murray, and Members of the Committee.

Thank you for the invitation to testify today about genome editing technology.

Our Nation has faced many emerging public health challenges and unfortunately, will face additional challenges in the future. Thankfully, our preparedness and the ability to respond to such challenges has improved greatly since the original enactment of the Pandemic and All-Hazards Preparedness Act.

Each emergency is unique. Many are the result of emerging infectious threats, but the technology for manipulating science for diabolical purposes is becoming more ubiquitous and widely understood. So we face new and pervasive risks.

2017 was marked by the risks posed by several extreme natural disasters, which caused significant devastation and human suffering. These tragedies tested our Nation's capabilities to respond.

Today, I am going to focus my remarks on the impact of these storms on medical products manufactured in Puerto Rico and the actions we are taking to mitigate existing and potential product shortages.

The impact of Hurricane Maria showed the importance of Puerto Rico to our medical product manufacturing base, as well as the intricate and sometimes fragile nature of that supply chain.

I want to focus on the complexities of the saline shortage because it has stressed our system and I know that many of you are deeply and rightly concerned by this situation.

Saline solution has been in and out of shortage for several years. There are only a small number of primary manufacturers. So when one manufacturer lowers production, even for routine maintenance, there is stress on the entire system.

One of the largest manufacturers of I.V. saline is Baxter, and their primary sites for small volume bags are located in Puerto Rico. These sites struggled to regain power and return to full capacity following the storm when roads to some of the manufacturing plants were disabled.

We worked closely with Baxter in partnership with the Department of Homeland Security, and Puerto Rico authorities, and Bob—so thank you for your support, as well—to ensure that they were able to get back on the power grid on a priority basis to stabilize production.

We also worked with various saline manufacturers to find other manufacturing facilities globally that could help supply the U.S. until Baxter's Puerto Rico location was back up and running and the shortage was addressed.

To mitigate that shortage, we worked with manufacturers on the importation of saline from locations in Ireland, Australia, Mexico,

Canada, Germany, and most recently, Brazil. When we import from international facilities, generally, the manufacturers adjust their distribution to send some product to the U.S., but there is no actual increase in the total global production of product.

Baxter's manufacturing facilities in Puerto Rico are now stable and on the grid, although the power situation on the island is still fragile. We expect their return to normal production will improve the situation.

Before the storms hit, and in anticipation of the crisis, FDA also prioritized the approval of saline products by two manufacturers, Fresenius Kabi laboratories, and Grifols. Both should start production soon, and having these two additional manufacturers online will help increase the overall supply of saline produced and distributed in the U.S.

But this shortage has also had ripple effects. In order to find workarounds for the filled saline bags that were in shortage, providers have put various mitigation strategies in place. One strategy has hospitals compounding product themselves and this has caused an increased demand for empty I.v. bags. There have been signals indicating that this increased demand is putting pressure on the supply of empty I.v. bags. The FDA is taking steps to address that situation and determine which manufacturers could potentially increase capacity if necessary.

I have reached out to some of these medical device manufacturers personally to inquire about their capacity to increase production as demand for I.V. containers continues to increase.

The scope of the flu outbreak across the country has also added to the strain on this tight supply chain. The shortage, and the impact of the crisis in Puerto Rico, underscores the need to continuously elevate our preparedness.

There are going to be lessons learned from this episode, and already, we have made some key observations about our ability to detect device shortages. Since we lack authority to require notification of device shortages, we have had to depend on manufacturers and distributors reaching out to the FDA or had to seek them out proactively.

Our work in the shortage situation is an example of how the FDA has reacted in response to emergency situations. At the same time, we continue to work hard to improve our regulatory clarity and predictability for the development of medical countermeasures. That is an essential component of our national preparedness strategy.

Today, we released draft guidance on Material Threat Medical Countermeasure and Priority Review Vouchers which explains how the FDA is implementing the PRV program to incentivize the development of certain drug and biologics medical countermeasures.

I look forward to working with Congress to continue to increase our readiness for emergencies, and look forward to answering your questions today.

[The prepared statement of Dr. Gottlieb follows:]

PREPARED STATEMENT OF SCOTT GOTTLIEB

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to appear today to discuss reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). PAHPA, which was passed in

2006 and reauthorized in 2013, is a key piece of legislation that—along with other significant legislative achievements such as the Project BioShield Act of 2004, the Public Readiness and Emergency Preparedness (PREP) Act (2005), and the 21st Century Cures Act (Cures Act) enacted in 2016—has served to significantly strengthen our country’s preparedness for, and response to, public health emergencies involving chemical, biological, radiological, and nuclear (CBRN) threats as well as emerging infectious disease threats, such as the Zika virus and pandemic influenza.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), in particular, recognized the key role the Food and Drug Administration (FDA or the Agency) plays in emergency preparedness and response, and codified and built on FDA’s ongoing efforts to augment review processes and advance regulatory science to enable FDA to better respond to public health emergencies. The provisions in PAHPRA—as well as in the other key pieces of legislation I mentioned—have provided FDA with essential tools that continue to support us in our mission to protect and promote public health.

FDA’s Public Health Emergency Preparedness and Response Mission

FDA plays a critical role in facilitating preparedness for and response to CBRN and emerging infectious disease threats. These threats can and often do emerge without warning as was the case with the anthrax attacks of 2001, the 2009 H1N1 influenza pandemic, the 2014 Ebola outbreak in West Africa, as well as in the ongoing Zika virus outbreak.

FDA’s role in facilitating preparedness for, and response to, CBRN and emerging infectious disease threats focuses largely on facilitating the development and availability of medical countermeasures—such as vaccines, therapeutics, and diagnostic tests—to respond to these threats. FDA works closely with its HHS and other U.S. Government partners through the Public Health

Emergency Medical Countermeasures Enterprise (PHEMCE), as well as with regulated industry and non-governmental organizations (NGO’s), to build and sustain the medical countermeasure programs necessary to effectively respond to public health emergencies. FDA is also committed to working closely with the Department of Defense (DoD) to facilitate the development and availability of medical countermeasures to support the unique needs of our Nation’s warfighters. The Agency is already actively implementing the legislation enacted at the end of last year to further prioritize this critical work with DoD. Senior leadership at the Agency is leading these efforts, and we look forward to keeping Congress informed of our progress in these critical areas.

FDA’s Medical Countermeasures Initiative (MCMi)—established in 2010—brought additional resources to FDA that enabled FDA to hire additional expert staff and to become more deeply and thoroughly engaged in medical countermeasure activities. This program continues to be key to establishing clear regulatory pathways for medical countermeasures, advancing medical countermeasure regulatory science to support regulatory decisionmaking, and advancing important policies and mechanisms to facilitate the timely development and availability of medical countermeasures. FDA’s goal is to be modern and efficient in its regulation of safe and effective medical products, and that includes medical countermeasures.

FDA’s operations within its medical countermeasures mission cover a broad range of activities vital to facilitating the development of, and access to, safe and effective medical countermeasures, including:

- Reviewing medical countermeasure marketing applications and approving those that meet standards for safety and efficacy;
- Providing regulatory advice, guidance and technical assistance to sponsors developing medical countermeasures, as well as to U.S. Government partners, international regulators, and international organizations such as the World Health Organization;
- Supporting efforts to establish and sustain an adequate supply of medical countermeasures, including averting supply disruptions when feasible and, in certain situations, allowing products to be used beyond their expiration dates when supported by appropriate scientific evaluation;
- Enabling access to medical countermeasures that are not yet approved for use—when necessary—through an appropriate mechanism, including through FDA’s Emergency Use Authorization (EUA) authority;
- Proactively identifying and resolving regulatory challenges associated with medical countermeasure development and ensuring that FDA regulations and policies adequately support medical countermeasure development and enable preparedness and response activities;

- Fostering the professional development of FDA scientists to ensure that FDA personnel maintain the skills and abilities to support the medical countermeasure mission; and
- Supporting regulatory science to create the tools, standards, and approaches necessary to develop and assess the safety, efficacy, quality, and performance of medical countermeasures.

FDA is also a critical partner in preparing for, and responding to, natural disasters, as demonstrated by its ongoing 2017 hurricane recovery efforts, including its work in Puerto Rico following Hurricane Maria. FDA performs extensive preliminary work in advance of storms to help prepare for potential impacts. For example, FDA utilizes storm prediction data and firm registration data bases to prepare maps to identify FDA-regulated firms, including those that manufacture critical products that could be impacted by the storms. Where necessary, FDA may take contingency steps to help ensure a continuous supply of critical medical product manufacturing. The most significant role that FDA plays comes after the storm, as facilities come back on line and may need remediation, and farmers seek to put crops or farmland that were damaged back into commercial use. FDA has supported the many pharmaceutical and medical device manufacturers in Puerto Rico to help address and prioritize recovery operations based on the potential for medical product shortages based on public health needs. Many of the requests FDA received were for infrastructure support, primarily getting a reliable source of power, and FDA worked with partners at the Department of Homeland Security to support getting critical manufacturing back online. Through product registrations and communications with manufacturers, FDA was able to identify the medically necessary products manufactured in Puerto Rico and determine which were the top public health priorities. FDA continues to be focused on storm-related shortage issues, including shortages of saline solution and amino acids, as well as the cascading increase in demand for other medical products, such as empty IV containers which are now being used in higher quantities for compounded products. FDA has been in direct communication with manufacturers, distributors, hospitals and other health care providers, including the Department of Veterans Affairs (VA), and we are assessing existing product supply, demand trends and manufacturer capacity to increase availability of the empty IV containers.

Fostering Innovation in Medical Countermeasure Development

At FDA, we fully appreciate that the development of medical countermeasures can present complex and unique challenges. For example, it is not ethical to conduct human studies for many of the high-priority threat agents. In these situations, the Animal Rule, which enables animal efficacy studies to substitute for efficacy trials in humans if the results can reasonably be extrapolated to the expected human use, can be used to facilitate the development and availability of medical countermeasures. PAHPRA recognized the importance of the Animal Rule; and in 2015, FDA finalized guidance for product development under the Animal Rule, incorporating the learnings of considerable product development experience and providing scientific and regulatory expectations for animal data intended to support medical countermeasure approval.

To date, 12 medical countermeasures have been approved under the Animal Rule, including inhalational anthrax therapeutics, a botulism antitoxin, antibiotics for the treatment and prophylaxis of plague, and treatments for acute radiation syndrome. These approvals underscore the critical role the Animal Rule and animal studies can play in advancing medical countermeasures for some of the most challenging threats. Of note, through the use of regulatory science, FDA was able to approve the inhalational anthrax therapeutics and the botulism antitoxin for use in children as well as adults, despite the fact that pediatric patients were not actually studied in clinical trials, due to ethical concerns.

However, for many threats there are not yet adequate regulatory science foundation, such as animal models to support medical countermeasure development or sufficient biomarkers to enable the extrapolation of data generated in animal models to humans. Without such tools, it is difficult to generate the data necessary to support regulatory decisionmaking.

FDA has established a broad and robust portfolio of cutting-edge research under MCM's Regulatory Science Program to help develop these tools and promote innovation in the development of medical countermeasures. A few examples of projects include: supporting the development of organs-on-chips models to assess radiation damage in lung, gut, and bone marrow, and then using these models to test candidate medical countermeasures; collaborating to establish a publicly available genomic sequence reference data base for use by developers seeking to validate can-

didate multiplex in vitro diagnostic tests that could be used to diagnose multiple pathogens simultaneously; developing reference materials for developers to use to validate nucleic acid-based and serological diagnostic tests for Zika virus; supporting a project to identify and correlate biomarkers of host response to Ebola virus infection in animal models and humans to support medical countermeasure development; developing methods for obtaining safety and limited efficacy data from patients who receive medical countermeasures during public health emergencies; and establishing the Animal Model Qualification Program designed to support medical countermeasure development by promoting the development of animal models for use across multiple product applications, thereby minimizing duplication of effort and resources.

PAHPRA also provided authorities to ensure that FDA personnel are well-trained in how to review medical countermeasure applications for approval. Under these authorities, FDA has established a professional development program, including speakers' series and academic certifications, to ensure that FDA scientists are working through the regulatory challenges posed by new areas of science and technology as they relate to medical countermeasure development. FDA also has spent considerable energy and resources establishing an efficient approach to conduct and support training within the agency.

More recently, the Cures Act included several provisions that are intended to advance innovation in medical product development more generally, but will also help to facilitate the development of medical countermeasures, including the provisions to encourage novel trial designs, and to develop new antimicrobial drug products.

Through the Cures Act, Congress also provided a new priority review voucher (PRV) program to help incentivize the development of material threat medical countermeasures. Under this program, FDA will award a PRV upon approval of a material threat medical countermeasure application provided that certain criteria are met. The PRV may in turn be used by the sponsor who receives it, or sold to another sponsor, who may then use it to obtain priority review for a product application that would otherwise not receive that benefit, enabling a developer to potentially bring a product to market sooner than otherwise possible—something that may be of great value to product developers. FDA plans to issue guidance to address medical countermeasure-specific considerations with the intent to implement the program consistently with the other PRV programs, such as the Neglected Tropical Disease Voucher Program.

There are tremendous opportunities to continue to further the development of groundbreaking, innovative medical countermeasures, and the Agency intends to fully seize and build upon these opportunities. Toward that goal, this past July FDA announced the launch of a comprehensive Innovation Initiative aimed at making sure its regulatory processes are modern and efficient so that safe and effective new technologies, including medical countermeasures, can reach patients in a timely fashion.

Facilitating Access to Safe and Effective Medical Countermeasures

Enabling access to medical countermeasures when they are needed is a high priority for FDA. Amended and new authorities provided by Congress have enabled the Agency to further prepare for, and better respond to, emerging public health threats. For example, PAHPRA amended FDA's EUA authority to provide additional flexibility for issuing EUAs. These additional flexibilities have enabled FDA to better support responses to emerging health threats by issuing nearly 40 EUAs to enable the emergency use of in-vitro diagnostic devices for H7N9 Influenza virus, Enterovirus D68 (EV-D68), Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Ebola virus, and Zika virus. FDA also issued an EUA to enable the emergency use of an auto-injector medical countermeasure to maintain preparedness for chemical threats, which has been critical for supporting both warfighter and first responder preparedness goals related to an emergency involving nerve agents. The authority for prepositioning medical countermeasures provided in PAHPRA also proved useful to allow the manufacturer to ship, and the U.S. Government stakeholders to receive, certain strengths of the unapproved auto-injectors that were not yet authorized for use under that EUA.

PAHPRA also provided FDA with several new streamlined authorities to facilitate the emergency use of approved medical countermeasures without the need for issuing an EUA. For example, PAHPRA provided FDA with the authority to issue emergency dispensing orders (including mass dispensing at a point of dispensing (POD)) for approved medical countermeasures during an actual CBRN emergency without requiring an individual prescription for each recipient of the medical countermeasure, if permitted by state law or in accordance with an emergency dis-

dispensing order issued by FDA. FDA has used this authority to issue emergency dispensing orders to permit emergency dispensing of doxycycline and ciprofloxacin for post-exposure prophylaxis of inhalational anthrax, to ensure government stakeholders can rapidly provide these therapies in the event of an anthrax attack.¹

Another new FDA authority created by PAHPRA is the explicit ability to extend expiration dating of eligible FDA-approved medical countermeasures stockpiled for use in CBRN emergencies, if the extension is supported by an appropriate scientific evaluation. This authority streamlines FDA's ability to authorize expiration dating extensions without the need to issue an EUA, which will enable faster response, and has been crucial to FDA's ability to support preparedness efforts. For example, when production stopped after quality issues were identified in the manufacturing process of auto-injectors used for the treatment of nerve agent and insecticide poisoning, FDA used this authority to help prevent shortages of auto-injector products to help ensure that the Nation's warfighters and first responders continue to have ready access to these products. FDA also used this authority to extend the expiration date of certain lots of doxycycline capsules held in strategic stockpiles by the Centers for Disease Control and Prevention, state and local public health, and other response stakeholders and issued draft guidance to provide recommendations to government stakeholders on testing that can be conducted to support future extensions, in order to help sustain preparedness levels.

The Cures Act also amended the EUA and related emergency use authorities to clarify their applicability to animal drugs. FDA encourages anyone interested in utilizing these authorities to contact FDA to discuss how to proceed.

Most recently, Congress passed H.R. 4374, legislation that amends FDA's EUA authority to enable FDA to issue EUAs for medical products to reduce deaths and mitigate injuries from agents that may cause imminently life-threatening and specific risks to United States military forces. Prior to the passage of this legislation, the EUA authority was only applicable to medical products to address CBRN threats. In addition, the legislation contains provisions codifying enhanced collaboration between FDA and DoD, in order to facilitate the development of medical products and countermeasures for the warfighter. FDA is working closely with DoD to implement these new and amended authorities as quickly as possible.

Conclusion

At FDA, we have made it a priority to proactively work with our private sector and government partners to help facilitate the translation of breakthrough discoveries in science and technology into innovative, safe, and effective medical countermeasures. FDA takes its responsibility seriously to help drive and foster innovation as part of advancing public health and our national security. Active FDA involvement is essential to encouraging industry engagement in medical countermeasure development. FDA remains deeply committed to working closely with its partners and continuing to use the authorities Congress provides to the fullest extent to help facilitate the development and availability of safe and effective medical countermeasures. We believe that partnership and innovation will continue to be key drivers to success in the medical countermeasure space and are taking steps to further empower FDA's scientific and clinical experts to drive the innovation necessary to help protect the Nation from the threats we may face.

FDA appreciates Congress's support in continually delineating, clarifying, expanding, and extending its authorities—and providing resources—to enable FDA to achieve its public health emergency preparedness and response mission. FDA stands ready to work with Congress and stakeholders to enable us to better achieve this critical work.

Thank you for inviting FDA to testify today. I am happy to answer any questions you may have.

Senator BURR. Thank you, Scott.
Dr. REDD.

¹ The term "stakeholder(s)" means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, state, or federal), or functional (e.g., law enforcement or public health range) or sphere of authority to prescribe, administer, deliver, distribute, or dispense oral doxycycline products in an emergency situation.

**STATEMENT OF STEPHEN C. REDD, M.D., RADM, DIRECTOR,
OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RE-
SPONSE, CENTERS FOR DISEASE CONTROL AND PREVEN-
TION, ATLANTA, GA**

Dr. REDD. Senator Burr, Chairman Alexander, and Ranking Member Murray.

I am Dr. Stephen Redd, the Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control. And I am pleased to be here to talk with you today about the role the CDC plays in public health preparedness and response, including those responsibilities under the Pandemic and All-Hazards Preparedness Reauthorization Act.

The CDC is the common defense of the country against health threats. Our work to prepare and respond to health emergencies require that we build on our day to day in two particular areas.

No. 1, our longstanding partnership with state and local health departments and;

No. 2, our medical, scientific, and program expertise.

I will describe the three pillars of our defense strategy: science, surveillance, and service.

First, the CDC has a unique collection of scientific expertise that exists nowhere else in the world. We have the ability to identify agents causing illness, whether that illness is caused by an infectious microbe, or a chemical, or a radiation exposure.

We are ready to respond to a broad range of threats including diseases like Ebola, small pox, and H7N9 influenza.

The CDC plays a key role in discovering new and emerging infectious diseases using advanced detection techniques to identify pathogens quickly and more accurately.

Every year, laboratories from all over the world send hundreds of thousands of specimens to the CDC for testing.

The second pillar enabling the CDC's common defense of the country is surveillance. Public health surveillance is the collection, analysis, and use of data to target public health prevention and response. It is basically making sure the best information is used to make the right decisions.

Examples of this work include what we do to track influenza, the National Syndromic Surveillance system and the Global Disease Detection Program.

Influenza is probably the greatest natural health threat we face. Influenza viruses change continuously and require vigilance to detect these changes. The CDC provides support to every state, to several major cities, and to a number of ministries of health throughout the world to conduct influenza surveillance and laboratory work.

With the National Syndromic Surveillance Program, the CDC collects de-identified health information on causes of emergency room, urgent care, and hospital visits. We, along with state and local health departments, use the data in real time to detect abnormal situations requiring public health response.

The CDC's Global Disease Detection Operation Center monitors 30 to 40 outbreaks every day across the globe, 24/7, and assesses the potential risk to the United States from these events. In addi-

tion to science and surveillance services, the final pillar is supporting the CDC's common defense of the country.

Let me focus on three particular programs, the Public Health Emergency Preparedness Program, the Strategic National Stockpile, and the Cities Readiness Initiative.

In each of these programs, the keys to success are the close collaboration between CDC and state and local public health departments, and the connection of these programs to CDC's scientific expertise.

The Public Health Emergency Preparedness grants go to every state and support staff, enable exercises to test and validate capabilities, and pay for laboratory and communications equipment.

The Strategic National Stockpile is a \$7 billion repository of pharmaceuticals, medical supplies, and medical equipment that is available for rapid delivery to support responses to health emergencies.

The CDC's Cities Readiness Initiative enhances preparedness in the Nation's 72 largest cities where nearly 60 percent of the U.S. population resides. These funds are used to develop, test, and maintain plans to receive countermeasures from the CDC's Strategic National Stockpile and rapidly dispense them.

I would like to leave the Committee with three primary points about the CDC's role in public health emergency preparedness and response.

First, the CDC is the common defense of the country against health threats.

Two, CDC's preparedness work is built on a day to day foundation of our broad and deep scientific medical and program expertise.

Three, the CDC's longstanding partnerships with state and local health authorities are essential.

Thank you for the opportunity to testify today.

[The prepared statement of Dr. Redd follows:]

PREPARED STATEMENT OF STEPHEN C. REDD

Chairman Alexander, Senator Murray, and other Members of the Committee. I am Rear Admiral Stephen Redd, Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention (CDC). I appreciate the opportunity to be here today to discuss CDC's public health preparedness and response mission, and the agency's role in implementing the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA).

CDC provides for the common defense of the country against public health threats. Through our dedication to science, surveillance, and service, CDC focuses on protecting the public health of the Nation from threats such as emerging infectious diseases, natural disasters, and terrorism.

In carrying out the mission set forth under the Pandemic and All Hazards Preparedness Reauthorization Act, CDC draws on expertise from throughout the agency. CDC's expertise includes world-class laboratory testing, surveillance (for disease detection), epidemiology, guidance to healthcare providers, incident management, logistics, emergency risk communication, disease control programs, distribution of medical countermeasures, human and animal medicine, and responder health and well-being. Our multidisciplinary workforce enables an integrated national system that is nimble and prepared to detect and respond to any developing situation that could affect the health of people in the United States. In addition, CDC draws on its long-standing relationships and close collaboration with state and local partners to protect the health of communities across the country, and collaborates closely with the Assistant Secretary for Preparedness and Response (ASPR), the Food and Drug Administration (FDA) and other Federal partners.

CDC experts lead and staff every activation of the agency's Emergency Operations Center (EOC), ensuring response activities are effective and efficient. HHS/CDC has an emergency management program accredited by the Emergency Management Accreditation Program. CDC activated its incident management system for 67 responses over the last 16 years, between September 2001 and December 2017. During a response, CDC's EOC rapidly deploys scientific experts, coordinates the delivery of supplies and equipment to the incident site, monitors response activities, provides resources to state and local public health departments, and disseminates timely and accurate information within government, to health care providers, and to the public. During the agency's Zika and Ebola responses, CDC deployed over 1,700 and 3,700 staff, respectively. CDC also responds to public health events that do not require EOC support. In fiscal year 2017, CDC assisted state, local, and overseas public health authorities in 23 epidemiologic investigations of emerging infectious disease outbreaks as well as more than 20 environmental responses.

CDC Programs under the Pandemic and All Hazards Preparedness Reauthorization Act

The Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) reauthorized several public health preparedness programs. The discussion immediately below focuses on two of those programs: CDC's Public Health Emergency Preparedness cooperative agreement program (which includes the Cities Readiness Initiative (CRI) and the Strategic National Stockpile (SNS). Later in the testimony I will discuss CDC's work related to a third PAHPRA program, biosurveillance.

Public Health Emergency Preparedness Cooperative Agreement (PHEP) Program: The PHEP cooperative agreement program is the largest CDC state program and provided approximately \$600 million to state, local, and territorial public health departments in 2017. The program developed the first playbooks for public health preparedness and response, and has been instrumental in integrating state and local health departments into their jurisdictions' emergency response structures. PHEP currently supports 62 awardees—including all 50 states, eight territories and freely associated states, and directly funded cities (New York City; Washington, DC.; Chicago; and Los Angeles). Funding is awarded according to a base-plus population formula prescribed by statute, which ensures a minimum amount of funding to each awardee. These funds support preparedness and response staff, enable exercises to test and validate capabilities, provide for timely training, and pay for laboratory and communications equipment essential to maintaining preparedness. In addition, CDC personnel support PHEP awardees by helping to identify and address gaps in preparedness capabilities, providing planning resources to ensure the needs of at-risk individuals are incorporated into response strategies, and improving response capabilities from experience gleaned during public health responses, most recently to Ebola and Zika.

Strategic National Stockpile (SNS): The SNS is the largest federally owned repository of vaccines, drugs, medical supplies, Federal Medical Stations, and medical equipment available for rapid delivery to support federal, state, and local response to health security threats. The SNS was created in 1999 to ensure the Nation's readiness against public health emergencies by ensuring delivery of lifesaving medical countermeasures (MCMs) during deliberate or naturally occurring outbreaks and other events that threaten public health. Since its inception, SNS products and staff have been deployed more than 100 times for events ranging from natural disasters to infectious disease outbreaks. CDC works with the HHS Assistant Secretary for Preparedness and Response and with other Federal agencies through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to prioritize Federal investments in medical countermeasures based on analysis of risk, benefits to the American people and sustainability of the MCM pipeline.

Management of the SNS and deployment of its assets are complex endeavors which rely on a broad range of scientific expertise, surveillance systems, public health communications systems, and state and local partners. The SNS ensures that the right medical countermeasures and supplies are available when, where, and in the quantity needed to stop or slow a public health emergency and save lives. And, scientific experts ensure that medicine and supplies expeditiously get to our public health partners at the state and local levels, who have had the necessary training, exercises, and clinical guidance to effectively and efficiently receive those assets from the SNS and get them to those who need them.

Cities Readiness Initiative (CRI): CRI, funded through the PHEP cooperative agreement, enhances preparedness in the Nation's largest population centers, where nearly 60 percent of the population resides. The 72 cities (at least one in every

state) use CRI funds to develop, test, and maintain plans to quickly receive medical countermeasures from the SNS and distribute them to local communities. This program, through reliance on local boots on the ground, enables effective response to large-scale public health emergencies needing life-saving medications and medical supplies.

Public Health Preparedness through Science, Surveillance and Service

In carrying out its public health mission CDC's subject matter experts from across the agency collaborate to detect and respond to emerging threats that could affect Americans' health.

Science:

Exceptional and world-renowned scientific expertise and world-class laboratories ensure CDC is ready and able to respond to a broad range of threats, including highly hazardous and infectious diseases like Ebola, smallpox, and H7N9 influenza. For example, CDC's research on the smallpox virus helps find better drugs to treat the disease, stop the virus from spreading, make safer vaccines, and improve tests to detect the virus. Additionally, CDC's global influenza capacity-building efforts helped facilitate the rapid detection of the novel Asian lineage influenza A (H7N9) virus in 2013. Most human infections resulted from exposure to infected poultry, but CDC assesses that the virus poses the greatest pandemic risk of all influenza viruses not yet circulating among humans, and is working with global health partners to monitor that virus and detect changes in it that could trigger a pandemic. CDC has developed two candidate vaccine viruses and shared them with vaccine manufacturers, for use in BARDA-supported vaccine production and in clinical trials by NIH's National Institute of Allergy and Infectious Disease. If the H7N9 virus develops the capacity to spread among humans, an effective vaccine would be key for preventing a pandemic.

CDC plays a critical role in discovering new and emerging infectious diseases, using advanced molecular detection techniques that combine next-generation genomic sequencing, high-performance computing, and epidemiology to identify pathogens faster and more accurately. Laboratories from all over the world send specimens to CDC, often in cases where the cause of illness is unknown. Annually, CDC receives hundreds of thousands of specimens to examine and helps diagnose hundreds of cases of unexplained illness or death. Through advanced molecular detection investments, CDC is seeing improvements in faster detection of outbreaks (catching them when they are smaller) and in faster development of diagnostics, applying these technologies in dozens of areas such as foodborne disease, influenza, antimicrobial resistance, hepatitis, pneumonia, and meningitis. CDC shares genetic sequencing technologies with state and local health departments, and funds them to acquire new technology that helps them to respond quicker and more efficiently at a local level.

CDC is critical to preparing for the next influenza pandemic. In an influenza emergency, CDC's public health and infectious disease experts use advanced molecular detection techniques to identify disease strains that could cause a pandemic, release recommendations for the prevention, diagnosis, and treatment of disease, and provide communication to the Nation about the pandemic. For example, each human case of infection with a new animal influenza virus represents the potential for a pandemic. CDC receives and studies viruses like these in its laboratories to better understand where and how they spread and the nature of illness they cause. This informs development of clinical and public health recommendations before and during emergency responses. In the event of an influenza pandemic, CDC's scientific experts use the best epidemiologic and laboratory data available to update or develop guidance to inform purchasing, distribution, and use of medical countermeasures including vaccines, antiviral drugs, respirators or masks, and ventilators. CDC also develops and evaluates solutions to lessen the impact of an influenza pandemic through non-pharmaceutical interventions or actions that people and communities can implement to help slow the spread of influenza, such as staying home when ill, coordinating school closures, and postponing mass gatherings.

CDC has longstanding collaboration with countries and institutions around the world. These strategic partnerships coupled with forward deployment of our scientists stationed in more than 60 countries enable CDC to identify new pathogens, assess risks, and devise effective control measures. Our partnerships provide the platforms for timely sharing of laboratory specimens, innovations and distribution of diagnostic materials and technologies to prevent epidemics, and promptly respond to disease outbreaks before they cross international borders.

Vector-borne diseases present another preparedness challenge, as we saw in the Zika emergency. CDC is one of the Nation's public health authorities on vector-borne diseases, like Zika, plague, and dengue. CDC scientists who specialize in vector-borne disease have deep expertise in entomology, microbiology, virology, veterinary medicine, zoology, and public health that does not exist elsewhere. These experts develop diagnostic tools and clinical guidance, as well as methods of treatment, prevention, and vector control, in order to slow the spread of these diseases. For example, CDC scientists have determined that a natural plant ingredient called nootkatone effectively repels and kills the mosquitoes and ticks that can spread disease. Nootkatone appears to work differently than available insecticides, and it could help fight mosquitoes that are resistant to existing insecticides.

CDC's scientific experts protect people from environmental health threats like contaminated water, radiation, and chemical emergencies. To do so, CDC identifies the environmental exposures that make people sick, investigates how those exposures are transmitted in the environment, and finds ways to eliminate the threat to people's health. For example, CDC's radiation guidelines help public health officials and clinicians prepare for, and respond to, radiation emergencies and treat exposures.

The list of CDC's scientific expertise is much longer than I have detailed, including myriad chronic diseases and also includes foundational scientific expertise critical to effective public health impact such as in the areas of workforce, laboratory systems, and data sciences.

Surveillance:

Public health surveillance—the collection, analysis, and use of data to target public health prevention and intervention activities—is the foundation of public health practice. CDC monitors health surveillance information around the clock to detect and track diseases and protect Americans. As one example, following 9/11, CDC made investments in enhancing syndromic surveillance—using health-related data based on patient symptoms that precede diagnosis—as an early warning system for bioterrorism. This system now allows officials to detect a much wider range of health threats—from opioid overdoses to chemical spills to disease outbreaks. Moreover, CDC collects, analyzes, and interprets human, animal, environmental, and food surveillance data, in order to identify and respond to potential health threats before they become emergencies. In aggregate, CDC's specialized surveillance systems provide prompt situational awareness and early warning for unknown or unexpected threats. CDC's surveillance activities directly support states in their primary responsibilities in protecting the public's health. Surveillance data, collected in collaboration with domestic and international partners, inform CDC's threat assessments and ensures response actions are at the right speed, scope, and scale to protect Americans.

CDC supports integrated disease surveillance activities at the state and local level through funding and provision of surveillance tools and services. The following are examples of the surveillance systems and support that CDC provides to state, local, and territorial public health departments to develop and strengthen their surveillance activities:

- **National Notifiable Diseases Surveillance System (NNDSS):** NNDSS is a nationwide system that enables all levels of public health—local, state, territorial, Federal, and international—to collect and share data on approximately 100 diseases and conditions that are required to be reported in all 50 states, and keeps them under continuous surveillance. This system provides comprehensive, timely, and high-quality data for public health decisionmaking, enabling CDC programs to work with state partners to better monitor disease occurrence, identify potential outbreaks, recognize emerging trends, track the impact of public health interventions, and respond.
- **Influenza Surveillance:** Influenza viruses are constantly changing, and, thus, require continued vigilance to protect the United States and the rest of the world from both seasonal and pandemic influenza threats. Influenza surveillance, both epidemiologic and virologic, is at the core of influenza preparedness. The surveillance platforms used year round to combat seasonal influenza threats serve as the foundation for pandemic influenza surveillance. CDC provides support to every state, and several major municipalities and territories, to conduct influenza surveillance and laboratory work. For many decades, CDC has served as an international leader in global influenza surveillance. We have partnered with more than fifty countries to establish, maintain, and expand influenza surveillance and laboratory capacity, in order to find influenza viruses where they emerge as quickly as possible to mitigate their potentially devastating impact

on the United States. Domestic funding supports seasonal influenza surveillance through a network of interrelated systems that provide data on where influenza and influenza-like illnesses, hospitalizations, and deaths occur.

National Syndromic Surveillance Program (NSSP): CDC, through state and local collaborations, collects de-identified health information on emergency room, urgent care, and hospital visits, as well as pharmacy and laboratory data. This investment has revolutionized public health surveillance to include this new type of data collection on top of traditional type and methods of data collection. States and local public health departments use the syndromic data to detect and characterize abnormal situations meriting further public health investigation. This strengthens local public health capacity to detect, respond to, and manage, outbreaks and other critical public health events. CDC has negotiated access to the data to enable situational awareness at regional and national levels. The series of three recent hurricanes presents a poignant example that demonstrates the usefulness and flexibility of this asset. Before the hurricanes, CDC and ASPR had begun establishing a mechanism to share National Disaster Medical Assistance Team (DMAT) data during mass gatherings. As the hurricanes hit, CDC and ASPR established data flow mechanisms and rules, and in 2 days put in place a system to receive hourly data from DMATs, resulting in timely information that helped responders target communities at greatest need for public health interventions.

- **Vector-Borne Surveillance:** CDC operates systems that allow for national and state-based monitoring of specific vectors, such as ticks and mosquitoes, which carry diseases and pose risks for outbreaks. These systems monitor laboratory documented cases of disease, allowing for the early detection of outbreaks and helping decisionmakers determine when and how to act in the interest of the public's health. State, territorial, city, and local health departments populate CDC's surveillance systems to inform vector control and management activities.
- **Antibiotic Resistance Surveillance:** Beginning in fiscal year 2016, Congress recognized the large and growing threat of antibiotic resistance and appropriated funding to CDC to detect and respond to resistant pathogens, prevent the spread of resistant infections, and collaborate with partners to encourage innovation for new prevention strategies. CDC has multiple surveillance systems that can detect and track resistant threats across healthcare, food, and the community. One important investment begun in 2016 is CDC's Antibiotic Resistance Laboratory Network (ARLN), which supports nationwide laboratory capacity to rapidly detect antibiotic resistance in healthcare, food, and the community, and inform local responses to prevent spread and protect people. The ARLN includes seven regional laboratories, the National Tuberculosis Molecular Surveillance Center, and laboratories in 50 states, five cities, and Puerto Rico. The ARLN is vital to detecting new and emerging resistant pathogens, including those that are untreatable, to trigger infection control response measures to prevent spread. The ARLN collects actionable data on threats including the "nightmare bacteria," carbapenem-resistant Enterobacteriaceae (CRE), *Candida auris*, and *Neisseria gonorrhoeae*; some strains of these pathogens have become resistant to all or nearly all available antibiotics. In addition, samples from the ARLN can be made available to researchers to support innovations in antibiotic and diagnostic development.
- **Global Disease Detection:** CDC's Global Disease Detection (GDD) Operations Center monitors outbreaks 24/7 across the globe, assesses their potential risk to the United States and communities around the world, and improves global public health surveillance. The GDD Operations Center monitors approximately 30–40 public health threats each day, including outbreaks, disasters, poisonings, and chemical, radiological, or nuclear events. Since 2007, CDC has tracked more than 170 unique diseases globally and identified outbreaks in more than 190 countries. This tracking provides the agency with critical early warning and response capabilities.
- **Global Polio Surveillance:** CDC, as part of the Global Polio Eradication Initiative, supports polio surveillance to track potential cases and circulating viruses and to effectively target polio immunization efforts. The goal of these efforts is polio elimination in every country and eventual worldwide eradication, and we are closer than we have ever been to achieving that monumental accomplishment. In 2017, the Global Polio Eradication Initiative identified just 20 wild poliovirus cases worldwide, down from 350,000 cases in 1988 when the global eradication initiative began. The global polio surveillance system, coupled with the CDC-supported Global Poliovirus Laboratory Network (comprised of 145 laboratories around the world), also detects and assists in the diagnosis of other epidemic prone diseases such as measles, rubella, and yellow fever.

Taken together, these surveillance systems provide an early warning alert, allowing CDC to protect the health of Americans through rapid, evidence-based action.

Providing Public Health Services:

State and local public health agencies are the cornerstones of preparedness and response. When states are prepared to respond, communities are better protected and more resilient in the face of threats. CDC has long-established relationships with state and local officials, and coordinates with them effectively and efficiently during public health emergency responses. CDC also collaborates with foreign ministries of health to protect global health security that directly impacts United States health security. Examples of CDC's critical support of state, local, and foreign health agencies to ensure they are ready to respond to emergencies include:

- 24/7 public health consultation and disease expertise.
- Enabling a quality public health laboratory system while maintaining critical laboratory infrastructure and specimen testing support.
- Managing and delivering medical countermeasures.
- Public health workforce development that complements preparedness-specific provision of guidance, training, and exercises to ensure jurisdictions are ready to detect and respond to an emergency.

In the event of an outbreak, bioterrorist attack, or chemical or radiological release, laboratory capacity is essential to quickly detect, diagnose, and treat those who are impacted. CDC's Laboratory Response Network (LRN) maintains an integrated network of state and local public health, Federal, and international laboratories that can respond to all types of public health threats. The linking of state and local public health laboratories, and veterinary, agriculture, and water-and food-testing laboratories is unprecedented and provides for training, rapid testing, timely notification, and secure messaging of laboratory results. With the LRN, CDC has developed and deployed tests to combat our country's most pressing infectious and non-infectious health issues, from Ebola to Zika to ricin toxin to nerve agents.

CDC ensures the Nation is able to respond to influenza pandemics, vector-borne or vaccine-preventable disease outbreaks, other emerging infectious disease threats, and environmental health threats by supporting planning efforts among health departments, hospitals, and emergency responders. CDC tests its pandemic influenza response capabilities with federal, state, and local partners through virtual tabletop and functional exercises. CDC evaluates and improves its response plans based on lessons learned from previous responses and exercises. CDC supports state and local health departments directly during vector-borne and environmental health incidents by developing and evaluating novel repellents and other prevention tools; improving and deploying diagnostic tools and tests; responding to toxic health threats; and providing unique expertise and training regarding radiation.

The existing public health system, its people, networks and resources, form the basis for response to health emergencies. For example, CDC's National Center for Immunization and Respiratory Diseases funds state infrastructure awards, manages vaccine shortages, prevents disease outbreaks and responds early and rapidly should they occur, and stands ready to respond quickly and comprehensively to other urgent emergencies requiring vaccination such as a pandemic or biologic attack. CDC also funds state and local public health agencies through the Epidemiology and Laboratory Capacity for Infectious Diseases cooperative agreement (ELC). This funding allows jurisdictions to strengthen their basic epidemiologic and laboratory capacity to address infectious disease threats. Multiple CDC programs use the ELC platform to protect the public health and safety of the American people by supporting health departments to effectively detect, respond to, prevent, and control a wide range of known and emerging (or re-emerging) infectious diseases. These CDC programs and others provide ongoing support to prevent, prepare for, and respond to public health emergencies.

An outbreak that starts in another country can hit our shores in a matter of hours. Strengthening global health security protects Americans' health. New diseases, like MERS and influenza H7N9, can emerge without warning and have the potential to cause widespread infection and fear. CDC works with 31 Global Health Security Agenda partner countries to help them build the core public health capacities necessary for identifying and containing outbreaks before they become epidemics that could affect us all. This work is focused on strengthening four critical areas: surveillance, laboratory, workforce development, and rapid response capability. In addition, CDC medical and public health officers staff United States Quarantine Stations that are located at 20 ports of entry and land-border crossings where the majority of international travelers arrive. These health officers are the first line of defense to prevent the introduction and spread of infectious diseases.

Conclusion

I want to leave the Committee with three primary points about CDC's role in public health emergency preparedness and response.

- CDC is the common defense of the country against threats to public health,
- CDC's preparedness work is built on a foundation of our broad and deep scientific, medical, and programmatic expertise, and
- CDC's longstanding partnerships with state and local public health authorities are essential to the health security of our country.

Through the three interconnected pillars of science, surveillance, and service, CDC plays a critical role in working to ensure that the United States is ready to respond to public health emergencies. CDC has over 70 years of experience in bringing top scientific expertise to health emergencies and remains a trusted partner in the United States and around the world. CDC stands ready to do its part to protect the health and well-being of the American public and save lives. We cannot necessarily predict the next disaster, but we know that being prepared protects health, saves lives, and prevents economic losses.

Thank you for the opportunity to testify.

Senator BURR. Dr. Redd, thank you very much.

You won the award for getting the closest to the 5 minutes of all our witnesses today.

[Laughter.]

Senator BURR. The Chair would recognize himself and the Ranking Member, and then Senator Alexander, Senator Casey, and then Members in the order of attendance to today's hearing.

Dr. Bob, my first question is simple. Are we prepared for public health threats we face?

Dr. KADLEC. Sir, I would have to say equivocally for some, but not all.

I think the reality is when this concept of PAHPA first came up in 2005, we had witnessed the terrorist attacks of 9/11. We were anticipating potentially a pandemic and we had just experienced Katrina. But those are all in the rearview mirror in terms of the threats that we are prepared to deal with.

Quite frankly, if you had to look at Nation State threats that we are considering today, or multiple Nation States that are willing to use terrible weapons against, both physical as well as potentially cyber, I think we are not prepared. And quite frankly, those are the things that keep me up at night as well as a pandemic that could emerge again from Asia. As well as the risks that have come up that Dr. Gottlieb identified with synthetic biology tools now that allow nefarious people to do unimaginable things potentially.

So I think we have a long way to go. We have done very well in some areas; again, a compliment to the effort that was done by the Federal Government in support of state and local authorities. And again, for those three hurricanes nearly consecutively, I think that was a great commitment of effort by everyone.

But there is no time to rest on our laurels in that respect.

Senator BURR. The statute is very clear on BARDA's specific and targeted medical countermeasure mission to ensure that BARDA is staying focused in bringing forward the countermeasures we need to protect the American people from a range of chemical, biologic, radiologic, and nuclear threats. All of BARDA's work should be tied to this threat context.

Why is it important that BARDA's mission not be diluted by matters or mandates that would require BARDA work on areas outside of those tied to threats specifically? And how does the com-

ment of 34 innovations out of BARDA relate to a focus on its mission?

Dr. KADLEC. Yes, sir.

Well, I think the key thing here is to remember what the mission was originally. And again, BARDA was only part of the puzzle here.

Project Bioshield, which was a 10-year advanced appropriation, was another critical element of that formula of success, which was a guaranteed market to manufacturers should they get across the finish line.

But the key issue that you have raised, sir, is that we cannot boil the ocean. Quite frankly, the BARDA model works. The resources that have been given to BARDA to date have been somewhat limited. We have had, literally in some circumstances, to rob Peter to pay Paul given events that have transpired with Ebola and other events.

We do not have a sustained level of funding necessarily, a line item for pandemic influenza, for example. That would give us great confidence that we would have a sustained, uninterrupted funding stream.

So the answer is arguably, you could do more things, but the answer is you cannot do more things with limited resources. If we focus on the national security mission which, I think, is vital—again, vital to the role of BARDA—then I think we have to stick to our lane and highlight the fact that right now, to use a defense analogy, we are operating with about half an aircraft carrier of resources to basically do this mission. A national security mission to basically protect 320 million people and that is a challenge.

Senator BURR. Dr. Gottlieb, in your experience, what is working well in the agency's review of medical countermeasures? And what challenges have you seen in the medical countermeasure pipeline?

Dr. GOTTLIEB. I think we are doing a much better job now. I look at this over a 15 year period.

I came into the agency shortly after the animal rule was implemented back in 2002. Between my two tours at the agency, I think we are doing a much better job at leaning in with respect to trying to bring some of these technologies forward; trying to look at ways that we can lean forward and develop the animal models that are going to form the basis of some of the product approvals; trying to put out perspective guidance and talk to manufactures and provide more regulatory clarity.

I think there are still challenges around the incentives in this market. Frankly, I think having been on the other side of this in the private sector, the prospect of being able to commercialize something just for stockpiling purposes sometimes is not enough of an incentive to offset the enormous capital costs of some of these endeavors.

I think we are also looking at, we focused on some of the immediate dangers, some of the pathogens we knew and we are developing countermeasures on them. I think we are looking at a future where it is going to be much easier to bioengineer some of these things in ways that we cannot fully anticipate and create very new risks.

Senator BURR. Senator Murray.

Senator MURRAY. Well, thank you very much to all of you.

In the wake of Hurricane Irma, as hospitals were evacuating, the top priority was protecting vulnerable populations including people and individuals with disabilities, and children, and pregnant women.

In every public health emergency, we have to pay unique attention to people with functional needs that put them particularly at risk. That is true for preparedness planning and for emergency response, including, for example, making sure that there is adequate medical countermeasure development and dosing guidance for children and pregnant women.

PAHPA actually acknowledges that there must be specific attention paid to at-risk individuals, and we want to build on that last authorization, because I think we can do better.

So I wanted to ask each of you to briefly describe your agency's efforts to meet the needs of all people. And, what more can we do to ensure that when it comes to public health preparedness, we are prepared for everyone?

Dr. Redd, let me just start with you, and if we could, just go down the panel.

Dr. REDD. Thank you for that question.

Let me just highlight a couple of things that we are doing at the CDC.

First of all, our guidance through the Public Health Emergency Preparedness Program requires that states have a plan for persons with functional needs. So that is part of the planning process.

We also work closely with the American Academy of Pediatrics and the American College of Obstetrics and Gynecology, depending on what the emergency is, but work with them to make sure that those needs are being covered.

I would also say in the stockpile that we have made progress in procuring products that are needed to treat children.

For example, there are 100,000 treatment courses of Oseltamivir in suspension form that are intended, or targeted, for children.

Senator MURRAY. What could we do better?

Dr. REDD. I think there is always more work to do.

I think that we need to make sure that these plans are exercised and that we have actually covered all the bases. That they are not just written on paper, but that we actually are able to execute the plans that we have made.

Senator MURRAY. Dr. Gottlieb.

Dr. GOTTLIEB. I would just highlight that PAHPA gave us new authority to put forward, to your point, treatment guidelines that can help guide the applications of some of these therapeutics, particularly with respect to pediatric dosing, which we have used. We have approved 12 drugs under the animal rule; 7 have been approved with pediatric dosing requirements.

I think this is something that we can continue to do better. I think one of the ways that we are going to do that is to have better development of animal models that have better natural histories associated with the pathogens in those animal models that allow us to predict what the therapeutic impact is going to be on a pediatric population.

So, this is some basic research that we need to do to develop those models that are going to, then, allow us to extrapolate into a pediatric population; and other populations, for that matter, other vulnerable populations, to your point, and allow us to have dosing guidelines for those populations.

Senator MURRAY. Is there anything we can do within PAHPA to help improve that?

Dr. GOTTLIEB. I think to Senator Burr's point as well, I think this, as a scientific basis, still needs further development. PAHPA gave the agency resources and we have developed discrete expertise in this area as a result of the legislation.

I think that is a place where we can continue to make more investment.

Senator MURRAY. Okay. Dr. Kadlec.

Dr. KADLEC. Thank you, ma'am, for the question.

I would just like to highlight during the hurricanes, we actually did some very specific things around people with functional disabilities.

I do not know if any of the Members have heard of emPOWER. It is a program that allows us to basically identify, in the CMS data base for Medicare, people who are dependent on durable medical equipment.

Based on requests from states, we can provide actually very specific information where these people live by ZIP Code and by address. In cases like Irma, Florida was able to do a reverse 9-1-1 call to those people at-risk well before any evacuation orders went out to the general public to advise them that they should consider leaving before things got worse.

In the cases of Maria, we actually used that data to identify, on the islands St. Thomas and St. Croix, people who were dialysis dependent. And after the storm passed, we were able to basically link up with the urban search and rescue teams, and actually recover dialysis dependent people, and basically evacuate them to safety. So there is that part of it.

One of the limitations currently is that it is only for Medicare data. The State Medicaid data is limited. We can do that if we have access to that and provide the same information. So that is one area that we could probably benefit from working with you all to see how we can have the states work collaboratively to use that information prospectively.

To add to the points that were made by the other gentlemen, clearly BARDA has looked at specific products for pediatric patients, as well as people with immunocompromise, and there are products that are in the stockpile today that are to benefit both of those populations.

One of the areas, and I highlighted it in my testimony, is on the National Disaster healthcare System. One of the specific areas we would like to do is take the learnings or lessons learned from Ebola where we created a national Center of Excellence at Nebraska University for infectious disease and replicate that for other very important trauma-related or disaster-related areas like pediatrics.

We think that that would be a way where not only can you create the necessary, if you will, critical mass of expertise, but also

teach through telemedicine and through teleconsultations to provide support during disasters.

The last area I would like to do, and a shout out to our V.A. colleagues, is the V.A. was a very significant contributor to our response to Harvey. HHS responded and took care of 36,000 patients. The V.A. provided care to 21,000 patients, many of those were V.A. beneficiaries, but some of those, many of those were families of V.A. beneficiaries. And then a larger number were actually the general public.

The V.A. has unique capabilities as it relates to geriatric populations, and that is one area that we can probably benefit from in terms of utilizing some of their expertise.

Senator MURRAY. Thank you very much.

Senator BURR. Chairman Alexander.

The CHAIRMAN. Thanks, Mr. Chairman.

Dr. Kadlec, Dr. Gottlieb, let us talk about the flu. This is the 100th anniversary of the 1918 influenza pandemic that killed an estimated 50 million people worldwide; 600,000 in the United States.

According to the Centers for Disease Control, year in and year out, between 12,000 and 56,000 Americans die as a result of seasonal flu.

We heard last week in our opioids hearing that opioids kill more Americans than car accidents. And those statistics that I just read would suggest that in a severe year, so could the flu.

Dr. Collins, the head of the National Institutes of Health, has made the prediction before our Committee that if we keep up our investments in biomedical research—which Senator Blunt, and Senator Murray, and the rest of us have been doing pretty well the last 3 years—that we may have a universal flu vaccine, as well as a vaccine for Zika, within the next decade.

Dr. Fauci at NIH has said that the most effective method for protecting Americans against another pandemic influenza is to encourage and invest in the development and stockpiling of influenza vaccines that will broadly protect against the virus.

Well, in Tennessee right now, the hospitals are filling up with people with the flu. So Dr. Kadlec and Dr. Gottlieb, if researchers at NIH, or any partners with them, discover a platform technology that could speed the development of a universal flu vaccine, what would BARDA do to support the advanced research and development of that technology?

Dr. Gottlieb, what is the FDA ready to do to encourage the use of that technology for new and innovative vaccines?

I have 3 minutes.

Dr. KADLEC. Chairman, I will be very brief, then, in the sense that BARDA has an integrated portfolio with NIAID. So once a product gets through Phase 2a clinical trials, it would be transitioned over to BARDA, which would take the advanced development through to fruition. So that part of it is done.

They have the capacity to basically identify manufacturers who could produce that either in eggs, or tissue cell culture, or emerging technologies.

The CHAIRMAN. Dr. Gottlieb.

Dr. GOTTLIEB. Yes. I will just quickly add, we already have, in development, vaccines that might be universal flu vaccines that, presumably, could elicit a T-cell response and could achieve what you are outlining.

We continue to provide advice to clinical developers and manufacturers on the proper pathway for looking at trying to bring those new technologies through.

I would point to one place where the legislative suite that we have adopted to try to address some of these biological threats has been helpful in the development of manufacturing capacity. That could greatly aid in the scope of these new vaccines, particularly cell-based manufacturing, which we have made a lot of investments in, as you know, that could provide the proper platform for the development of these vaccines.

The CHAIRMAN. Dr. Gottlieb, this is a related matter.

We are all concerned about Puerto Rico and the impact of the hurricane there. I think you told me at one point that maybe one-third of the economy of Puerto Rico has to do with medical technology.

Is that right?

Dr. GOTTLIEB. That is about right. It is about 30 percent.

The CHAIRMAN. And many of those facilities, as you described, were destroyed.

Are they rebuilding in Puerto Rico, or are they rebuilding other places, or do you know yet, because that could have a major effect on Puerto Rico's future?

Dr. GOTTLIEB. Right. And we are obviously very concerned about the situation in Puerto Rico for a host of reasons, not the least of which is that the Puerto Rican economy is very dependent upon that skilled manufacturing base.

I am happy to tell you that all of the facilities that we are concerned about—that produce product that we were worried could go into shortages if the facilities continued to remain offline—are now back on the grid.

So the facilities themselves actually did not sustain a lot of damage. It was the power grid and the infrastructure in between the facilities to try to move equipment in and off the island, and that sustained a lot of the damage. The facilities actually were fairly hardened.

But the ones we were worried about are back on the grid. There are still some facilities that are not on the grid, but they have such redundant electric generation capacity that we do not really have concerns about the product supply coming out of facilities.

So the situation now looks a lot better than it did 4 months ago.

The CHAIRMAN. Mr. Chairman, I think my time is about up, and I will give the rest of it back.

Senator BURR. Senator Casey.

Senator CASEY. Thank you, Mr. Chairman.

I wanted to start with the reference that I made earlier to the train derailment in Philadelphia as an example of good preparation. Part of that has its origin in the fact that it happened in an urban area where you have not just the resources, but you have hospitals and the healthcare infrastructure, which is close by way of distance, as well as by way of coordination.

I represent a state that has 48 rural counties out of a total of 67 counties. So we have a lot of small towns and rural areas where you do not have the institutional capacity necessarily. In the event of an emergency, that could be exacerbated by distance and other challenges, so you have this type of gap or potential gap, where some communities may be particularly vulnerable.

I would start with Dr. Kadlec and then go to Dr. Redd.

In terms of the Hospital Preparedness Program, the so called HPP, as well as PHEP, how do those programs attempt to close the gap in preparedness among states and regions?

Dr. KADLEC. Thank you, sir, for the question.

I think the point is that the way we are structuring it right now, we are trying to actually build healthcare or promote healthcare coalitions which are collections of hospitals, as well as other entities like emergency medical services. So you can build a regional.

That is why we would like to expand that effort to basically do it so not only would it cover specific regions within a state, but statewide and across states so that you can develop a much stronger backbone, if you will, to do this.

I think the idea of basically building out the National Academy of Sciences' study on trauma systems is worthy of reviewing because it highlights the important role that has a foundational capability for the country. Not only for day to day routine activities, but for these extraordinary events, train derailments that happen not only in Pennsylvania, but in the State of Washington, as an example, become a central piece of that.

My interest in this is seeing how we can leverage all those pieces together with some of the Federal assets the V.A. identified. Madigan Army Medical Center was a critical first responder in the train derailment in Washington State.

The thing is, how do we basically build, forge a public-private partnership for those purposes that can basically strengthen it? So not only do you have the transport mechanisms with emergency medical services, but also telemedicine and teleconsultation that would be available from this specialty services, these Level I trauma service hospitals or Level I expert hospitals like Nebraska that basically deal with a range of topical areas.

Senator CASEY. Doctor, before moving to Dr. Redd, I just want to inject another question.

This is an authorizing Committee and a reauthorization process. But I want to specifically ask, in light of the question I posed, are there additional authorities you need or additional dollars?

Dr. KADLEC. Sir, I would suggest both. We have a \$3.3 trillion healthcare system for which, right now, we invest approximately \$250 million annually for preparedness and resilience. I think it just highlights the fact that it is kind of a drop in the bucket.

I do not think it is necessarily the role of the Federal Government to pay for the whole bill, but certainly, we need to look at a variety of incentives, whether that is through CMS reimbursements, whether that is through insurance programs, or tax benefits that would incentivize hospitals to do it.

Our conversations with some of the outside partners, we held kind of a listening session with 35 stakeholders last week, including hospital associations. They are all willing and we have the hos-

pitals volunteering to help. I think they are just looking for a means to do this in a way that is mutually beneficial.

Senator CASEY. Thank you, doctor.

Dr. Redd, I only left you 45 seconds.

Dr. REDD. I will be brief.

We actually met with selected state health officials last spring to ask this exact question that you asked. Are there things that we should be doing differently to support rural health departments?

The conclusion was, it was a little bit surprising to me that the capabilities needed for rural districts and urban are largely the same: detection capability, communications, incident command or the structure to run responses. But there are additional, as you mentioned, there are additional layers of challenge with transport and access to medical care.

I think that this is an issue a little bit beyond emergency response and I think the idea of telemedicine as a tool is a great idea. But it is essentially a question of, how do we make sure that those communities have access to medical care during and not during emergencies?

Senator CASEY. Thank you, Mr. Chairman.

Senator BURR. Senator Isakson.

Senator ISAKSON. Thank you, Senator Burr.

Thank you for your work on pandemics and on BARDA for a long period of time. It is very valuable. The Committee has worked on it a long time.

I appreciate Chairman Alexander and Senator Murray, and the work that they have done.

Thanks, Dr. Kadlec, for calling out the V.A.

As Chairman of the Veterans Committee in the Senate, I have learned a lot of things about our delivery system and capabilities in terms of V.A. healthcare, which is the second largest employer in the United State Government. A lot of people do not realize that, but that is how big and pervasive the V.A. is, and they provide significant healthcare to seniors by virtue of their delivery system.

Your callout for them and what they did in Houston, Houston has appreciated it.

Also, I would say that most of the research dollars that are invested by the U.S. Government in control groups are through the V.A. because you have a control group of patients where you can do a good research sample. Our veterans, and our Veterans Administration, provide a great service in terms of that, which brings me to Admiral Redd.

You have your emergency preparedness grant that you give to the local governments. When we had the incident we had happen in Hawaii last week, where we had a false alarm on a missile attack, which was rather unsettling to the people of Hawaii and, quite frankly, it was unsettling to me. That is an emergency grant challenge you want to make sure you do not ever have with a pandemic where you get the wrong information going out from a designated agency at the wrong time.

Do we concentrate a lot on that to protect ourselves from bad information getting out on pandemics or on diseases?

Dr. REDD. I think that really gets to one of the core requirements that we have, which is to be sure that the information we are pro-

viding is as valid as it can be. And if we are not certain, but we believe people need to know, we make sure that those caveats are expressed.

It really gets to some of the basic principles of risk communication to tell people what we know, what we do not know, and what we are doing to find out those things that we do not know.

Senator ISAKSON. Dr. Gottlieb, I appreciate your mention of Priority Review Vouchers.

Senator Casey and I worked on PRV's for rare diseases that affect children and successfully passed legislation. I think the first drug has been approved now and put on PRV. It was issued by the department, and we appreciate that.

Your use of that to expand the use of PRV's to encourage the development of drugs that are either very costly to develop or hard to develop is very important.

How do you intend to use that to expand the development in terms of new pharmaceuticals?

Dr. GOTTLIEB. Well, as you know, the PRV program provides an additional incentive for manufacturers to try to develop products for these purposes. And so, I think it is one of the tools that Congress contemplated to try to address some of the challenges that we have already talked about that I mentioned, which is that sometimes this is not a typical market where you have the usual market-based incentives to try to make the capital investments to develop these products.

There is work going on to look at what impact the PRV's have had. We have implemented the program. We have seen sponsors come forward and be awarded these PRV's and sell them in the secondary market as a way to try to recoup some of the cost of the investment.

Senator ISAKSON. On that same subject, I have done a lot of work on a disease called Batten's, which is an incurable disease of young people. I had a personal situation that piqued my interest in my district when I was in the House, and I have remained interested in that.

It is a very difficult disease for which there is no cure, but with the gene therapy development and the delivery system of pharmaceuticals to specific parts of the body, and the brain in particular, there is hope and promise for that.

Do you issue guidance letters to research hospitals or research facilities to give them guidance on how they can test or develop to work on a breakthrough drug for a disease like Batten's?

Dr. GOTTLIEB. Senator, I think one of the areas of the most promise right now that we are looking on when we look across our portfolio is what is going on, as I said, with biologics with respect to cell based therapies, machine based therapies where we have the ability to cure inherited disorders, devastating inherited disorders that were not treatable just a short time ago.

We are going to be putting out this starting probably this spring, maybe a little earlier, a suite of products with specific guidance on how sponsors can address certain disorders with gene therapy to try to provide as much regulatory clarity as possible.

We are going to look at some of the more common disorders first, but we are going to try to work through some of these rarer dis-

eases to make sure that product developers have a lot of clarity around what the pathway forward would be.

Senator ISAKSON. I commend you on the leadership you have shown in that effort already and plan to support you in any way we can to help you do that in the future.

Thank you very much. Thanks to all of you for testifying.

Senator BURR. Senator Smith.

Senator SMITH. Thank you very much, Senator Burr, and Chair Alexander, and Senator Murray.

I am so pleased to be able to serve on this Committee. Thank you very much.

I would like to come back to something that Senator Murray and, I think, several others have talked about, which is the importance of a connection and support to local public health organizations.

In the past year in Minnesota, we have dealt with three infectious disease outbreaks: measles, multidrug resistant tuberculosis, and also syphilis. And all of these outbreaks have required a really immediate response, as well as a sustained response, as we have gone forward.

Minnesota has traditionally, as I am sure you know, invested heavily in emergency preparedness and dealing with infectious diseases, probably because of our history in agriculture more than anything.

But in these particular situations, the financial resources that we had were not enough and so, we turned to the CDC for support. And, of course, no fault of yours, there were no resources there.

What we did is we moved forward with the state legislature to pass an emergency public health response account so that we could respond quickly because speed is of the essence when you are dealing with these kinds of outbreaks.

My question is in what ways do you think that an emergency response fund would strengthen our federal and state efforts during an outbreak or after a disaster?

Maybe if you could just talk a little bit about that, that would be helpful.

Dr. REDD. Thank you very much.

I think that resources are critical in responding to an emergency. We had lengthy delays, both in the Ebola response and in the Zika response before funding became available, and I think that hindered what we were able to accomplish.

There has been discussion both in Congress and in the Administration about how to do that, and I think that those discussions will continue. But I think something along those lines would be quite helpful.

Let me mention one thing that we have done specifically once funds are available to make sure that they are used more quickly.

We had a Notice of Funding Opportunity that we opened to our grantees through the Public Health Emergency Preparedness program and allowed them to apply for funds. There were no funds in this award, but we have an approved, but unfunded, grant mechanism so that we do not get delayed at the Federal level once funding is appropriated.

Senator SMITH. Thank you.

Dr. KADLEC. Senator Smith, if I could just add.

There exists already in authorizing language for a fund for HHS that has \$57,000 in it. Obviously, it is not an authorization problem.

But I just want to highlight the fact that, yes, there is a fund that is needed. It should be a fund that necessarily is managed by the Secretary and based on a public health emergency. There can be, if you will, distribution of funds from that, and that it can be used across HHS, or to fund states and locals in a way that would be rapid.

Obviously, there is going to be a need for, it would be like the medical equivalent of the disaster relief fund, I think. But I think there would be, obviously, a requirement to notify Congress in those sorts of situations on a basis of reporting back on some occasions to make sure the funds are being spent appropriately.

Senator SMITH. Right. Thank you.

Essentially, we need to make sure we have good accountability.

Dr. KADLEC. Right.

Senator SMITH. That the funds are being spent the way they are supposed to be spent—

Dr. KADLEC. Yes, ma'am.

Senator SMITH —which I would completely agree with.

I realize that this is an authorizing question and not an appropriating discussion here, but Dr. Kadlec, if such a fund were to be made available, what would you advise in terms of the level of funding that would be necessary to have this actually be workable?

Dr. KADLEC. Well, ma'am, I would have to back in a firm number, but I think what you probably looked at is what happened with Ebola or the original pandemic influenza appropriations, which are on the order of \$2.5 to \$3.5 billion.

Again, what you need to hedge is the opportunity for Congress to weigh in fully, and again, on the basis of time. So obviously, there are a lot of factors to be considered in there, but there is a rich, historical record that could probably be drawn upon to identify an appropriate level that would get us through the initial crisis to the point where Congress can basically perform its fiduciary responsibilities.

Senator SMITH. Right. Thank you very much.

Senator Burr, I was struck by what you said about how we need to stick to our knitting on this Committee and not expand too much. And also how important it is to think about the processes that we have in place with this authorized legislation, to make sure that it works well.

I appreciate your comments. I think it gives us some good food for thought as we consider how we can respond as quickly as possible when there is an emergency.

Thank you.

Senator BURR. We, again, welcome you to the Committee.

Senator Young.

Senator YOUNG. Well, thank you, Chairman.

The World Organization for Animal Health estimates that roughly 60 percent of known human diseases are transmitted from animals to people. They are of so called zoonotic origin.

Every year, an average of five human diseases appear such as Ebola, HIV, and new strains of influenza; three of which are zoonotic.

In my home State of Indiana, we suffered considerable losses in the widespread bird flu outbreak, one that led to the destruction of 400,000 turkeys. And this followed in 2015 and the outbreak that led to the loss of 48 million poultry.

Dr. Kadlec, what are we doing now to prevent the spread and transmission of diseases from animals to human beings?

Dr. KADLEC. Well, sir, I have to say that, quite frankly, we need to do more.

The one health concept that you are outlining is an important one. Influenza is not the only disease that is of zoonotic importance that has pandemic potential; SARS and MERS are examples of others.

But I think I need to really defer to Admiral Redd to talk about the role of the CDC here and their role of surveillance because, quite frankly, they are on the cutting edge to ensure that you can recognize those events rapidly as they have in Iowa, I think.

Senator YOUNG. Thank you. Admiral.

Dr. REDD. Thank you, Dr. Kadlec and Senator Young.

We are working very closely with USDA on this issue and particularly on influenza. We were really joined at the hip in the response to this importation of these avian influenza viruses.

Our role was to make sure that we understood the biology and that if any human infections occurred, that those were rapidly detected and treated, and to protect workers in the process of the culling that was going on.

Senator YOUNG. You, no doubt, do the best you can with the resources and authorities you have.

No. 1, how are we doing with respect to tracking and then the responding to these situations and preparing for the next one?

Then secondarily, speak to any additional authorities or resources you might need to optimize your efforts.

Dr. REDD. I think that given the strategy that we have, which is a reactive one, I think we are doing well at detecting and containing importations.

Senator YOUNG. That predicate caught my attention.

Dr. REDD. Yes.

Senator YOUNG. Given that our strategy is a reactive one.

Dr. REDD. Right.

I think that the ability to prevent importation of influenza viruses that could be transmitted by migratory waterfowl, for example.

Senator YOUNG. Yes, sir.

Dr. REDD. It is very challenging.

I think there is a lot being done on the animal health side. I think that it is a challenge and the basic strategy is to identify and limit, to the extent possible, to one flock or as small an area as possible. And through that process to prevent human infection should the virus have the capability to be transmitted or to be infectious to humans.

Dr. GOTTLIEB. If I may, just for 15 seconds.

I would also talk about the importance of thinking about animal drugs in our approach. And Cures, as you know, extended the EOA authority to animal drugs. We might also contemplate trying to think about how we create incentives for the development of animal drugs to target some of these threats including maybe a breakthrough therapy designation for animal drugs or other kinds of creative policy approaches to make sure that that is a part of our approach as well.

Senator YOUNG. Well, thank you.

I look forward to working with each of you. I will probably have some follow-up questions I will submit in writing, and hopefully we can improve our current systems for dealing with these matters.

Senator YOUNG. Dr. Gottlieb, you just once again mentioned incentives in the animal context, but I would like to pivot to our antibacterial resistance threats.

Every year, at least 2 million people in the U.S. acquire serious bacterial infections that are resistant to one or more types of antibacterial drugs.

However, as I understand it, there are very few companies that are developing new antibiotics, and those that are focused on the most serious bacterial threats are even fewer.

Is additional action needed to immediately incentivize the development of drugs to combat this growing global problem? And if so, what might new incentives look like? And what might we do as Members of Congress to provide those incentives?

Dr. GOTTLIEB. Senator, thank you for the question.

As you know, Cures created a number of new vehicles, and some incentives, for development in this space. We are encouraged by the early interest we are seeing in those pathways, things like the LPAD pathway. I think we are going to have more information soon on how well they are working.

I mean, we can always contemplate additional policy steps, and I would be happy to talk to your office and work with you on that. I think that this is an area, to your point, that we need to think about what more we can be doing.

But Congress has done, taken some steps recently that we are very encouraged by. We are seeing a lot of good, early interest in them.

Senator YOUNG. Thank you.

Senator BURR. Senator Kaine.

Senator KAINE. Thank you, Mr. Chair, and thanks to the witnesses.

I have great confidence in this Committee's ability to work on this PAHPA reauthorization in a bipartisan way. I have two observations and a concern. So an observation is this and some of you have alluded to it, and Senator Isakson's questions alluded to it.

One of the tasks of emergency preparedness is to prepare for attack, and you have talked about chemical and biological. Senator Isakson talked about the incident in Hawaii this weekend.

I just want to say for the record and for the public. The prospect of nuclear war is being discussed with a lot of frequency in this building to a degree that I have not seen in the time I have been in the Senate.

I am on the Armed Services and Foreign Relations Committees. We have had a series of hearings, even open, where there has been discussion about the prospect of land war on the Korean peninsula.

We had an Armed Services hearing recently where a witness volunteered in public—and it was sort of a non sequitur, why he would bring it up as a Member of the Administration—about what the likely cost of reconstructing Kansas City would be after a nuclear attack.

I noticed an article in “The New York Times” a few days ago. “The C.D.C. Wants to Get People Prepared for Nuclear War.” That was supposed to happen yesterday.

“On January 16, the Centers for Disease Control and Prevention will present a workshop titled ‘Public Health Response to a Nuclear Detonation,’ for doctors, Government officials, emergency responders, and others whom, if they survive, would be responsible for overseeing the emergency response to a nuclear attack.”

Quote, “While nuclear detention is unlikely,’ the C.D.C. stated on its Website, ‘It would have devastating results and there would be limited time to take critical protection steps. Despite the fear surrounding such an event, planning and preparation can lessen deaths and illness.’”

Quote, “Join us for this session of Grand Rounds to learn what public health programs have done on a Federal, state, and local level to prepare for a nuclear detonation. Learn how planning and preparation efforts for a nuclear detonation are similar and different from other emergency response planning efforts.’” That is off the CDC Website.

The article goes on to say, “The agenda for the day includes, ‘Preparing for the Unthinkable,’ to ‘Roadmap to Radiation Preparedness,’ and, ‘Using Data and Decision Aids to Drive Response Efforts.’”

I understand the CDC rescheduled that, canceled it from yesterday, and had a roundtable on the flu instead, but this is a realistic discussion about these prospects. And then add to it the “Dr. Strangelove” like incident over the weekend where a state sent out a mass e-mail telling people there was a ballistic missile incoming to Hawaii, which occasioned 38 minutes of panic.

Then on Tuesday, the Japanese state broadcaster, NHK, put out a warning that North Korea had fired a nuclear missile and urged Japanese citizens to take cover. That was retracted within a very few minutes.

There is a lot of discussion, some very intentional and some frightening, about the prospect of nuclear war that is happening, and this is in the provenance of your agencies.

I just want to put that on the record that that is sort of a normal area for discussion these days. I find it incredibly frightening and the normality of it I find incredibly frightening.

The second observation I want to make is this. This is a discussion about national security. We are involved in a budget debate right now. Right now, the spending bill ends January 19 and one of the points of argument is whether we might fund defense accounts over the budget caps of nondefense accounts.

You are about national security. You are about national defense and all of your agencies are funded through the nondefense accounts of the Federal budget.

Any suggestion that we would increase defense budgeting, but hold the line and put nondefense agencies subject to their caps, would not really fund the national security priorities that you are here about, and that is something we have got to grapple with.

Here is my question.

I am very worried about this Hawaii incident because in a time of heightened tension, we know from history that wars often start accidentally. There is a miscommunication and a misunderstanding; there is an overreaction. That is how World War I started. That is how most wars start.

I know there is going to be a hearing later in the week, I think, on the House Armed Services Committee about this. I am sure that there is an investigation at the state level. But part of the responsibility—and Dr. Kadlec, I guess this is mostly directed to you—part of the responsibility in the emergency preparedness and response side is accurate communication. As a former mayor and Governor, that depends heavily upon communication between Federal, state, and local officials.

As you approach this thought of thinking about reauthorization in this climate where things can sometimes be pretty tense, how do you look at that state, local, and Federal coordination effort, especially as it deals with the communication of accurate information, and knocking down inaccurate information?

As quickly as you can.

Dr. KADLEC. Well, sir, we take it very seriously, No. 1.

No. 2 is the experience we had with the hurricanes, particularly Hurricane Maria, I think, highlighted some of the challenges. In my testimony, I identified some of the incident command issues that we have to address, which really is not only information out, but information in.

I think the issues that we need to work with—not only with our CDC brethren, but with state and local authorities, as well with FEMA; I met with them just as of yesterday—talking about, how do we integrate our efforts closer so that we have better information exchange on these kinds of issues? Whether they are hurricanes, pandemics, or whatever it is that, quite frankly, you need to kind of think through, learn through not only experience, as we did with the hurricanes, but exercises, as we did.

Sir, just to highlight one thing, since I have been around the block on these sets of issues. Going back to 2000, it has been a routine practice in the U.S. Government, the Federal Government at least, to exercise the idea of a nuclear detonation. Most concerning then was terrorism as a matter of an improvised nuclear device.

It is not necessarily new. Obviously, the context is different.

But I think the point here, though, to your issue is it does require a closer lash up with our Federal partners on these issues to make sure that we have good cross lateral, horizontal flow of information, as well as with our state and local folks.

We are investigating with FEMA just as another example of how we can basically work together in bed both our health and disaster

people in state and local state EOC's to, again, work more seamlessly with our state colleagues.

We are looking at all kinds of options right now to that effect. Senator Kaine. I appreciate it.

Mr. Chair, thank you for letting me go over.

I hope you will follow the investigation of the Hawaii incident for your own purposes because for purposes of having good information and that coordination, I suspect there will be some lessons that will come out of that that would be relevant to other circumstances as well.

Thank you, Mr. Chair.

Senator Burr. Thank you, Senator Kaine.

Senator Collins.

Senator Collins. Thank you, Mr. Chairman.

I want to applaud you for your leadership in this area.

More than a decade ago, we established a Port Security Program that led to radiation portal monitors being installed at our major ports so that they could screen incoming and outgoing cargo, trucks, and individuals for radiological material.

I contrast that port security effort with what I perceive to be a real vulnerability in our ability to detect and effectively and quickly respond to an attack using biological or chemical agents.

Dr. Kadlec and Dr. Redd, I would like you both to address the level of preparedness that we have to respond and detect, first of all to detect, a biological or chemical attack and to respond to it.

I would like specifically to know whether cities have used some of the Federal funds that the Admiral referred to, to install sensors that would be able to detect these agents.

I would also like you both to comment on the preparedness of our hospitals to cope with the victims of a biological or a chemical attack.

I remember being in Israel many years ago and being so impressed with their preparation and their ability to convert their hospitals to respond to that kind of attack.

Dr. Kadlec, why do we not start with you and then Admiral Redd?

Dr. Kadlec. Thank you, Senator Collins. I think one of the issues, and again, I have some insights on this historically.

But currently, the biologic program run by the Department of Homeland Security provides area protection for cities. So I think there is a real desire.

I have met with the new WMD, I do not know, directorate, Assistant Secretary over at DHS about improvements we can make to our chemical and biological attack kind of detection.

Quite frankly, our capabilities are fairly still limited and primitive, quite frankly. And I think there is a sincere desire on the part of DHS and HHS between ourselves to basically do improvement to do that.

To your second issue, how well prepared we are. Certainly, we have a Strategic National Stockpile that can address many, but not all, of these threat agents. So there is work to do there in terms of some of the development and procurement we need to do on those issues.

But one of the critical areas that collectively the CDC and our office are considering is really on the last mile of distribution.

As mentioned by Senator Murray, we can move Strategic National Stockpile resources anywhere in the country within 12 hours. The question is from that point forward getting it into the hands and into the mouths of every American person who is at risk is a significant challenge that, I think, collectively, we need to work on.

But now, I will defer to Admiral Redd for his comments.

Dr. REDD. Thank you. I think this is a really important question. If we are attacked in this way, the effectiveness of our response will depend on the speed and the scale with which we respond.

I think that the way that a biological attack would manifest itself would probably be different than a chemical attack. A chemical attack would primarily require a local, a near-instantaneous local response.

The CDC's Strategic National Stockpile has deployed antidotes for nerve agents. Over 1,000 different locations have pallets of these antidotes that are available to supplement the treatment that would be available immediately.

We also have and getting ever better capability to determine exactly which toxin has been used. So there is a laboratory element that the CDC is also responsible for.

On the biological side, we have made great strides with the laboratory response network. Every state has at least one laboratory that is able to use advanced techniques to diagnose these infections. There are a total of 150 laboratories around the world, including laboratories that can test food, can test water, and environmental samples from animals.

So looking to the future, the technology of whole genome sequencing is something that we need to continue to push out that would allow very rapid—

We talked about faster and more accurate. This is actually more information than we can get from current technologies; things like resistance to antibiotics or relationships of certain organisms to other, “where did it come from?” kinds of questions.

Senator COLLINS. Thank you.

Dr. KADLEC. Ma'am, can I just add one thing?

Senator COLLINS. Yes.

Dr. KADLEC. To your question about how our hospitals would do.

Senator COLLINS. Yes.

Dr. KADLEC. I think it was noted by the Chairman that even a bad flu seasons, as the current one we have, is overwhelming our hospital system.

Senator COLLINS. Exactly. That is one reason that I asked the question.

Thank you.

The Chairman [presiding]. Thanks, Senator Collins.

Senator Jones, welcome. We are glad to have you a part of this Committee. I acknowledged your new membership a little earlier, but we are glad to have you here. This is a Committee that has many different points of view, but works well together. So this is another subject that we intend to have some bipartisan success on.

Senator JONES. Thank you.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

So we are here today to talk about PAHPA, the framework for our response to all sorts of emergencies: natural disasters, accidents with hazardous materials, terrorist attacks, pandemics, you name it.

I returned, just a few days ago, from a trip to Puerto Rico and I know some of my colleagues have also been to Puerto Rico recently.

During my trip, it was clear that nearly 4 months after the storm, the crisis in Puerto Rico is a daily reality for tens of thousands, hundreds of thousands of people.

Dr. Kadlec, you are the top official in charge of preparedness and response at HHS. What is the biggest thing you have learned from the situation in Puerto Rico and the U.S. Virgin Islands about how we need to strengthen our preparedness and response capabilities?

Dr. KADLEC. Well, thank you, ma'am.

I think there are a couple of levels to go here.

One is improving the resilience of our innate hospital healthcare structure. That is one area.

The other thing is really the resilience of our public health system, which is a separate piece, but a related piece.

In Puerto Rico in particular there were, in the initial stages—after that terrible devastation that literally devastated the whole island and every life was touched—it was very difficult for the local public health and medical infrastructure.

There are some incredible heroic stories of doctors, nurses, laboratorians who basically responded, public health officials, who left their families, left their houses in disarray and basically went to respond to help their neighbors and their communities. But I think that is one piece of this that needs to be addressed, what happens before the storm.

The second piece is, how quickly can we move in? We had deployed teams to Puerto Rico in advance of both Irma and Maria to be available once the storm passed, both storms passed, to basically respond quickly. But even so, with the level of devastation, that was a huge piece of it. And a huge piece of it was the lingering devastation, not only the loss of communications and electricity, but also the damage to the ports and the airfields that limited some of the movement.

So I think one of the lessons learned was you want to go in aggressively before the storm, if you can. We literally put peoples' lives at risk from our response teams, including people from Massachusetts, Massachusetts One, that responded to all three storms.

Senator WARREN. Yes.

Dr. KADLEC. They are great people and, again, representative of your constituents from other states around the country that responded.

But also, there is a piece of this that we have to somewhat remove some of the dependencies in the responses. Seeing how we can move quicker and faster, if that is possible. A lot of it was dependent on being able to transport through air or barge, again, responding to an island is a tough one.

Senator WARREN. So I appreciate this and I am glad we are trying to think about what we need to do and what we need to do better, and to acknowledge heroic efforts, but we need a better structure here.

But to apply these lessons, we also need good data. We need to know not just what we got right or what we got wrong, but when we got it right, when we got it wrong, by how much, and what kind of difference it would make on the ground.

One of the things that struck me during my trip last week was how sketchy the data are. For example, I met with the Federal and Puerto Rican officials at FEMA's field office and they said, "No more issues with potable water." No waterborne diseases, all the water is drinkable. And I asked this specifically. Turn on the taps. You hold a glass under it. The water will be drinkable, is drinkable, everywhere on the island. It sounds great.

Not so much though.

I met with the Massachusetts State Police volunteers who told me that they had observed raw sewage in the water. At the public health center that I visited in Loiza, they said they still do not have potable water, no drinkable water for their patients. They said they serve 100,000 people and that none of them have drinkable water.

We heard the same kind of contradictions when it came to statements about how many people lacked power.

Dr. Kadlec, I get that public health emergencies are really challenging circumstances, and it is hard to get good data. But how does HHS and other agencies collect data in a way that is reliable so that you can deploy your resources effectively, hold yourselves accountable to get the job done that needs to be done?

Dr. KADLEC. Well, ma'am, we learned a lot from the experience in Puerto Rico and we are trying to rectify that.

Because of the loss of communications, cell towers, and the like, the ability to get information either from local authorities or local hospitals or clinics was practically nil.

We literally went to the point, at one time, to basically use runners from the National Guard who would have satellite phones to basically go to hospitals and clinics to report information out.

But that is a major consideration and lesson that we are still learning that we have to address because it is a major shortfall. Because if you were to add, again, a terrible event like this, a terrible earthquake or a nuclear or radiological event, you could imagine that the circumstances would be even more challenging.

But that is an area of great, intense concern, quite frankly, and work that we have to do.

Senator WARREN. I am very concerned about this and I do not have time. I am out of time now, so I cannot ask Rear Admiral Redd and Dr. Gottlieb about their work in Puerto Rico.

But Senator Cassidy and I sent a letter to Chairman Alexander signed by seven other Members of this Committee asking for a hearing on the recovery efforts in Puerto Rico and the U.S. Virgin Islands, and I hope we will be able to hold that hearing.

Puerto Rico might not be on the front pages anymore, but it is a humanitarian crisis and we have a moral, and a constitutional,

responsibility to exercise oversight responsibilities here. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

Senator Cassidy.

Senator CASSIDY. Well, thank you.

Dr. Kadlec, I am going to put you on the payroll, man. Earlier, you were responding to Senator Smith regarding a possible bill. We have that bill.

The Public Health Emergency Fund, actually stimulated by conversations with Dr. Frieden. He said that in the Ebola crisis, "There were ten different authorizations that had to be signed off on," before he could get somebody to travel immediately to Africa. Kind of crazy.

And, "I kept on contrasting the authorization process we were going through, which was cumbersome and slow with that before and after Katrina." Before Katrina, FEMA had to come to get the initial dollars. After Katrina, Congress recognized that is not the best way, so there is a pot of money that can immediately be accessed. And if it goes over that, then they come back and get another authorization.

Senator Schatz and I have put together a bill that, one, waives these contracting requirements for that immediate period so you can actually deploy people.

Second, based upon—and Dr. Kadlec this is where you nailed it—the previous 14 years of public health emergencies, we take the average of that expenditure and we make those dollars available upfront to be immediately drawn down.

Still accountability; GAO is going to do a report and make sure that the CDC has not used it to go to Hawaii for a conference as opposed to Africa to fight Ebola. No offense, Dr. Redd. But still, the point being that we would have the accountability built in, but we think it is a good bill.

Now, let me move onto something different.

Dr. Redd, I was struck speaking to people after Zika hit that in retrospect—and of course, everything in retrospect, if I could do things in retrospect I would be a millionaire on the stock market—but in retrospect, you could have predicted what was going to happen because supposedly Brazil was flying in folks from the South Pacific to work on their Olympic stadiums that Zika had been breaking out in the South Pacific where these workers were coming from. Brazil is like a Petri dish for Zika, and you could have predicted it.

Now, of course, it is retrospective. But the thought occurs to me with Big Data, we can actually put in travel patterns. We can put in areas of receptivity. We can put in where there are outbreaks and make some, at least, first blush guess as to where the next epidemic is going to be.

Is that just me, "would that not be great," sort of thing or is this something practical? And if it is practical, is the CDC doing it?

Dr. REDD. I agree with your overall statement.

I think another way of looking at this is that the pathway that Zika followed was very similar to Chikungunya just a few years be-

fore where it existed in the Pacific and then caused big outbreaks in Brazil and South America.

Another point that is the same is when we had outbreaks in the Caribbean, we knew locations of lots of travel to the U.S. and where the vector was, the *Aedes aegypti* mosquito lived. It is the same place that we have seen small dengue outbreaks in the past.

Senator CASSIDY. So, can we use this predictively? Because if we could use it predictively, if we could see, “Well, Brazilians are going to be having this problem. Let us go down there and encourage them to spray for mosquitoes,” et cetera.

Dr. REDD. I think it is hard to do that.

I think that the vector is very resilient and there were some questions—

Senator CASSIDY. Now, I was just giving the example of spraying the mosquitoes as a concrete action. But what I am asking about is not the vector of resilience.

Can we use Big Data just to look at travel patterns where there is an outbreak and guess where there might be a spread of such an outbreak?

Dr. REDD. I think we can. I think the challenge is what do you do with that information. And is there a way to use that, for example, to have prevented the Zika outbreak in Miami-Dade County?

I think that the things that you do—

Senator CASSIDY. So you were ahead of us. What you use the information is different than if you can actually acquire the information.

If it is practical and right, if you will, to acquire the information, are we putting such systems in place?

Dr. REDD. Well, just to take the Zika example, there was a lot of communication with Texas and Florida, Louisiana, the Gulf Coast areas that have the *Aedes aegypti* mosquito recognizing that—

Senator CASSIDY. Okay. You are still after me because that is after it hit Brazil and after we knew that there was going to be travel from Brazil up.

I am actually trying to go proactively before that in that we could see the Brazilians were bringing in lots of workers from the South Pacific and therefore, it was predictable that whatever was breaking out there was going to breakout here.

Now, that is taking the battle to the enemy, if you will. Are we doing that?

Do we have a worldwide kind of map—and I have seen such a map of hotspots of infectious diseases—overlaid with travel patterns to guess whether or not? And I understand the CDC has worldwide outposts.

So again, I am asking something closer to the point—

Dr. REDD. Sure.

Senator CASSIDY —than whether it gets to Texas.

Dr. REDD. I think the quality of information is variable. I do not think we have—

For example, I think the information we have about influenza is much better than we have about all the vector-borne, all the mosquito-borne diseases that are out there where we know what vi-

ruses are circulating in China because of the known importance of influenza and the risk it poses for a global pandemic.

Senator CASSIDY. Now, I have seen maps—and I am overtime, and I will stop after this—but I have seen maps put out by the CDC and the World Health in which it shows, “Oh, yes. Here is this and there is that.” And it is a hotspot of a particular virus.

Can that not be, again, overlaid with travel patterns?

Dr. REDD. Well, there are parts of the world that some of the discussion earlier about the number of zoonotic diseases that are detected that cause infections in humans, there are certain parts of the world that are more prone to those emergences.

I think, again, your question is, how do we use that information? We certainly do have travel maps of where people travel to and from. We have information about where various diseases occur at variable degrees of granularity. I think those two things do go together.

I think how we would use that to take a preemptive action is really, I think that is the question that you are getting at.

Senator CASSIDY. Okay. I yield back.

The CHAIRMAN. Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman.

This is incredibly informative. Thank you to all of the witnesses.

I want to raise two concerns that I have emanating from conversations I have had with companies in Connecticut that operate in the pandemic response field.

The first is regarding response to an influenza outbreak and this is for either Dr. Kadlec, I think, or Dr. Redd.

Dr. Kadlec, in your testimony, you write that we have sufficient domestic vaccine manufacturing capacity to produce a bulk vaccine for every American within 6 months.

But I want to ask either of you about the question of vaccine delivery. This comes from conversations with a manufacturer in Connecticut, B-D, which is one of the bigger syringe manufacturers.

My understanding is that if you needed to get a vaccine to everybody, you would need about 600 million drug delivery devices. Now, B-D is one of the biggest manufacturers, but it would take them 6 years to do 600 million units.

What are your thoughts on preparation to make sure that we not only have the right amount of vaccine, but the right amount of vaccine delivery devices?

Dr. KADLEC. Well, thank you, sir.

That is one of the issues, and then problems, that has to be addressed, quite frankly, and I have my Director from BARDA, if he wants to make a comment. He is welcome to at this point.

But I think part of the strategy we are looking at also is, how can we innovate and either have better delivery devices? Or specifically, can we make better vaccines that only require one dose? Remember, the 600 million doses are for two per person.

The third thing is there are maybe new vaccine technologies that allow you to do it orally, or intranasally, or a variety of other means beside subcutaneously with a needle. So I think all those issues are being evaluated and pursued.

But yes, there are some very significant shortfalls and there are other disposables as well that are a matter of concern when you get into that kind of circumstance.

Rick, do you have anything?

Senator MURPHY. I am sorry.

Dr. KADLEC. I just wanted to make sure if I left something out, if Dr. Bright could offer it.

Dr. REDD. I think this is a modeling problem. Particularly from the supply standpoint, making sure that we are tapping into the existing commercial market, and we are able to leverage that system in addition to stockpiling what that market cannot produce.

Senator MURPHY. Dr. Kadlec, back to you, and my second concern.

BARDA, as we have talked about, is such a wonderful model and working with industry, you have developed 34 approved medical countermeasures, 23 influenza vaccines.

Again, coming back to a company that BARDA has worked with in Connecticut, Protein Sciences, which as you may know, has come up with an innovative way to develop a vaccine; not the traditional egg-based vaccine, but a recombinant DNA technology mechanism.

They raised the issue of how you make sure that having spent the money to develop these vaccines, there is a market so that they can continue to develop processes and make sure that they are available.

What is the responsibility of BARDA, or HHS or, I guess, if the CDC wants to weigh in, on how you make sure that the money being spent on research ends up on a marketable vaccine? And that you are working with companies to make sure that a bridge market exists so that they are available in the case that you need them for a pandemic.

Dr. KADLEC. Well, clearly, that is one of the factors that goes into this public-private partnership. And I would also invite Dr. Gottlieb because it has been the case with the PRV's, like with the vouchers, if you get through that you can get some benefits. But we need to look at the whole variety of incentives to not only get companies into the market, but keep them in the market and keep them viable going forward.

There is this issue of "the second valley of death," which has been raised at some point in time that once you have delivered your vaccine—and if you do not get either the opportunity to replenish or use that technology for some other commercial purpose—that the company may still be at risk, and you may still basically be confronted by the limitations that you do not have the producer.

So these are issues that are still pretty thorny and, quite frankly, that is one of the areas, I think, that probably deserve a little more consideration during your reauthorization.

Senator MURPHY. I do not mean to keep Dr. Gottlieb out of this conversation.

You raised this in some of your earlier testimony, some of the market disincentives here and I would love to hear your thoughts.

Dr. GOTTLIEB. Yes, I think you raise a very valid point, Senator.

If you are talking about a countermeasure that does not necessarily have a dual use for another public health application, you only market is going to be in preparedness and presumably the

only market is going to be for stockpiling. And if it is not something that turns over a lot, so you are not going to have to constantly replenish your stockpile.

Depending on what you are developing, the cost of capital to try to develop that product might be too high to justify the investment. I saw this when I was on the other side of this equation.

We have tried to offset some of that with the PRV's, but I will say that the value of the PRV's in the marketplace have diminished as we had more PRV's. So the value of the incentive has also gone down over time.

So I think this is something we should all contemplate.

Senator MURPHY. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman.

Appreciate the discussion here this morning.

Dr. Kadlec, you recognized, in response to Senator Warren's question, the challenge that Puerto Rico faced after the devastating hurricanes. I mean, it is difficult in an island area where you are not connected, where you are remote.

Well, that brings it close to home to me. We are not an island in Alaska, but we are not connected to the continental United States, and we are really big, and we do not have a lot of roads.

It was just about 75, 78 years ago that we had a diphtheria outbreak in Nome and we were able to deliver the serum by dogsled. We are not doing that anymore, thankfully.

But it does speak to the reality of how to respond when you have an outbreak, and your ability to move in quickly is limited either because of weather or just access limitations.

We were reminded of this at 9/11 when all the airspace was shutdown, when you now have 80 percent of your communities that have no way to get things in and out. A major earthquake that can take out a major port that serves access or airports. And so, for us particularly in Alaska, we had to be our own little island when it comes to response.

But when you are trying to get stockpiles of vaccines or the like, that makes it very, very challenging. And I do not recall whether it was you, Dr. Kadlec or Admiral Redd, mentioned that you can get stockpiles, I believe, of vaccines anywhere in the United States within 12 hours.

Did I hear that correctly?

[All nod in assent.]

Senator MURKOWSKI. Should I be worried in a small, remote, not accessible by road, shut out by weather? We cannot even get a state trooper in for 3 days into certain of our villages at certain points in time.

What can you do to assure me that we can be that responsive in our more rural areas? That is one part of the question.

The other part is when it comes to infrastructure itself.

Several years back, we had the first sizable cruise ship going through the Arctic. We had all kinds of emergency preparation drills and it was not because we were most fearful of an oil spill from a ship that might hit the ice. But an issue on a ship where

you now have 500 passengers who need some level of healthcare and there is no healthcare facilities to be had in the region.

So for purposes of how we can be responsive when there is a public health crisis, whether it is an outbreak or some kind of a disaster, manmade, natural, or otherwise, what assurances can you give us from these rural states?

I will turn to Dr. Kadlec and you, Admiral.

Dr. KADLEC. Well, thank you, ma'am.

That is a challenge. I think the reality is the Strategic National Stockpile can get anywhere to be delivered to the state authorities within 12 hours.

Senator MURKOWSKI. So that would get to?

Dr. KADLEC. To Anchorage, for example. And then, it is really the state's responsibility to basically get those products, or those vaccines, or drugs to the last terminal mile to those people who need them.

That is an issue, quite frankly, I think ASPR and the CDC share concern, that that is an area where concerted work has to be done because there are other places in the country that probably would have similar challenges.

Admiral Redd, do you want to?

Dr. REDD. Yes, I think this is a very challenging scenario and I think that if it were a challenge to move product to a location, there would be other challenges as well; understanding the problem of the disease in that location.

We might have telecommunication, but access to laboratories, access to epidemiologic investigation, those would also be things that would be limited.

I think this probably needs to be thought of as a broader set of capabilities that are needed to assure the protection of these populations. Not just the stockpile, but medical care and really situational awareness as to what is happening in those locations.

Senator MURKOWSKI. Well, and it is something, of course, that we clearly think about.

The last thing I am going to leave you with. The State of Alaska just conducted an Alaska Health Impact Assessment. It was a framework based on the current National Climate Assessment predictions and the impact to Alaska as a state that is seeing the impact of climate change as warming temperatures. You might not feel it here on the East Coast, but it is warmer back home.

It outlines some of the potential health effects that could be coming our way several decades out. We recognize that.

But one of the concerns, of course, is infectious diseases that are particularly associated with vector borne. Usually, we are able to freeze those nasty mosquitoes and they cannot move these levels of outbreaks.

But it is something that, as we think about public health emergencies, we are so focused on the here and the now, and the disaster of the day, but I do think it is important that we be thinking long term about the changes that might be headed our direction.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murkowski.

Senator Jones.

Senator JONES. Thank you, Mr. Chairman.

Once again, thank you for your kind welcome to this Committee. To kind of followup on, I think, Senator Casey may have highlighted it and Senator Murkowski was talking about the rural health areas.

I can understand the challenges when there is a pandemic and you need to get access, but I have a state that is also very rural, but we have roads. We have the ability to get serum in and things like that. But yet, we are in Tornado Alley. We are in Hurricane Alley. It comes through.

My concern is the preparedness for healthcare delivery on an immediate basis when you have those disasters because in Alabama, like so many other states, rural healthcare is disappearing, and that is a real challenge.

So I would like to have you address what is being thought about, what is being done to prepare for those types of emergencies for those communities that do not have the daily healthcare that they have got, so that immediate healthcare needs can be given to them.

Dr. KADLEC. Sir, I would just say one of the areas I touched in my written testimony is on this idea of creating a National Disaster Healthcare System, really taking advantage of the nascent trauma system that we have in our country that clearly needs to be amalgamated or, if you will, kind of unified.

We would like to basically use the Hospital Preparedness Program as a means to do that. It certainly would need more resources to do that. But basically expand the regional coalitions to not only cover states, but regions, Mississippi, Alabama, that part of the country where you can actually share resources and basically do better coordination, mutual aid in those kinds of situations. Build the kind of relationships where you know about bed availability, work with the EMS systems in terms of transportation to basically identify the appropriate places to take people with different injuries or different kinds of casualties to the right place to ensure their survival.

There is a lot that can be done and quite frankly, we think by regionalizing this will help. Because Alabama has a few major cities, Mobile, clearly there are some great facilities there, as well as other parts of the state, as well as adjacent parts in Mississippi. If you can build that coalition on a regional basis, you can probably address some, but not all, of those issues.

Dr. REDD. This is a little bit beyond preparedness, but one of the things we had done at the CDC is to examine rural health. The way that we have done that as a first step is to actually examine the data that we have.

There are a series of publications on issues related to rural health in our in-house journal, "The Morbidity and Mortality Weekly Report," and we would be happy to get those to you to define the problem.

Senator JONES. Okay, that would be great.

I also was going to ask a similar question about citizens with disabilities.

Do you have specific guidelines, things that you do to take care of those with disabilities, whether it is a physical disability, a mental disability, or whatever?

Dr. KADLEC. Sir, we have a program at HHS and the ASPR that basically uses CMS data, Medicare data to basically identify people in different regions or in states by ZIP Code, by home address, even by phone number to identify people who are dependent on durable medical equipment.

So in advance of a hurricane, for example, we provide the states, like in the case of Florida and, I believe, in Alabama too prior to Norm, before that hit that we identified people who would be at-risk to power outages or who need probably special assistance if they needed to be evacuated. That is one piece of the problem.

Quite frankly, we do not have that data from Medicaid from individual states. So that would be another way to enhance that if we could get data on that.

But that is just one way to basically pre-identify people at-risk and it goes a long way to basically take care of folks.

Senator JONES. All right.

Dr. REDD. Just three quick things.

Senator JONES. Sure.

Dr. REDD. We require our state grantees to include a section on vulnerable populations in their emergency response plans. So that is one thing.

The second is that we work with professional associations—predominantly, I am thinking more of the American Academy of Pediatrics, the American College of Obstetrics and Gynecology—when there is an emergency to make sure that we are addressing those populations.

Also, when we activate our operations center for an emergency response, there is a functional desk on vulnerable populations to try to deal with the kinds of issues that come up.

Senator JONES. Great, thank you. Thank you, gentlemen. Thank you for your testimony.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Jones.

Senator Casey, do you have any questions or concluding remarks you would like to make?

Senator CASEY. Mr. Chairman, just some concluding remarks, and I will read through them quickly.

I want to thank our witnesses, obviously, for their insights and expertise today and their ongoing as part of the Federal Government to develop and maintain the necessary public health preparedness capabilities.

I will have some questions for the record in addition to the ones I asked already.

Senator CASEY. Next week, we look forward to hearing from non-governmental stakeholders about how we can continue to strengthen our readiness for future public health emergencies and keep the American public safe.

As we heard today, preparedness is continuous and must evolve to face new and different types of threats. I remain committed to ensuring we sustain the progress we have already made in preparing for public health emergencies, while continuing to work to anticipate the next threat.

We have a strong, bipartisan history of working together on this Committee to improve our communities' ability to respond to all

manner of public health threats, and I look forward to continuing that tradition in the months ahead.

Mr. Chairman, I want to thank you for your work on this, as well as Ranking Member Murray and Senator Burr, of course.

Thank you.

The CHAIRMAN. Thank you, Senator Casey.

Senator Casey is exactly right. This is one of the many areas that this Committee has effectively worked on, both in the authorization and reauthorization of legislation to prepare our country for the unexpected disaster that might occur to us.

A lot of progress has been made and I want to thank Senator Casey and Senator Burr, especially, for their leadership over the years in this area.

As he indicated, we will be having our second hearing on this topic next Tuesday, January 23 working with Senator Murray, Senator Casey, Senator Burr, and others. We hope to be able to write legislation revisiting this Act, and mark it up in Committee this spring, and present it to the Senate for bipartisan action.

I thank the witnesses for coming today. The testimony has been very helpful. The attendance has been good.

The hearing record will remain open for 10 days. Members may submit additional information within that time, if they would like.

The CHAIRMAN. Our Committee will meet again tomorrow on a different topic at 10 a.m. for a hearing entitled, "Reauthorizing the Higher Education Act: Financial Aid Simplification and Transparency."

We have been working for more than 4 years on taking a new look at the Federal Government's relationship to our colleges and universities. There are 6,000 of them. Our major role is that we appropriate about \$34 or \$35 billion a year in grants for students to attend colleges. There is more than \$100 billion of new student loans each year.

In connection with all of that money, there is a lot of opportunity and a lot of need for us to take a look at accreditation, innovation, simplification, getting through the jungle of red tape, another whole set of activities.

That will be our major focus during this year and we hope also to have that bipartisan legislation to the Senate floor some time this spring.

Thank you for being here today.

The Committee will stand adjourned.

[Whereupon, at 12:08 p.m., the hearing was adjourned.]