

EXAMINING THE REAUTHORIZATION OF THE
PANDEMIC AND ALL-HAZARDS PREPAREDNESS
ACT

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
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EXAMINING THE REAUTHORIZATION OF THE PANDEMIC AND ALL-HAZARDS PREPARED- NESS ACT

WEDNESDAY, JUNE 6, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

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

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

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

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Let me just ask all of our guests to please take their seats. The Subcommittee on Health will now come to order. The chair recognizes himself for 5 minutes for an opening statement.

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

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

So it's appropriate that we convene today to authorize the Pandemic All-Hazardous Preparedness Act. Again, a century ago, our country was in the worst pandemic in its history, claiming the lives of almost 700,000 Americans and killing more than 50 million people worldwide. We have elicited testimony and we will discuss this critical legislation. It is paramount that we remember the significance of this centennial anniversary. Sporadic flu activity had been spreading through the United States, Europe, and Asia. In the months following, the country and our soldiers faced an illness that we were not prepared to handle. In that October over a hundred years ago, more than 100,000 Americans died as a result of the Spanish flu.

It goes without saying that we have indeed come a long way. A century later we were substantially more prepared. As we consider this legislation, we must remember that there is more to be done to support America's public health security.

The creation of the Assistant Secretary of Preparedness and Response under the original legislation in 2006 has helped us to make monumental strides in preparedness, coordination, and response. Close collaboration and efforts between the Centers for Disease Control, the Food and Drug Administration, our local, state, and tribal and territorial health partners has been vital in making progress in this regard.

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

I do want to thank my fellow Texan on our second panel, Dr. Umair Shah, for being here today and to share his testimony and for his leadership in protecting the health of Harris County, Texas. Recently, Dr. Shah and his team responded on the front lines for Hurricane Harvey, which caused such catastrophic damage in the Houston metropolitan area and did require a large coordinated response from all of the organizations that we have before us today.

You'll hear more about critical issues that must be addressed to continue and strengthen the nation's preparedness and response capabilities.

We will talk about proposals to strengthen the Strategic National Stockpile, our cache of life-saving medications and supplies for public health emergencies. We also must address the policies that affect our regional disaster response system. It is essential the program continues to integrate and coordinate at the local level. Additionally, we must provide assurances to protect those who respond to our health emergencies.

We will also discuss sustaining the robust and reliable security capabilities such as disease surveillance, containment, risk, and countermeasure distribution. We must evaluate the domestic biologic surveillance systems such as BioWatch, taking a closer look at what can be done to bring these programs up to date so that

they are operating with the most efficient technologies and capabilities. I believe we must look for innovative ways to continue to advance medical countermeasures, ensuring that Americans can access medications that will provide critical protection in the future. As we consider the problem of antimicrobial resistance in this country, we must address new methods to curb this growing problem.

Frontline facilities and responders in Dallas, Texas experienced this firsthand in 2014 when a patient presented with Ebola in a DFW emergency department. We must remember that infectious diseases are a mere plane ride away and we must continue to ensure that we are prepared and ready to respond.

This Pandemic All-Hazards Preparedness Reauthorization is critical in protecting the lives of all Americans and providing the necessary tools and infrastructure to ensure that they are in place when disaster strikes. I want to thank both Representative Susan Brooks and Anna Eshoo for working on this draft legislation which is being considered today.

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

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

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Today, we convene to consider legislation to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA). One century ago our country was in the midst of the worst pandemic in its history, claiming the lives of almost 700,000 Americans and killing more than 50 million people worldwide. As we listen to testimony and discuss this critical legislation, it is paramount that we remember the significance of the centennial anniversary of the 1918 influenza pandemic. On this very day, in 1918, the first large-scale battle of World War I had begun, and hundreds of thousands of soldiers traveled across the Atlantic to be deployed for war. At the same time, sporadic flu activity was spreading throughout the United States, Europe, and Asia. In the months following, the country and our soldiers faced an illness that we were not prepared to handle. In that October alone, more than 100,000 Americans died as a result of the Spanish flu.

It goes without saying that we have come a long way. A century later, we are substantially more prepared. As we consider this legislation, we must remember that there is more to be done to bolster America's public health security.

The creation of the Assistant Secretary of Preparedness and Response under the original legislation in 2006 has helped us to make monumental strides in preparedness, coordination, and response. Close collaboration and efforts between the Centers for Disease Control and Prevention, Food and Drug Administration, and our state, local, tribal, and territorial public health partners has been vital in making this progress.

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

I want to thank my fellow Texan, Dr. Umair Shah, for being here today to share his testimony and for his leadership protecting the health of Harris County. Recently, Dr. Shah and his team responded on the front lines of Hurricane Harvey, which caused catastrophic damages in the Houston metropolitan area and required a large coordinated response from all of the organizations before you today.

We will hear more about the critical issues that must be addressed to continue to strengthen the nation's preparedness and response capabilities.

We will talk about proposals to strengthen the Strategic National Stockpile, our cache of life-saving medications and supplies for public health emergencies. We also

must address the policies that affect our Regional Disaster Response System. It is essential that the program continues to integrate and coordinate at the local level. Additionally, we must provide assurances to protect those who respond to health emergencies.

We also will discuss sustaining robust and reliable security capabilities such as disease surveillance, containment, risk, and countermeasure distribution. We must evaluate the domestic biological surveillance systems such as BioWatch. We must also take a closer look at what can be done to bring these programs up to date, so that they are operating with the most efficient capabilities and technologies. Finally, we must look for innovative ways to continue to advance medical countermeasures, ensuring that Americans can access the medications that will provide critical protection in the future. As we consider the problem antimicrobial resistance in this country, we must discuss new methods to curb this growing problem.

Frontline facilities and responders in Dallas experienced this firsthand in 2014 when a patient presented with Ebola in a DFW emergency department. We must remember that infectious diseases are a mere plane ride away, and we must continue to ensure we are prepared and ready to respond.

This Pandemic All-Hazards Preparedness Reauthorization is critical in protecting the lives of all Americans, and providing the necessary tools and infrastructure are in place when disaster strikes. I want to thank both Representatives Susan Brooks and Anna Eshoo for their work on the draft legislation being considered today.

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

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

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

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

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

The chair recognizes the gentleman from Texas, the ranking member of the subcommittee, Mr. Green, 5 minutes for an opening statement, please.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman, and again I'd like to welcome the panels—both the first panel and I particularly want to thank Umair Shah, the executive director of Harris County Public Health, for joining us this morning on the second panel. They help keep my constituents healthy.

Events in recent years including natural disasters, cyber terrorism, influenza epidemic has posed a threat to our public health systems and our national security. PAHPA provides a framework that allows us to address in a coordinated way various threats both natural and manmade. As a founding member of the Congressional Public Health Caucus and a long-time advocate for public health, I hope our committee will look at the very real threat that antimicrobial resistance poses.

Antibiotics and antimicrobial agents have been used for the last 70 years to treat patients who have infectious diseases. These drugs greatly reduce illnesses and death from infectious diseases. However, these drugs are being used so widely and for so long that

the infectious organisms that the antibiotics are designed to kill have adapted to them and make the drugs less effective. Each year in our country at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die annually as a result of these infections.

In the past years, the Generating Antibiotic Incentives Act—GAIN—and the Antibiotic Development of Advanced Patient treatment—ADAPT—have sought to address both the economic hurdles and the regulatory barriers to the development of new antibiotics. Through the reauthorization of PAHPA we need to ensure that the proper incentives are in place that will lead to investment in the development of new antibiotics and antimicrobial agents.

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

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

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

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

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

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

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

[The prepared statement of Mr. Green follows:]

PREPARED STATEMENT OF HON. GENE GREEN

Thank you, Mr. Chairman, for holding today's hearing on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). I also thank our witnesses, particularly Umair Shah, Executive Director of Harris County Public Health, for joining us this morning.

Events in recent years, including natural disasters, cyberterrorism and the influenza epidemic have posed a threat to our public health systems and our national security. PAHPA provides a framework that allows us to address in a coordinated way various threats both natural and man-made.

As a founding member of the Congressional Public Health Caucus and longtime advocate for public health, I hope our committee will look at the very real threat that antimicrobial resistance poses.

Antibiotics and antimicrobial agents have been used for the last 70 years to treat patients who have infectious diseases. These drugs have greatly reduced illness and death from infectious diseases. However, these drugs have been used so widely and

for so long that the infectious organisms the antibiotics are designed to kill have adapted to them, making the drugs less effective.

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

In past years, the Generating Antibiotic Incentives Now (GAIN) and the Antibiotic Development to Advance Patient Treatment Act (ADAPT) have sought to address both the economic hurdles and the regulatory barriers to the development of new antibiotics.

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

I believe the creation of a market entry reward program that incentivizes manufacturers to develop novel antibiotics would provide the best bang-for-your-buck in this space. I would like to work with my colleagues on this critical issue.

In addition to addressing antimicrobial resistance, we also need to further consider the proposal to move the Strategic National Stockpile (SNS) from the CDC to the Office of the Assistant Secretary for Preparedness and Response. My home state and my district were heavily impacted by Hurricane Harvey last year. In response to the flooding, the SNS was deployed to Houston to provide needed materiel to help local and state health departments respond to the overwhelming needs of the community.

The SNS been deployed countless times. Since its inception, it was placed in the CDC. Over the years, the CDC has worked closely with state and local health departments, to respond to public health emergencies.

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

Thank you, Mr. Chairman. I yield the remainder of my time to my colleague, Congresswoman Eshoo of California.

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

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

Congress realized that our country was not prepared to coordinate responses to mass casualty events or chemical attacks. I authored legislation with then Representative Richard Burr, who was a member of the Committee, that established the Office of the Assistant Secretary for Preparedness and Response—we refer to it as ASPR—to be responsible for coordinating federal responses and the Biomedical Advanced Research and Development Authority we call BARDA to be responsible for developing the needed medical countermeasures for chemical, biologic, radiological, and nuclear threats. That important bipartisan legislation, the Pandemic All-Hazards Preparedness Act, or PAHPA, was signed into law in 2006.

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

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

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

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

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

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

The chair recognizes the gentleman from Oregon, the chairman of the full committee, Mr. Walden, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

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

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

Since the terrorist attacks of September 11th, 2001, our country has taken important steps to fortify our health preparedness and response infrastructure. The Federal Government has recognized that we must foster development of important medical countermeasures in the event of a potential chemical, biological, radioactive, or nuclear attack.

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

Recent diverse threats illustrate the importance of our country having an effective and an efficient emergency preparedness system in place. In the last few years alone, we have seen the arrival of the Zika virus, last year's devastating hurricane season, the WannaCry malware outbreak, and looking ahead, I can think about other prospects including the projected devastating earthquake of Cascade event that they predict could hit the Oregon coast as it did hundreds and hundreds of years ago.

In 2004, Congress authorized Project BioShield. I was here when that happened, and later in 2006 enacted the Pandemic and All-Hazards Preparedness Act. In addition to establishing a strategic plan to direct research, development, and procurement of medical countermeasures, PAHPA also created the Assistant Secretary for Preparedness and Response—ASPR—and the Biodefense Advanced Research and Development Authority—BARDA—within the Department of Health and Human Services.

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

This bipartisan bill builds upon our previous work to modernize our health preparedness and response systems, ensuring that we are well equipped across all levels and government agencies to handle current emergency—emergent bio threats, chemical attacks, radiological emergencies, cybersecurity instances, and mass casualty events.

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

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

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

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Since the terrorist attacks on September 11, 2001, the Nation has taken important steps to fortify our health preparedness and response infrastructure. The federal government has recognized that we must foster development of important medical countermeasures in the event of a potential chemical, biological, radioactive, or nuclear attack.

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

Recent, diverse threats illustrate the importance of our country having an effective and efficient emergency preparedness system in place. In the last few years alone, we saw the arrival of the Zika virus, last year's devastating hurricane season, and the WannaCry malware outbreak. Looking ahead, I think about the prospect of a devastating earthquake "Cascadia" predicted to hit my home state of Oregon.

In 2004, Congress authorized Project Bioshield, and later in 2006, enacted the Pandemic and All-Hazards Preparedness Act (PAHPA). In addition to establishing a strategic plan to direct research, development and procurement of medical countermeasures, PAHPA also created the Assistant Secretary for Preparedness and Response (ASPR) and the Biodefense Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services.

Today's hearing will take a closer look at a bipartisan discussion draft lead by our Energy and Commerce Committee colleagues, Reps. Susan Brooks (R-IN) and Anna Eshoo (D-CA). Thank you both for your leadership on this critical bill.

This bipartisan bill builds upon our previous work to modernize our health preparedness and response systems, ensuring that we are well-equipped across all levels and government agencies to handle current and emerging biothreats, chemical attacks, radiological emergencies, cybersecurity incidents, and mass casualty events.

It's an important conversation, and I look forward to continuing our work today. Lastly, I'd like to thank our witnesses for being with us today. We look forward to gaining your feedback. This is a critical reauthorization that can have a tremendous impact on our country, and it's imperative we get it right.

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

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

As everyone here knows, this is not a question of if we will face a threat. It is more of a question of when we will face the threat. The threat of chemical, biological, radiological, or nuclear incidents continues to grow. Every day our adversaries are looking for more effective and faster ways to produce a threat. We have already faced threats from naturally occurring outbreaks such as Ebola and Zika as well as from hurricanes. In addition, cyber-attacks like the WannaCry incident illustrate the vulnerability of our public health system. Reauthorizing PAHPA is an important public health and national security issue and I look forward to working with all members of the committee on this bipartisan effort.

The discussion draft bill that we have written creates a PAHPA—a Public Health Emergency Response Fund for the HHS secretary to use as a funding bridge when we face an outbreak like Ebola so that immediate funding is available so that we can supplement them with an emergency appropriation bill. The bill strengthens the hospital preparedness program to improve surge capacity by allowing grantees to use federal funding for health care surge capacity response activities in addition to the preparedness activities. It establishes a pandemic influenza program as well as an emerging infectious disease program at BARDA. Our bill includes and this draft includes requests from CDC, ASPR, HHS, and FDA, and we look forward to working with everyone to improve the bill and ensure that it's ready for introduction later this month.

Thank the PAHPA, already we have seen 14 products placed in the Strategic National Stockpile to be used in an emergency. Our bill increases funding for the Strategic National Stockpile to \$610 million per year in order to keep the authorized level consistent with what we have currently appropriated.

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

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

I yield back.

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

The chair now would like to recognize the ranking member of the full committee, Mr. Pallone of New Jersey, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

Today, we will examine the reauthorization of a critical law known as the Pandemic All-Hazards Preparedness Reauthorization Act, or PAHPA. It's designed to prepare for and respond to health security events and emergencies that unfortunately are all too common, and these include bioterrorism acts, the spread of emerging infectious diseases, and natural disasters.

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

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

broken legislative process to date, and now the administration is limited in the feedback it can provide on the specific provisions of the bill. And I hope, moving forward, we will work together to ensure that these policies are fully understood.

Federal funding and support for local, State, and tribal public health activities is critical to saving lives. This existing public health infrastructure is how we respond to all types of hazards. Unfortunately, our public health capacity and infrastructure is not as strong as it could be. Public dollars have been depleted and the workforce has shrunk. Public funding is also not stable or reliable from year to year, making planning across all levels of government difficult.

I am worried that there is a lack of public health funding at a time when communities are facing increased need. For example, climate change is creating conditions for increased extreme weather events. Last year, hurricanes in Texas, Florida, Puerto Rico, and the U.S. Virgin Islands placed significant stress on our public health system and we need to increase public health funding including to programs authorized by this bill to bolster both our ability to prepare for and respond to these threats.

While I am generally supportive of the draft bill, I'd like to outline some specific concerns and questions. First, the public health emergency response fund is funded under transfer authority, and this is short-sighted. We witnessed the downside of this approach firsthand during the Zika outbreak when the Republican Congress forced the administration to fund our initial Zika efforts through transfers of existing appropriations. As a result, a state like Michigan, which was confronting its own public health emergency—the Flint water crisis—had some of its public health funding sent to states at high risk of local Zika transmission. Michigan lost funding that it could have used to address its own crisis in Flint and we shouldn't have to pick one crisis over another. New real funding should be put in this fund.

Second, I have yet to hear a strong argument for moving the Strategic National Stockpile—or SNS—from the Centers for Disease Control and Prevention to the Assistant Secretary of Preparedness and Response—or ASPR—in statute. The Secretary of HHS has already started the process of moving the SNS under existing law and I see no reason to codify this move before we know the consequences. We must make certain that placing the SNS in ASPR instead of CDC does not weaken our current preparedness and response capabilities before making such a move permanent. From what I can tell, we are trading some debatable improvements and procurement efficiency on the front end for the ability to more effectively reach communities and individuals with the materials they need in case of a public health emergency, and I would argue that ensuring that we can reach people with potentially lifesaving drugs and medical supplies in the event of a public health emergency must be our top priority. CDC has the relationships and expertise that make the most sense managing and operationalizing the stockpile as well as the record of successful stewardship of the SNS.

And third, I have numerous questions regarding the intent of the cybersecurity language in this draft. As many are aware, the Over-

sight and Investigations Subcommittee has been working on this issue and has discovered challenges regarding internal and external cybersecurity preparedness within HHS. I agree we need to do more to protect our health system from cyber-attacks and the potential interruptions of care because of these attacks. However, we need to make certain that placing increased cybersecurity authorities within ASPR as part of other emergency preparedness and response programs is the optimal solution, and if it is, that we authorize the resources to support any new authorities. Simply adding the word cybersecurity to certain programs within the Public Health Service Act and FDA's emergency use authorities will do little to boost our preparedness and response for cybersecurity threats unless it is done thoughtfully and with consideration for the problems we are trying to solve.

So I look forward to learning what exactly the role of the Assistant Secretary for preparedness and response would play under this legislation in the event of a cybersecurity attack on the health care system.

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

So thank you, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today we will examine the reauthorization of a critical law known as the Pandemic All-Hazards Preparedness Reauthorization Act or PAHPA. It is designed to prepare for and respond to health security events and emergencies that unfortunately are all too common. These include bioterrorism acts, the spread of emerging infectious diseases, and natural disasters.

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

That is why I am disappointed that on a bill of such magnitude my staff and our witnesses, including the Administration, did not receive the draft legislation until late last week. This has been a very broken legislative process to date. And now the Administration is limited in the feedback it can provide on the specific provisions of the bill. I hope moving forward we will work together to ensure that these policies are fully understood.

Federal funding and support for local, state, and tribal public health activities is critical to saving lives. This existing public health infrastructure is how we respond to all types of hazards. Unfortunately, our public health capacity and infrastructure is not as strong as it could be. Public dollars have been depleted and the workforce has shrunk. Public funding is also not stable or reliable from year to year, making planning across all levels of government difficult.

I am worried that there is a lack of public health funding at a time when communities are facing increased need. For example, climate change is creating conditions for increased extreme weather events. Last year, hurricanes in Texas, Florida, Puerto Rico and the U.S. Virgin Islands placed significant stress on our public health system. We need to increase public health funding, including to programs authorized by this bill, to bolster both our ability to prepare for and respond to these threats.

While I am generally supportive of the draft bill - I'd like to outline some specific concerns and questions. First, the Public Health Emergency Response Fund is funded using transfer authority. This is short sighted. We witnessed the downside of this approach firsthand during the Zika outbreak when the Republican Congress forced the Administration to fund our initial Zika efforts through transfers of existing appropriations. As a result, a state like Michigan, which was confronting its own public health emergency, the Flint water crisis, had some of its public health funding sent to states at high risk of local Zika transmission. Michigan lost funding that it

could have used to address its own crisis in Flint. We shouldn't have to pick one crisis over another. New, real funding should be put in this fund.

Second, I have yet to hear a strong argument for moving the Strategic National Stockpile (SNS) from the Centers for Disease Control and Prevention (CDC) to the Assistant Secretary of Preparedness and Response (ASPR) in statute. The Secretary of HHS can and has already started the process of moving the SNS under existing law, and I see no reason to codify this move before we know the consequences. We must make certain that placing the SNS in ASPR instead of CDC does not weaken our current preparedness and response capabilities before making such a move permanent. From what I can tell, we are trading some debatable improvements in procurement efficiency on the front end for the ability to more effectively reach communities and individuals with the materials they need in case of a public health emergency. I would argue that ensuring that we can reach people with potentially life-saving drugs and medical supplies in the event of a public health emergency must be our top priority. CDC has the relationships and expertise that make the most sense for managing and operationalizing the stockpile, as well as a record of successful stewardship of the SNS.

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

Thank you, I yield the remainder of my time.

Mr. BURGESS. The Chair thanks the gentleman. The gentleman yields back.

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

And we do want to thank our witnesses for being here this morning and taking the time to testify before the subcommittee. Each witness will have the opportunity to give an opening statement followed by questions from members.

Our first panel this morning we will hear from Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response from the United States Department of Health and Human Services. We will also hear from Rear Admiral Stephen Redd, Director of the Office of Public Health Preparedness and Response, Center for Disease Control and Prevention, and Ms. Anna Abram, Deputy Commissioner for Policy Planning, Legislation, and Analysis at the United States Food and Drug Administration.

We appreciate each of you being here today and, Dr. Kadlec, you're now recognized for 5 minutes to summarize your opening statement, please.

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

STATEMENT OF ROBERT KADLEC

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

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

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

One of our Constitution's sacred obligations to our citizens is to provide for the common defense, to protect the American people, our homeland, and our way of life. The ability of our nation's public health and medical infrastructure to quickly mobilize a coordinated national response to 21st century threats like pandemics, deliberate attacks, and natural disasters is a national security imperative and is at the heart of my efforts at the ASPR.

When ASPR was originally established by PAHPA, the objective was to answer a very simple question: who's in charge of federal public health and medical preparedness and response functions. The approach adopted was modeled on the Goldwater-Nichols Act that created the unity of effort at the Department of Defense. My goal is to ensure that we can mobilize the capabilities of the federal government to support state, local, tribal, and territorial health authorities to save lives and protect Americans.

I have four key priorities: provide strong leadership; develop a regional disaster health response system; advocate for CDC sustainment of robust responsive public health security capabilities; and advance an innovative medical countermeasure enterprise. I will elaborate on two of these. The importance of national health care readiness and medical surge capacity was highlighted during the last hurricane season when ASPR led Federal medical and public health response and recovery activities under the national response framework. We worked closely with FEMA and state and territorial health officials to augment health care with HHS disaster medical assistant teams, many of whom are your constituents who are health care providers, and public health commission core officers as well as physicians and health care providers from the VA, Department of Homeland Security, and the Department of Defense.

As we speak, we are implementing many lessons learned from the hurricanes and from the 2014 Ebola outbreak two work with

our colleagues across HHS and the Federal interagency to better coordinate our national preparedness and response to the current Ebola outbreak in the Democratic Republic of Congo as well as actively monitoring the dynamic global national security landscape as well as the weather landscape.

As we look forward, we are actively engaging our public and private partners in health care delivery to understand how we can most effectively improve their readiness for potential catastrophic threats. I believe we need to modernize our existing programs to build a tiered regional system utilizing local health care coalitions and trauma center systems that integrates all medical response capabilities, expands specialty care expertise in trauma and other related disciplines such as burn and radiation treatment, and incentivize the health care system to integrate measures of preparedness into daily standards of care. I call this the foundation of a regional disaster health response system.

The second area to highlight is our medical countermeasure enterprise. PAHPA established the Biomedical Advanced Research and Development Authority, or BARDA, which is the component of ASPR to bridge the so-called valley of death in the late stage of development of vaccines, drugs, and diagnostics where many products historically languished or failed. By using flexible nimble authorities, multi-year advance funding, strong public-private partnerships, and cutting-edge expertise, BARDA has achieved a remarkable 35 FDA approvals.

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

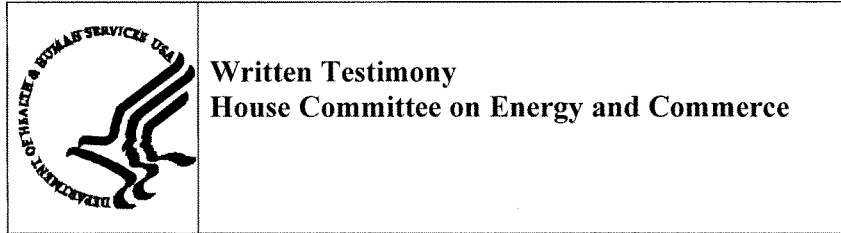
It is the brainchild of this committee in the 21st Century Cures Act. At a time when synthetic biology and personalized medicine are not just conceivable but attainable, the time is right to apply an innovative approach to some of the most daunting far-reaching health security problems such as sepsis and early diagnosis of infectious disease.

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

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

Thank you.

[The prepared statement of Dr. Kadlec follows:]



**Examining the Reauthorization of the
Pandemic and All-Hazards Preparedness Act**

Statement of

Robert Kadlec, MD, MTM&H, MS

Assistant Secretary For Preparedness and Response



For Release on Delivery
Expected at
TBD

Good morning Mr. Chairman, Ranking Member Pallone, 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). Thank you for the opportunity to testify before you today to discuss the state of our nation's preparedness for 21st century health security threats, including biological incidents, as you prepare to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). 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 health security threats to our national security. This Committee championed the bipartisan oversight and analysis that led to the drafting and passage of this groundbreaking legislation, led by Representatives Mike Rogers and Anna Eshoo. 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 the Senate HELP Committee's Subcommittee on Bioterrorism 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 twenty 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 weeks ahead as you continue your oversight and legislative drafting.

Readiness for 21st Century Health Security Threats: A National Security Imperative

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. Health security threats facing the United States during the 21st century are increasingly complex and dangerous. Therefore, improving national readiness and response capabilities for 21st century health security threats is a national security imperative.

Terrorist organizations such as ISIS and al-Qaida remain determined to attack; further, ISIS has demonstrated no compunction about using chemical and other unconventional weapons in attacks overseas. State actors have already threatened our homeland with nuclear weapons and have shown the means to employ both chemical and biological weapons.

Additionally, we have witnessed the impacts of naturally occurring outbreaks such as influenza, Ebola and SARS. We are currently monitoring other potential emerging infectious diseases that

could cause a pandemic, such as the H7N9 influenza strain circulating in China. This year 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 2017 WannaCry incident that affected approximately 150 countries remind us that technological advancements have trade-offs in the form of new vulnerabilities and risks, as our healthcare 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 and destruction, reminding us of the awesome destructive power of nature and our vulnerability.

These are threats that most people would rather not think about. However, when natural disasters, disease outbreaks, or attacks occur, the people expect our federal government to be ready to quickly respond to save lives and decrease morbidity. Since September 11, 2001, the nation has made great progress in building our defenses to protect America from health security threats; however, we still have much to do.

Assistant Secretary for Preparedness and Response: Mission & Duties

ASPR's mission is to save lives and protect Americans from 21st century health security threats. On behalf of the Secretary of HHS, ASPR leads public health and medical preparedness for, response to, and recovery from disasters and public health emergencies, in accordance with the National Response Framework (NRF) (Emergency Support Function (ESF) # 8, Public Health and Medical Services), as well as the National Disaster Recovery Framework (Health and Social Services Recovery Support Function). ASPR also supports HHS' role in the delivery of mass

care and human services in emergencies (NRF ESF # 6, Mass Care, Emergency Assistance, Temporary Housing, and Human Services).

When ASPR was established by Congress a decade ago in PAHPA, the law's objective was to create "unity of command" by consolidating 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 coordinates across HHS and the Federal interagency to support state, local, territorial, and tribal health partners in preparing for, responding to, and recovering from emergencies and disasters. In partnership with HHS agencies, ASPR works to enhance U.S. medical surge capacity by organizing, training, equipping, and deploying HHS public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for HHS personnel responding to public health emergencies. ASPR supports readiness at the state and local level by coordinating federal grants and cooperative agreements, such as the Hospital Preparedness Program (HPP), by programs like the Medical Reserve Corps (MRC), and carrying out drills and operational exercises. ASPR also 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. As such, 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. However, we still have work to do to ensure we are ready to save lives and protect Americans. ASPR has four key priorities for building the necessary readiness and response capabilities for 21st century health security threats:

- First, provide strong leadership, including clear policy direction, improved health security threat awareness, and secure adequate resources.
- Second, seek the creation of a “regional disaster health response system” by better leveraging and enhancing existing programs – such HPP and 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. For ASPR to accomplish its mission, the Centers for Disease Control and Prevention (CDC) and other partners need support to quickly detect and diagnose infectious diseases and other health security threats. This is critical to rapidly and effectively dispensing medical countermeasures in an emergency.
- Fourth, advance an innovative medical countermeasures enterprise by capitalizing on new authorities provided in the 21st Century Cures Act and advances in biotechnology and science to develop and maintain a robust stockpile of safe and efficacious vaccines, medicines, equipment, and supplies to respond to 21st century health security threats, as well as the flexible response capabilities needed to handle the unexpected.

PAHPA Reauthorization Proposals

As you consider the reauthorization of PAHPA, the Administration has shared with you and your staff a list of proposals. I will highlight a few here today.

Strong Leadership

In the area of strong leadership, ASPR should continually evaluate and incorporate national health security threats by regularly coordinating with the Director of National Intelligence, the Department of Justice, and the Department of Homeland Security to assess current and future national health security threats.

Regional Disaster Health Response System

The 2017 hurricane season highlighted the importance of regional healthcare readiness and medical surge capacity. ASPR led the public health and medical responses to Hurricanes Harvey, Irma, and Maria under the NRF Emergency Support Function # 8 mission. ASPR worked closely with state and territory health officials in affected areas to augment care with NDMS teams, U.S. Public Health Service Commissioned Corps Officers, Department of Veterans Affairs personnel and facility support, and DoD transportation, facilities, naval vessels with medical and surgical capability, clinicians and support personnel. Federal personnel under the supervision of HHS treated over 36,000 patients, and evacuated nearly 800 patients. HHS deployed over 4,500 personnel, awarded over 200 contracts, and provided nearly 950 tons of equipment. Today, HHS continues to support recovery efforts in impacted communities.

Despite our successes, we 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 countermeasure development, the nation's healthcare delivery infrastructure is mostly a private sector enterprise. We must better leverage and enhance existing federal programs – such as HPP

and NDMS – to create a more coherent, comprehensive, and capable regional system integrated into daily care delivery. I call this the foundation of a “regional disaster health response system.”

NDMS was created during the Cold War jointly by the Departments of Health and Human Services, Defense, and Veterans Affairs, along with the Federal Emergency Management Agency, to take care of military casualties from overseas conflicts in U.S. civilian hospitals. To modernize NDMS, strengthen capabilities, and ensure NDMS continues to provide critical support during and immediately after national public health and medical emergencies, ASPR is implementing administrative modifications to the program. However, several improvements to the NDMS statute will aid in ASPR’s efforts to modernize this critical asset, including:

- Direct hire authority for NDMS intermittent personnel for one to two years. Currently, NDMS is staffed at half capacity. Limited direct hire authority was included in the Hurricane Supplemental for 270 days. HHS is using this authority to its full extent but anticipates staffing shortfalls will remain after the expiration of this authority in November.
- Provide NDMS personnel with Public Safety Officer Benefit (PSOB) Act coverage. The PSOB Act provides death benefits and educational assistance to survivors of fallen public safety officers killed in the line of duty, as well as disability benefits to officers catastrophically injured. This coverage is currently offered to FEMA employees who perform hazardous duties while deployed to declared major disaster and emergency areas; extending coverage to NDMS personnel would ensure consistent coverage for all first responders.

- An increase in the authorization of appropriations for NDMS consistent with the FY2019 President's Budget of \$57 million. This funding will enable ASPR to rebuild and train NDMS teams to respond to 21st century health security threats.

The Hospital Preparedness Program (HPP) was established after the September 11, 2001, terrorist attacks, with the goal of improving the capacity of local hospitals across the country to deal with disasters and a large influx of patients in an emergency. Using HPP funding, state grantees initially purchased equipment and supplies needed for emergency medical surge capacity. Over time, the program successfully evolved to support local coordinated healthcare coalitions, including hospitals, public health facilities, emergency management agencies, and emergency medical services providers. Fifteen years after it was established, HPP can be further strengthened to better utilize existing resources and enhance healthcare preparedness and response capabilities at the local level. Congress should consider the following enhancements:

- Include healthcare coalitions and other entities as eligible entities for HPP "partnership" awards (separate from the formula awards) to acknowledge the value these coalitions provide and grant flexibility in making awards to carry out program goals.
- Expand the use of HPP awards from preparedness alone to preparedness, response, and medical surge activities. HPP's mission is to enhance community and regional health care system capabilities for emergency preparedness and response. Clarifying that HPP's mission includes strengthening both regional health care system preparedness as well as response capabilities will minimize confusion and balance investments between both preparedness and response activities.
- Expand the withholding period for failure to reach benchmarks from one year to two years to allow time to repurpose funds. Such modification will give the program time to

provide technical assistance to awardees so they are able to make corrective actions to achieve performance benchmarks.

Medical Countermeasures Enterprise

Congress established BARDA to speed up the availability and use of medical countermeasures by bridging the so-called “valley of death” in late stage development where many countermeasures for health security threats historically languished or failed. By using flexible, nimble authorities, multiyear advanced funding, strong public-private partnerships, and cutting edge expertise, BARDA has successfully pushed innovative medical countermeasures, such as vaccines, drugs, and diagnostics, through advanced development to stockpiling and FDA approval or licensure.

In the last decade, BARDA’s strong partnerships with biotechnology and pharmaceutical companies, the National Institutes of Health, and other HHS components have led to 35 FDA approvals for 31 unique medical countermeasures addressing chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging and re-emerging infectious diseases. This is a staggering accomplishment in just 12 years.

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 and seven have achieved FDA approval. BARDA also

has supported the development of 23 influenza vaccines, antiviral drugs, devices, and diagnostics to address the risk of pandemic influenza.

Because of this progress, more medical countermeasures than ever before are eligible to be procured for the Strategic National Stockpile, thereby creating new challenges in terms of acquiring and maintaining sufficient quantities of medical countermeasures to address the requirements for identified health security threats.

As this Committee considers reauthorization of PAHPA, please consider the following proposals, which primarily relate to increasing authorization of appropriations levels for the medical countermeasures enterprise:

- Authorization for a 10-year advance appropriation for Project BioShield, an approach which will help incentivize private industry to dedicate resources to developing medical countermeasures to meet the government's national security requirements. Without this "guaranteed market," companies may be reluctant to incur the opportunity costs required to focus on a limited government market that may not materialize when product development is complete.
- Increase the authorization of appropriations for BARDA's advanced research and development of medical countermeasures to \$512 million. This increase will enable BARDA to implement new innovation authorities provided in the 21st Century Cures Act and build rapid response capabilities for unknown health security threats, without detracting from continued investments in CBRN medical countermeasures.
- Authorize a \$245.9 million direct funding line for BARDA's pandemic influenza preparedness activities. This authorization of appropriations will help sustain domestic

influenza vaccine manufacturing capacity, as well as support better, faster influenza vaccine technologies and antivirals now.

- Increase the authorization of appropriations for the Strategic National Stockpile (SNS) to \$575 million. The increase in the authorization of appropriations will strengthen SNS operations and procurements to meet requirements and best protect the public against public health and medical threats.
- Modifying existing annual reporting requirements to ease administrative burden and ensure staff time is dedicated to medical countermeasure development. Specifically, we propose merging reporting requirements for Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan with requirements for an SNS annual review and a multi-year budget report.

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 weeks 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.

Mr. BURGESS. The chair thanks the gentleman.

The chair now recognizes Rear Admiral Redd. Dr. Redd, you're recognized for 5 minutes, please.

STATEMENT OF STEPHEN REDD

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

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

Today, I will highlight CDC's role in protecting the Nation against health threats and I will describe that in three areas: preparedness, protection, and response. Within that discussion, there are three themes that I would like you to appreciate: first, the work that CDC does every day in public health lays the foundation for responding to emergencies; second, CDC's world-class scientific and medical expertise ensures we are ready to respond to any threat; and third, our longstanding connection to state and local health departments ensures that public health systems function effectively both day to day and during emergency responses.

Let me first address the issue of preparing for emergencies. CDC works every day with state and local health departments. In fact, we have 590 staff assigned to state and local health departments. We fund the public health emergency preparedness cooperative agreement program and the Cities Readiness Initiative.

Our public health emergency preparedness grants go to every State, eight territories, and four cities. These funds support staff, enable exercises to test and validate capabilities and pay for laboratory and communications equipment. Cities Readiness Initiative funds the Nation's 72 largest cities to develop and test plans to receive and dispense medical countermeasures from the Strategic National Stockpile.

Turning now to detecting threats, CDC's laboratories and surveillance systems are able to detect and identify agents causing illness, whether that cause is microbial or from chemical or radiation exposure. Every year, laboratories from all over the world send several hundred thousands of specimens to CDC because they know that we will be able to identify pathogens other laboratories cannot.

Rapid identification of disease permits intervention before a health threat becomes a crisis. CDC's laboratory response network maintains an integrated, scalable, and flexible system of 153 Federal, State, and local laboratories. The development of this network over the past 15 years has provided a larger capacity to test and report more quickly than was possible before. For example, during the Zika outbreak, CDC and other laboratory response network laboratories processed over 207,000 specimens.

Now, turning to response, when there's a crisis, CDC responds. We are able to deploy scientific and medical experts anywhere in the world. For example, by the end of the 21-month Ebola response, 3,700 CDC staff, more than a quarter of our workforce, shifted from their day-to-day duties to assist in the response. Fif-

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

During health emergencies, CDC communicates. For example, during the 2009 H1N1 response, CDC held 39 press conferences and 21 telebriefings. During the Zika response, CDC published 51 morbidity and mortality weekly report articles ensuring that the public and health professionals had the latest and best information. Being able to prepare for, detect, and respond to public health threats is a top priority for CDC. Our preparedness and response capabilities are built on a broad and deep scientific medical and program expertise. Our longstanding partnerships with State, local, and public health authorities assured an integrated approach wherever that approach is needed, resulting in better responses and better public health outcomes.

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

[The prepared statement of Admiral Redd follows:]



Written Testimony
House Energy and Commerce Committee,
Subcommittee on Health

Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act

Statement of

RADM Stephen C. Redd, M.D.

*Director, Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
Department of Health and Human Services*

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Chairman Burgess, Ranking Member Green, and other members of the subcommittee. 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 advances the health security of the nation by helping communities prepare for, detect, and respond to public health consequences of all hazards. These hazards include chemical, biological, radiological, and nuclear threats, natural disasters, and emerging infectious disease. For 72 years, this has been CDC's core mission. CDC's multidisciplinary workforce supports an integrated national system that continually monitors the public's health and is able to respond when a threat is identified. This ability is enhanced by our long-standing relationships and close collaboration with federal, state, and local partners.

In carrying out the mission set forth under PAHPRA, CDC draws on expertise from throughout the agency, including 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.

Prepare

The Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) reauthorized several public health preparedness programs. The CDC's Public Health Emergency Preparedness Cooperative Agreement Program (PHEP) (which includes the Cities Readiness Initiative (CRI)) is crucial to CDC's close collaboration and longstanding relationships with state and local health departments and ensures the nation is prepared for the next public health emergency. Additionally, CDC's role in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is critical to national preparedness for chemical, biological, radiological, nuclear threats, pandemic influenza, and emerging and re-emerging infectious diseases.

Public Health Emergency Preparedness Cooperative Agreement Program (PHEP)

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 FY 2017. The program supports these jurisdictions to develop plans 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 – the 50 states, eight territories and freely associated states, and four directly funded cities (New York City; Washington, D.C.; 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 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.

Cities Readiness Initiative (CRI)

CRI, funded through the PHEP cooperative agreement, enhances preparedness in the nation's 72 largest population centers, where nearly 60% of the population resides. These cities use CRI funds to develop, test, and maintain plans to quickly receive medical countermeasures from the Strategic National Stockpile (SNS) and distribute them to local communities. This program, which relies on local boots on the ground, enables effective response to large-scale public health emergencies that require life-saving medications and medical supplies.

Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

Through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) led by ASPR, CDC works with HHS agencies and other federal partners to enhance preparedness for chemical, biological, radiological and nuclear threats, pandemic influenza, and emerging and re-emerging infectious disease. The PHEMCE employs a collaborative approach to make scientifically and clinically sound decisions in prioritizing federal investments in medical countermeasures. CDC brings together its scientific expertise and its experience in public health practice to inform the use of preventative measures and treatment during a public health emergency.

Specifically, CDC subject matter experts:

- Develop clinical guidance on the use of PHEMCE medical countermeasures – crucial to ensure health departments and clinicians know the safest, most effective way to use medical countermeasures.
- Inform operational details for SNS deployment – this includes informing which products should be deployed first based on epidemiology and laboratory data and clinical guidance.
- Provide technical expertise to state and local partners for the development and execution of deployment and dispensing plans for PHEMCE medical countermeasures.
- Conduct regular operational readiness reviews and exercises with state and local partners to prepare them and build their capacity to receive and dispense PHEMCE medical countermeasures.

- Provide regulatory science expertise to inform legal mechanisms (Emergency Use Authorizations, Emergency Use Instructions, Investigational New Drug Protocols) and guidance on the use of non FDA approved MCM or the use of FDA approved MCMs for unapproved indications

To ensure that our partners have the knowledge and skills they need to dispense MCMs in a timely manner CDC offers virtual and in-person training, guidance documents, technical assistance, exercises, and other training programs. In FY 2016, CDC supported 18 full-scale exercises, and trained 2,232 federal, state, territorial, and local emergency responders representing 43 different jurisdictions on how to receive and distribute products from the SNS.

Detect

World-class scientific expertise in disease progression, epidemiology and laboratory methods ensures CDC is ready and able to detect and develop a response to a broad range of threats, including highly hazardous and infectious diseases like Ebola, smallpox, Zika, anthrax, and H7N9 influenza.

CDC uses 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 because they know CDC will be able to identify pathogens that other laboratories cannot.

Through Advanced Molecular Detection investments, CDC is able to detect outbreaks faster, before they have become widespread. These advances are applied in dozens of areas such as foodborne disease, influenza, antimicrobial resistance, hepatitis, pneumonia, and meningitis. Moreover, CDC shares genetic sequencing capabilities with state and local health departments, and funds them to acquire these tools that help them respond more quickly and effectively at the local level, lessening the chances that disease outbreaks will spread.

Vector-borne diseases present a specific preparedness challenge, as we saw in the Zika emergency. CDC is one of the nation's 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 -- 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 also maintains unique laboratory capability to rapidly detect exposure to radionuclides and more than 150 chemical threat agents. This information about human exposure helps public health officials rapidly assess health risk, determine the most effective treatment, and reduce additional exposures.

A Strong Laboratory Response Network

Rapid identification of disease is critical to addressing public health threats before they become a crisis. This requires that the highest quality specialized laboratory testing be available around the country. CDC's Laboratory Response Network is an integrated system of federal, state, and local laboratories that provides early detection and characterization of biological, chemical and other public health threats. The linking of these laboratories through the Laboratory Response Network has advanced our preparedness capabilities and provided for rapid testing, timely notification, and secure communication of laboratory results. The close partnership between laboratorians, epidemiologists and clinicians at CDC, state and local health departments, and healthcare facilities ensures the most rapid detection and mitigation of health threats.

For example, in response to the MERS (Middle East Respiratory Syndrome), Ebola and Zika virus outbreaks, CDC provided Laboratory Response Network laboratories across the United States with assays authorized for Emergency Use to quickly identify cases of infection during these outbreaks.

Public Health 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 at CDC, and continues to represent CDC’s core work, whether as detective work in the field, or advanced analysis to understand disease transmission. CDC monitors population health information around the clock to detect and track diseases. For example, following 9/11, CDC invested in using health-related data based on syndromic surveillance in Emergency Departments as an early warning system for a bioterrorist attack. Those investments are paying dividends as this system now allows officials to detect a wide range of health threats, from opioid overdoses to chemical exposures to disease outbreaks. Moreover, CDC collects, analyzes, and interprets human, animal, environmental, and food surveillance data, to identify and respond to potential health threats before they become emergencies.

To ensure a nationwide surveillance capability, CDC supports surveillance infrastructure and practice at the state and local levels through the National Notifiable Disease Surveillance System, the National Syndromic Surveillance Program, the National Healthcare Safety Network, the Emerging Infections Program Active Bacterial Core Surveillance, and components of national influenza surveillance. As part of CDC’s Surveillance Strategy, we are modernizing the tools and services used in the National Notifiable Disease Surveillance System and the National Syndromic Surveillance Program and are implementing standards for exchanging data. CDC’s Surveillance Strategy guides our agency’s efforts to make U.S. surveillance systems:

- More adaptable to rapidly changing technology
- More versatile in addressing evolving health threats
- More adept at accessing and leveraging healthcare data
- More capable of meeting demands for timely, population-specific, and geographically-specific information

Beginning in FY 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, 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 Antibiotic Resistance Laboratory Network includes seven regional laboratories, the National Tuberculosis Molecular Surveillance Center, and laboratories in 50 states, five cities, and Puerto Rico. The Antibiotic Resistance Laboratory Network is vital to detecting new and emerging resistant pathogens, including those that are untreatable, to trigger infection control response measures to prevent spread. The Antibiotic Resistance Laboratory Network collects actionable data on threats including 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 Antibiotic Resistance Laboratory Network can be made available to researchers to support innovations in antibiotic and diagnostic development.

CDC's Global Disease Detection Operations Center monitors outbreaks 24/7, assesses their potential risk to the United States and communities around the world, and improves global public health surveillance. Since 2017, CDC has tracked more than 170 unique diseases globally and identified outbreaks in more than 190 countries. CDC works with the 17 Phase 1 and 14 Phase 2 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. The 17 Phase 1 countries receive direct financial support and technical assistance from CDC and the 14 additional countries receive only technical assistance from CDC. Our work through the Global Health Security Agenda emphasizes 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 an important line of defense to prevent the introduction and spread of infectious diseases.

Respond

CDC's number one priority during any public health emergency is to protect the health of the public. CDC subject matter experts respond regularly to events such as foodborne outbreaks, natural occurring anthrax and botulism cases, smallpox vaccine adverse event cases, and seasonal influenza. CDC's readiness activities, expertise, and infrastructure provides the foundation for all types of public health emergency responses and is scalable and can surge to support larger events such as the 2012 - 2013 meningitis outbreaks and MERS. The expertise and systems used in such responses can be augmented further for larger public health emergency responses such as the 2009 H1N1 response, 2014 Ebola response, and the Zika response.

State and local public health agencies are the front lines of public health preparedness and response. CDC provides ongoing technical assistance and, where requested, on-the-ground personnel and materials to assist with response efforts. CDC's established relationships with state and local health departments ensure that day-to-day public health systems function effectively and efficiently and that emergency response actions are appropriate to the threat. These continuous relationships, between and during emergency responses, ensure a level of trust and collaboration that cannot be overemphasized. During the stress of an emergency response, having a trusted partner you can turn to immediately can mean the difference between life and death for patients, and ensures the rapid delivery of public health services, such as vaccinations and clean water, for communities.

CDC experts lead and staff every activation of the agency's Emergency Operations Center (EOC), ensuring response activities are effective and efficient. CDC has activated its incident management system for 67 responses over the last 16 years. 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 Ebola and Zika responses, 3,700 and 1,700 CDC staff participated in the response, respectively. During the Ebola response, CDC staff completed over 2,000 field deployments to West Africa. 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. In addition, the Global Rapid Response Team, stood up following the 2014 Ebola outbreaks, has over 400 ready and rostered experts. Since its inception, that team has provided nearly 9,000 person-days of support for response activities.

We are committed to continuously improving our response capability. After each activation, whether for a real event or exercise, we conduct a thorough after-action review to identify strengths to sustain and areas for improvement. Use of this information is key to improving performance for the next incident or event.

Conclusion

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

1. Our responses are built on our longstanding partnerships with state and local public health authorities;
2. Our detection capabilities and surveillance programs are based on our broad and deep scientific, medical, and programmatic expertise; and
3. Our response capacity ensures timely aid to state and local public health systems in times of crisis.

CDC has 72 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.

Mr. BURGESS. Thank you, Dr. Redd.

Ms. Abram, you're recognized for 5 minutes, please.

STATEMENT OF ANNA ABRAM

Ms. ABRAM. Thank you.

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

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

We are reminded of the urgency and need to remain ever vigilant against identified and emerging public health threats as we carefully monitor the current outbreak of Ebola virus disease, this time in the Democratic Republic of Congo. I can assure you that FDA is dedicated to helping end this outbreak as quickly as possible and we are actively engaged with our Federal colleagues testifying here with me today, as well as with medical product developers, international organizations including the World Health Organization, to support international response efforts. This most recent Ebola outbreak accentuates the continuing threat posed by emerging infectious diseases, which can and often do emerge with little to no warning and the need for us to continue to optimize our preparedness and response capabilities.

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

Prior to joining FDA, I worked for more than a decade on health care policy with your colleagues in the United States Senate, serving as a health policy director to U.S. Senator Richard Burr from North Carolina on the Health, Education, Labor, and Pensions Committee for many years. In that capacity, I collaborated with colleagues serving in the United States House of Representatives, including this committee, and it's nice to see some of those colleagues here today. I was actively involved in working on a range of health care issues and my tenure was very much highlighted by my work on medical and public health preparedness and response issues including the bipartisan 2013 PAHPA Reauthorization ACT, or PAHPA, and more recently the 21st Century Cures Act.

PAHPA recognized the key role FDA plays in emergency preparedness and response and codified and built on FDA's ongoing efforts to augment our review processes and advance regulatory science to enable better response to public health emergencies and emerging health threats. The provisions in PAHPA have been critical to FDA's efforts to drive innovation in the medical counter-

measure space and have provided FDA with essential tools that continue to support our mission to protect and promote public health.

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

We share Congress' goal to have safe and effective medical countermeasures available in the event they are needed and we have made key progress towards this important goal. As of the end of fiscal year 2017, FDA has approved, licensed, or cleared 121 medical countermeasures including supplementals to approvals, licensures, and cleared medical products. We have issued more than 60 emergency-use authorizations since 2005, including about 40 since 2013, including for Ebola and Zika. Medical countermeasures can face unique development challenges that require medical product sponsors to rely on animal models because even efficacy trials would not be ethical.

PAHPRA required FDA to issue final guidance regarding the development of animal models to support the approval and clearance of medical countermeasures. FDA finalized this guidance in October 2015 and to date, 13 medical countermeasures have been approved under the animal rule, including the approval of a new indication for a medical countermeasure to increase survival of adult and pediatric patients acutely exposed to myeloid suppressive doses of radiation as could occur after a radiological or a nuclear event. This is the third FDA-approved medical countermeasure that is indicated to increase survival in patients exposed to myeloid suppressive doses of radiation.

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

We have been actively implementing the new authorities within our medical countermeasures initiative, specific to our engagements with the Department of Defense as well. In January of 2018, the agency launched enhanced engagements with the Department of Defense under a joint program to prioritize the efficient development of safe and effective medical projects intended for our U.S. military personnel.

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

Finally, I am pleased to share that today we are releasing our medical countermeasures initiative program update which highlights the many notable achievements the agency has made to advance the development and availability of safe and effective medical countermeasures in fiscal year 2017. This report provides an in-depth insight into the breadth of activities and the progress FDA has contributed to our nation's medical countermeasure assets.

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

We look forward to partnering with this committee and the Senate in the reauthorization of PAHPA. Thank you again for the opportunity to testify today and I would be happy to answer any questions.

[The prepared statement of Ms. Abram follows:]

TESTIMONY
OF
ANNA ABRAM
DEPUTY COMMISSIONER FOR POLICY, PLANNING,
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FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH
UNITED STATES HOUSE OF REPRESENTATIVES

“EXAMINING THE REAUTHORIZATION OF THE PANDEMIC AND ALL-
HAZARDS PREPAREDNESS ACT”

JUNE 6, 2018

RELEASE ONLY UPON DELIVERY

Introduction

Chairman Burgess, Ranking Member Green, 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).

This most recent Ebola outbreak underscores the need to continue to optimize our preparedness and response capabilities. PAHPA, which was enacted 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 Nation's preparedness for, and capabilities to respond to, public health emergencies involving chemical, biological, radiological, and nuclear (CBRN) threats, as well as emerging infectious disease threats, such as Zika virus, Ebola virus, and pandemic influenza.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), in particular, recognized the key role FDA 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 better response 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 not just CBRN threats, but emerging infectious disease threats, which can and often do emerge with little to no warning as was the case with the anthrax attacks of 2001, the 2009 H1N1 influenza pandemic, the 2014 Ebola outbreak in West Africa, the emergence of Zika virus in 2016, and the recent Ebola outbreak in DRC.

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 (NGOs), to sustain and optimize the medical countermeasure framework necessary to effectively respond to public health emergencies. FDA is also committed to continuing to work 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 military personnel.

FDA's Medical Countermeasures Initiative (MCMi)—established in 2010—brought enhanced 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 providing clear regulatory pathways for medical countermeasures, advancing medical countermeasure regulatory science to support regulatory decision making, and advancing important policies and mechanisms to facilitate the timely development and availability of medical countermeasures. FDA's goal is to be efficient and to use the most up-to-date science 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 marketing applications for medical countermeasures 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 labeled expiration dates when supported by appropriate scientific evaluation;

- Enabling access to medical countermeasures that are not yet approved—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 timely medical countermeasure development and enable preparedness and response activities and capabilities;
- 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.

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, 13 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 ethical concerns precluded studying pediatric patients in clinical trials.

However, there are threats for which we continue to seek to strengthen our regulatory science because of current regulatory gaps, such as due to the lack of animal models to support medical countermeasure development or sufficient biomarkers to enable the extrapolation of data generated in animal models to humans for these threats. Without such tools, it is difficult to generate the data necessary to support regulatory decision making. Given the urgency inherent in our medical countermeasure work, addressing these regulatory science gaps remains a high priority for the Agency.

To that end, FDA has established a broad and robust portfolio of cutting-edge research under the MCMi Regulatory Science Program to help develop these tools and promote innovation in the development of medical countermeasures.⁴ 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 database for use by developers seeking to validate candidate 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 21st Century Cures Act (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, in addition to the medical countermeasure specific provisions included in that law.

Through the Cures Act, Congress 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 issued draft guidance in January 2018 that explains how the Agency is implementing the material threat medical countermeasure PRV program. FDA is considering comments received on the draft guidance prior to issuing a final guidance document.

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, in July 2017 FDA launched a comprehensive Innovation Initiative aimed at making sure its regulatory processes are efficient and use the most up-to-date science 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 military personnel 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) 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 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

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.

Additionally, PAHPRA specified that the HHS Secretary may, acting through an appropriate HHS official, create and issue emergency use instructions (EUI) about medical countermeasures to inform health care professionals and patients/recipients about the medical countermeasures' approved, licensed, or cleared conditions of use before or during an emergency. The EUI authority—which the HHS Secretary delegated to the Director of the Centers for Disease Control and Prevention (CDC) in 2013—allows CDC to provide streamlined information about the use of eligible, approved medical countermeasures needed during public health emergencies. To facilitate creation of EUI, FDA and CDC entered into a Memorandum of Understanding, and when feasible, FDA and CDC coordinate the issuance of EUI (as well as emergency dispensing orders). For example, FDA and CDC have issued “emergency preparedness packages,” including EUI and emergency dispensing orders, for doxycycline and ciprofloxacin for post-exposure prophylaxis during an anthrax emergency, should such an event occur.

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 military personnel 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 CDC, state and local public health agencies, and other emergency 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.

More 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 military personnel. Senior leadership at the Agency is working closely with DoD to quickly implement these new and amended authorities, and we look forward to keeping Congress informed of our progress in these critical areas.

FDA looks forward to working with Congress and continuing to improve the Agency's ability to effectively support public health preparedness and response efforts.

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 discoveries in science and technology into safe and effective medical countermeasures. FDA takes seriously its responsibility to help drive and foster innovation as part of advancing public health and strengthening 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 and accelerate the development and availability of safe and effective medical countermeasures. We believe that partnership and innovation will continue to be key elements to success in our medical countermeasure endeavors, and we are taking steps to further empower FDA's scientific and clinical experts to help support and drive the innovation necessary to protect the nation from the threats we may face.

FDA appreciates Congress's support in continually optimizing 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 look forward to answering any questions you may have about FDA's medical countermeasure work.

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

Let me recognize myself for 5 minutes for questions and, as always, I will run out of time before I finish questions. So we will be submitting some for the record.

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

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

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

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

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

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

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

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

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

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

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

Second is mobilizing the assets that were funded largely by BARDA, though NIH had some significant capabilities to include

diagnostics that were basically made available and donated by the company to DRC as well as vaccines that BARDA supported with Merck that was deployed and has immunized and the folks down there, the responders, have immunized 1,100 folks so far in vaccination.

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

Mr. BURGESS. What we discovered 2 ½ years ago, whenever the previous outbreak occurred, is a state like Texas, where you have got some big distances between communities, hospitals did form networks and were agreeable to helping each other at the same time. If you had a car show up with a group of folks where high index of suspicion for a problem, all of the assets in a local area could be consumed very quickly.

Are you looking at how to deal with that?

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

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

But just in general, as far as your position is concerned, there are some jurisdictional issues. There are some Interagency issues. There has been some discussion about designating the office of the vice president as part of that central command. What are your thoughts about that?

Dr. KADLEC. Sir, in an operational sense, I think the ASPR performs a function as part of the national response plan. In terms of orchestrating probably beyond the operational levels of the strategic levels, particularly for resourcing, having a friend or an ally at senior levels in the White House is a good thing.

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

Mr. BURGESS. Thank you, and my time expired. I will recognize the gentleman from Texas, Mr. Green, 5 minutes for questions, please.

Mr. GREEN. Thank you, Mr. Chairman.

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

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

growing threat of antibiotic resistance in public health as well as preparedness and response efforts.

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

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

It's the idea of creating public-private partnerships and in this case CARB-X and BARDA has basically interactions with 28 different companies who make novel anti-bacterial drugs, vaccines, or diagnostics, and as a result of that, there have been identified eight new classes of antibiotics. So that's important. But, significantly, for the taxpayer, \$70 million of Federal investment by CARB-X has resulted in about \$485 million in private equity following that investment.

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

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

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

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

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

So the thing is is that we work closely with NIAID on this. We do work with the Wellcome Trust as other organizations as well as with companies to basically identify these.

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

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

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

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

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

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

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

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

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

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

The chair recognizes the gentlelady from Tennessee, Mrs. Blackburn, 5 minutes for questions, please.

Mrs. BLACKBURN. Thank you, Mr. Chairman.

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

And until 2016, when we passed 21st Century Cures and included in that the Software Act, which deals with medical technology, medical software had been included in that definition of medical devices. And what happened or what we did in that was to remove some classifications of medical software from FDA oversight, and I know that you're familiar with the legislation and familiar that FDA is still in the process of implementing that law and making those determinations which products are going to go where. And we recently—I think it was the end of December—received more guidance documents to that fact.

So what I wanted to know from you is are there any types of medical software or applications currently in the stockpile that no longer fall under the device definition?

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

Traditionally, much of what has been procured into the stockpile has focused more on vaccines, therapeutics, diagnostics, and some of the other materiel—for example, I believe, like, personal protective equipment would be something purchased there.

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

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

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

And having just recently received the text we are having our subject matter experts look at it quickly because we understand this is an area of interest for the committee and we want to make sure we are providing very thorough and thoughtful input on these points because, as I mentioned, cybersecurity is, obviously, a very serious concern and we want to be responsive to it. We have looked at it in the context of devices form a total produce life cycle approach. At the same time, much of the framework that you're referencing has traditionally been looked at in a CBRN context.

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

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

Ms. ABRAM. Absolutely.

Mrs. BLACKBURN [continuing]. And include it in the information from this hearing.

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

Mrs. BLACKBURN. OK. That would be great.

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

But I am interested to hear your thoughts on how we can truly harness the services of health care professionals who are willing to volunteer their skills during emergencies.

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

So I would love a quick response on that.

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

I think the key thing is is, as many know, that sometimes even though volunteers come forward, their ability to help is going to be based on their knowledge and training. And so we would prefer that those people would be identified before an event and then we

have confidence what to do and the right things to do so they do not cause any further injury or harm.

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

Mrs. BLACKBURN. I yield back.

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

The chair now needs to recognize the gentleman from New York, Mr. Engel, 5 minutes for questions, please.

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

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

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

Cases of anti-resistant TB cost much more to treat than drug-sensitive TB in cases of multi-drug resistant TB, and extensively drug-resistant TB unfortunately becoming much more frequent. While we may typically think drug resistance is caused by inappropriate treatment, most drug resistant TB cases are now caused by transmission from person to person, making it much easier for drug resistant TB to spread to new parts of the world.

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

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

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

I mentioned the possibility of eight new classes of antibiotics. To this date, 30 potential high-quality antibacterial products have been identified and are being evaluated for this. So I think part of this is realizing that there is an ongoing activity that BARDA is working with NIAID on. It's informed by CDC in terms of its role subject to monitoring the environment and identifying those cases and evaluating the sensitivities of those organisms, whether it be TB or anything else, quite frankly, and the ability to evaluate what we can do to promote renewed interest and research and commit-

ment not only by the government but also by the private sector into these areas.

Mr. ENGEL. Thank you very much.

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

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

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

I think our work in the Democratic Republic of Congo is emblematic of the kinds of threats that we need to be able to detect and, working with host countries, contain at the source.

Mr. ENGEL. Thank you.

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

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

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

Mr. ENGEL. Thank you.

Thank you, Mr. Chairman. I yield back.

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

The chair recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for your questions, please.

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

Anyone who's followed this committee knows that I've been working on the antimicrobial resistance front for many, many years. Good to see folks who have been in this battle.

You probably heard me say that we need to develop products we hope we never has to use. The fact is we are in a race, you all know, against antibiotic resistance by bacterial and fungal pathogens and we are losing because these diseases are developing resistance faster than our efforts can develop new agents. And BARDA is very valuable to these efforts, but it's clear that BARDA's work, even combined with commercial potential, isn't enough.

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

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

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

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

Mr. SHIMKUS. Would you agree that the situation is dire?

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

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

Dr. KADLEC. Yes, sir.

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

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

Admiral REDD. I think the point I was going to make is that these products are used in a system and the detection and infection control procedures and assessment of effectiveness are all part of to ensure that these products are used to obtain the greatest effect.

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

Mr. SHIMKUS. Go ahead.

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

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

Mr. SHIMKUS. And I've always been concerned. My observation is that they're too small. I always talk about raising capital, assuming risk and a return. Now you want to raise capital, assume risk, hoping never to get a return.

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

So go ahead.

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

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

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

Mr. SHIMKUS. Excellent. Thank you very much.

Yield back.

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

The chair recognizes the gentlelady from Illinois, Ms. Schakowsky, 5 minutes.

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

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

So I am hopeful that this program can be reauthorized and make it a part of the underlying bill. EIS officers are health professionals who serve on the front lines of public health emergencies as boots on the ground, disaster detectives who investigate outbreaks and assist during natural disasters. And since its creation in 1951, the EIS program has trained more than 3,600 officers and based in state and local public health departments across the country. EIS officers are deployed more than 200 times every year, responding to public health emergencies at home and abroad.

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

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

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

I am not going to specifically address your bill but I can say that for myself when I came to the EIS program I did have student

loans and it would have been an incentive to have some method to have those loans repaid.

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

Ms. SCHAKOWSKY. So why don't you tell us all what EIS officers—how they protect the public's health, what kind of events do they respond to, and what role do they play in responding to those events?

Admiral REDD. Sure. So Epidemic Intelligence Service officers either have doctorate degrees in public health sciences or in medicine, generally finish their training, come to CDC for post-graduate training. So the EIS program is a 2-year experiential training program.

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

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

Ms. SCHAKOWSKY. That's really what I wanted to get at. After the EIS 2-year training period, 85 percent of EIS graduates enter the public health workforce.

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

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

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

Thank you so much for your service.

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

The chair recognizes the gentleman from New Jersey, Mr. Lance, for 5 minutes.

Mr. LANCE. Thank you, Mr. Chairman.

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

Scientists harness cutting-edge science that will combat bacteria in new ways and potentially reduce risk of resistance. Would you please talk about BARDA's role in fostering the discovery and development of non-traditional approaches?

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

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

Every bacteria has a counter virus that effectively can either disarm it, kill it, or potentially change its antibiotic resistance patterns. And so those are things that are actively being investigated right now. It is, I think, one of the areas that probably deserves more consideration. We welcome the opportunity through the 21st Century Cures Act to open these new doors to innovative approaches and to maybe non-traditional approaches and we look forward to Congress' continued support to do more of that, going forward.

Mr. LANCE. Thank you very much, Doctor.

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

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

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

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

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

Mr. LANCE. Thank you.

Would anyone else on the panel like to comment?

Yes. Go ahead.

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

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

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

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

I yield back 37 seconds, Mr. Chairman.

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

The chair now recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for questions, please.

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

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

Admiral REDD. Thank you for that question.

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

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

Another product that is frequently distributed—it's called Federal medical stations. These are basically hospitals but without the building. They've been deployed for the hurricanes.

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

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

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

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

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

The capability to dispense from a manpower standpoint, the staffing and then also staffing for security areas that are not universally but pretty general challenges that state and local health departments face.

Mr. PALLONE. All right. Thanks.

I understand that some of these training activities are funded through the SNS program appropriations. So, Dr. Kadlec, will SNS

funding continue to be used to pay for these important training activities?

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

And, again, to highlight one thing that Dr. Redd talked about is in a recent preparedness summit that was held in Atlanta, we did an informal survey of state and local authorities about what kind of help they need. And so what we found out is true to his characterization they need more people to help deploy and dispense these kinds of things, particularly if they were interested in the opportunity for residential delivery or potentially capitalizing on retail distributors that could be used to distribute some of these products in the event of an emergency and that's maybe the one, if you will, new area that we are hoping to work with CDC, going forward, is using our state representatives from ASPR to basically work together to help more on the sense of what can we do nationally to help state and local authorities do that. Part of it may be mobilizing the Federal workforce, which has been considered before. Part of it may be looking at alternative means to help with residential delivery. People have suggested even Amazon.

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

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

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

The chair recognizes the gentleman from Ohio, Mr. Latta, 5 minutes for your questions, please.

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

Mr. BARTON. I will only take 2 or 3 minutes.

Mr. BURGESS. The gentleman is recognized for 5 minutes.

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

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

Senator Kennedy has passed away but Senator Burr is still over there and they're both good men.

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

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

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

I am going to start with you, Admiral. You're the one who controls it now. Why should we keep it with you?

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

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

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

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

Well, I will go to you, Dr.—

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

That's something that we are working very closely on, I would say, on a more than weekly basis.

Mr. BARTON. OK. Well, that's a great answer.

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

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

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

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

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

Dr. KADLEC. Yes, sir.

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

Ms. ABRAM. The FDA stands ready to support the Strategic National Stockpile wherever it ends up being housed.

Mr. BARTON. It's a very politically correct answer.

With that, Mr. Chairman. I yield back.

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

The chair recognizes the gentlelady from California, Ms. Matsui, 5 minutes for questions, please.

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

Some of the scariest potential attacks that the world is vulnerable to today are now posed by chemical and biological weapons as well as cyber-attacks. We made so much progress with the innovation of new drugs and treatments as well as technology. But those new advancements come with new vulnerabilities.

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

PAHPA is critical to our success in both responding to public health emergencies including minimizing harm of any attacks and this field is constantly changing. So we need to keep up. I am pleased that we are working on the reauthorization in a bipartisan manner on this committee. I look forward to working with my colleagues, Representatives Eshoo and Brooks, to advance their legislation.

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

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

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

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

Admiral REDD. So I think the issue of assuring the safety of the material that is stored in the stockpile is a very important issue. The products are stored at undisclosed locations.

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

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

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

The agency, FDA, did put out information specific to some of the analysis we have been looking at in recent years. You're touching upon the phenomenon that can occur with glass vials. Glass affords many advantages as a packaging. However, there can be this phe-

nomenon where you have these thin flexible fragments that break off.

Ms. MATSUI. Right.

Ms. ABRAM [continuing]. And that's something that we've been studying to look at.

We issued an advisory in 2011 and went back and did some pretty extensive surveillance of products on market that had these type of vials, going back to fiscal year 2008 through fiscal year 2017.

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

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

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

Ms. MATSUI. So are you continuing to follow up on this to ensure that, you look at the glass, ensure—

Ms. ABRAM. Yes.

Ms. MATSUI. OK.

Ms. ABRAM. Absolutely.

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

Thank you. I yield back.

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

The chair now recognizes the gentleman from Ohio 5 minutes for questions, please.

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

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

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

I represent a very unique district—that I have more community hospitals than anybody else in the state of Ohio, and when I am out one of the things I hear from my community hospitals is on the cybersecurity and cybersecurity threats that they're under.

In the last Congress, Mr. Welch from this committee—from Vermont—and I did the Internet of Things Working Group and we heard from folks, especially when we are dealing with telehealth and when you look at electronic medical records and the Internet

of Things what's happening on the great things there. But then again, on the cyber side it's always a concern.

So the question I have is as I've seen in your testimony that the healthcare sector very nearly suffered a severe cyber-attack last year due because of WannaCry. In fact, while the United States was spared the worst of the damage, the U.K. had 34 percent of its hospitals affected and there are numerous other examples of recent and growing cybersecurity threats to the healthcare sector.

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

Dr. KADLEC. Thank you for your question, sir, and I just want to reiterate the importance of this issue as it relates to our health care systems because they can range from hospitals to actually individual devices that may be at risk and I think it's important to note that in the Department of HHS that the deputy secretary basically manages the overall cybersecurity of the department.

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

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

Did you agree with that designation?

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

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

Mr. LATTA. OK. Let me just follow up, though.

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

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

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

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

Mr. LATTA. And we look forward to that.

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

Mr. GUTHRIE [presiding]. The gentleman yields back his time.

The chair recognizes the gentlelady from California, Ms. Eshoo, 5 minutes for questions.

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

Just a couple of comments before I get to my questions. I wish Dr. Bright were here today, who heads up BARDA. He couldn't. I think there was a conflict relative to his schedule. But I want the members to have a deep appreciation of what BARDA has accomplished—35 approved measures in 10 years. I don't know of a pharmaceutical company that has produced 10 major drugs in a decade. And so that really is an outstanding record. Many members have raised the issue of the whole issue of antimicrobial infections. Now, God forbid there's an anthrax attack and we have something for that but you're in the hospital and you contract a terrible infection and I think that we are all worried about that. I don't know of conversation with friends of mine where someone doesn't mention someone having been in the hospital and contracted an infection.

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

Admiral, you described in detail how the CDC is responding today, and I know that we just heard Congressman Barton raise the issue of CDC, the stockpile. I think it's important for all members to know that the stockpile isn't moving anywhere. It's going to remain with the CDC.

There is an administrative change here. With the shift from—what's in the legislation from CDC to ASPR, what actually changes for you? Do you have to get permission from ASPR to do something? Is it that you and ASPR are going to coordinate? In a very clear way, can you just set down in a sentence or two what is going to change?

Admiral REDD. So thanks for that question, and you're correct. The people—

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

Admiral REDD. Sure.

[Laughter.]

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

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

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

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

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

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

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

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

Dr. KADLEC. Yes, ma'am.

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

Ms. ESHOO. Well, do you accept that?

Dr. KADLEC. I accept it that it's an estimate. I accept it that——

Ms. ESHOO. Look, there are two and there's a chasm between the two. So tell the committee what you're doing on the——

Dr. KADLEC. Sure, ma'am.

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

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

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

Ms. ESHOO. So you're having discussions with their public health people. Do you have people that are administering anything to the Puerto Rican people?

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

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

Ms. ESHOO. Well, my time is—my time has run out. But I really would like a full report from you on it.

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

Ms. ESHOO. Yes.

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

Ms. ESHOO. Thank you. Yield back.

Mr. BURGESS [presiding]. The gentlelady's time has expired.

The chair is pleased to recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for your questions, please.

Mr. GRIFFITH. Thank you very much.

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

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

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

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

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

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

Mr. GRIFFITH. And my concern is just this.

Ms. ABRAM. Yes.

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

But if there's a risk of delamination, which we've seen in the past, and there's a product that takes care of that, at least with the stockpile wouldn't we be better off using the glass that's less likely to have glass fragments floating around in what we are trying to then use in an emergency situation? Because when people are trying to get something in there in a hurry, whether before or after the storm, they're not necessarily handling it with kid gloves. Wouldn't you agree they're not handling it with kid gloves under those circumstances?

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

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

Mr. GRIFFITH. I appreciate that. Thank you.

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

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

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

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

Mr. GRIFFITH. But it's fair to say for both you and the rear admiral that there's a lot of interesting things going on out there and

it's hard to keep track of it. I will make sure you get some of the info on this.

Dr. KADLEC. Sir, and again, compliments to the committee with the creation of the Medical Countermeasure Innovation Partnership because that's one of the things we hope to do with this program called DRIVE is to basically set up the opportunity for great ideas to come in.

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

Mr. GRIFFITH. Thank you. I appreciate that.

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

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

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

So I yield back.

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

The chair recognizes the gentlelady from Colorado, Ms. DeGette, 5 minutes for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman.

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

Several of our witnesses have mentioned the 21st Century Cures Act, which Fred Upton and I authored but which everybody on this committee had input into, and Representatives Eshoo and Brooks were really instrumental in helping us put some of the medical countermeasures into that bill. They included encouragement of complex, adaptive, and other novel trial and medical advice designs, fostering potential use of real-world evidence for the development of drugs, and harmonizing FDA human subject protections with the common rule, otherwise known as the Federal policy for protection of human subjects.

And in addition, Cures includes provisions that would waive certain paperwork requirements during a public health emergency along with streamlining BARDA procurement process and allowing BARDA to enter into agreements with independent non-profit entities to support medical countermeasure development.

Now, Commissioner Abram, you spoke a little bit earlier about the recent Ebola outbreak in the Democratic Republic of the Congo.

I am wondering if you can talk for a minute about exactly how the lessons learned in the 2014 Ebola outbreak are being used to help contain the recent outbreak.

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

Ms. DEGETTE. Great.

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

We've also continued to engage with our international collaborators and conversations with developers around diagnostics and therapeutics. And so I think one of the continual lessons learned and actually that PAHPRA was very effective in doing is helping to make some accommodations and adjustments in our authorities so that we can be even better prepared in prepositioning which helps us then when we do have these emergent situations to be even more timely in the response effort.

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

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

Ms. DEGETTE. That's right.

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

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

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

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

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

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

Dr. KADLEC. Yes, ma'am. May I just insert that we have two candidate vaccines, one that's actually being used for ring vaccination.

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

Ms. DEGETTE. Right. OK. Thank you.

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

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

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

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

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

Ms. DEGETTE. Thank you.

Thank you very much, Mr. Chairman.

Mr. BURGESS. Gentelady yields back. The chair thanks the gentelady.

The chair recognizes the gentelady from Indiana, Mrs. Brooks, 5 minutes for your questions, please.

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

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

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

And so for our sake, maybe starting with Dr. Kadlec and then going to Admiral Redd, if we could please talk about where that stands right now and are there tools or resources you need to effectively carry out the execution of the Strategic National Stockpile for our citizens who expect it to work.

Dr. Kadlec and then Admiral Redd.

Dr. KADLEC. Yes, ma'am. Thank you, ma'am. I need—

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

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

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

There are issues around personnel, how many people would be, basically, transferred to the ASPR and would be the responsibility of ASPR to basically pay for or provide services to. And then, lastly, one of the areas that's still under negotiation is what percentage, if any, of those people who are working with the state and locals would be transferred to ASPR as well.

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

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

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

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

Admiral REDD. Yes, ma'am. I think actually Dr. Kadlec summarized the current situation quite well. The areas that I think are critical to just make sure we've got good clarity on are the role that subject matter experts at CDC will have both whether or not they're funded by the stockpile now or not—that that linkage with the stockpile and with planning, for example, in clinical guidance, how the product should be used, under what circumstances to control or to respond to emerging events, that we've got that part nailed down and then similarly work that we have been doing partly funded by the stockpile, partly by the state and local program that we've got very good agreement on the work that we are going to continue in that domain to make sure that state and locals are able to dispense products.

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

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

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

Mrs. BROOKS. Well, and I think integration is the key here and it is trying to ensure that everyone is clear as to what CDC's role is with state and local partnership and what ASPR's role is. But it sounds as if the contracting piece and the management of the product, so to speak, and mostly the vaccines, the diagnostic testing, is what would move to ASPR but yet both agencies will be or both parts of—will be working with state and local health officials. Is that correct? Fair to say?

Dr. KADLEC. I think that's the overall intent.

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

Ms. ABRAM. Right. When we think about medical countermeasures it runs the full gamut of medical products from vaccines, therapeutics, and, of course, diagnostics, and rapid point of care of

diagnostics is something that also colleagues at BARDA and ASPR are working on.

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

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

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

The chair recognizes the gentlelady from Florida 5 minutes for questions, please.

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

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

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

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

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

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

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

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

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

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

Previously, this has been an issue and it's been a problem because transfers during emergency situations resulted in automatic

cuts elsewhere in funding in critical areas for state and local governments. They were kind of left in the lurch—created a lot of uncertainty for communities back home.

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

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

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

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

Admiral REDD. Yes, ma'am.

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

Admiral REDD. So, first of all, this is a real problem. In the H1N1 response there was a 54-day interval between the request for funding and the appropriation. For Ebola there was a 4-month interval and for Zika 190 days. So this is a significant problem that is inhibiting the best response.

I am not going to speak directly to the bill but I will say that during the Zika response the PHEP award overall was cut by about 8 percent and we heard from states that that was causing problems with staffing. There was sort of a payback about 6 months later but there was a period of uncertainty and I think that uncertainty really is not helpful to the preparedness interval.

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

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

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

The chair recognizes the gentleman from North Carolina, Mr. Hudson, 5 minutes for questions, please.

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

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

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

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

Dr. Kadlec, you mentioned in your testimony that the strength of our nation's public health and medical infrastructure and the capabilities necessary to respond to emergencies and disasters are foundational to the quality of life of our citizens and I completely agree with you. But I believe these drug shortages hamstringing our ability to properly respond. So I want to see how we can work tighter to best fix these problems.

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

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

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

And we've also recognized that even though we have a very dedicated team that is focused on this at the agency among our CDER colleagues, we continue to see some challenges persist. The agency is doing everything that we can to mitigate and prevent. Particularly, we've been very forthcoming about some of our work in the IV saline solution shortages and our work to work with developers.

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

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

Mr. HUDSON. Thank you.

Dr. KADLEC. Sir, for the purposes of time, I would probably want to get back to you on the record on this. But I just want to highlight as—I think it was alluded to by Ms. Abram and that is the subject to the events in Puerto Rico and how that impacted on several critical supplies of critical medicines—not only saline solution but also pediatric oncology drugs and the like. And we have an interest in that in terms of how do you basically make sure that that critical infrastructure is more resilient. I will just highlight that there is some interesting legislation in the House subject to the

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

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

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

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

Just changing topics, Dr. Kadlec, I have become aware of the time-intensive process involved in producing a vaccine through egg-based production. Oftentimes, this manufacturing can take up to 6 months, which is a lifetime in the ever-changing world of infectious disease. I've recently become aware of the new flexible platform techniques—technologies that have the potential to reduce production time for vaccines from months to weeks.

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

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

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

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

So there's several reasons why we are relooking at what we are doing. But we really owe you and this committee probably a detailed brief on not only the situation we experienced in the past but what may be a strategy to address how to avoid those limitations and get us the most flexibility and speed in the future. I will turn to Anna.

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

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

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

The chair recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

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

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

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

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

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

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

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

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

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

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

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

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

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

So there are several areas. There's also mention about in your draft about the PHEMCE, or the Public Health Emergency Medical Countermeasure Enterprise. We think the idea of basically having that role to ensure that, as Dr. Redd said, that we use the expertise within the department and CDC, FDA, NIH to basically ensure that whatever we are trying to develop and produce is not only useable but safe and efficacious to use in our population, both children and adults and elderly.

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

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

That concludes my questions and I yield back.

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

The chair recognizes the gentleman from Missouri, Mr. Long, 5 minutes for questions, please.

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

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

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

Dr. KADLEC. Yes, sir. They have.

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

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

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

Dr. KADLEC. Sir, thank you for that question. As I outlined earlier, the center of gravity for the department is in the deputy secretary's office at the present time.

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

Mr. LONG. OK. Thank you.

And Mr. Chairman, I yield back.

Mr. BURGESS. The chair thanks the gentleman. The gentleman yields back and the chair is aware that Dr. Kadlec has another engagement at HHS. But we'll now recognize the gentlelady from

Michigan, who's not on the subcommittee, 5 minutes for questions, please.

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

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

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

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

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

Mrs. DINGELL. Thank you.

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

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

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

Mrs. DINGELL. Thank you.

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

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

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

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

I would urge all of my colleagues to support that. We are down to 1 minute so, Deputy Commissioner Abram, some have advocated that as a part of the reauthorization of PAHPA that we should make the MCM PRV program permanent.

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

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

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

So these are pretty serious—is the more vouchers you have, it diminishes then the incentive and the value of the voucher. And so I think Congress had good foresight to consider that this would need to be looked at as how many vouchers are out there—is the program having the intended effect.

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

Mrs. DINGELL. Thank you.

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

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

Also, you mentioned in your prepared testimony about the BioWatch program and I will note that the Shattuck Lecture that was published in this week's New England Journal of Medicine given by Bill Gates, the subject innovation for pandemics also talks about an early detection system. I will probably be submitting a question for the record for you on that because I believe that should be part of our work here.

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

Mr. BURGESS. Mr. Green, any parting comments?

Mr. GREEN. No.

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

And we will transition immediately to our second panel.

[Pause.]

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

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

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

We are pleased today to welcome Dr. Umair Shah, Executive Director of Harris County Public Health; Dr. Michelle Berrey, President and CEO, Chimerix, Incorporated; and Mr. Erik Decker, Chief Security and Privacy Officer, University of Chicago School of Medicine.

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

Dr. Shah, you are now recognized 5 minutes for an opening statement.

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

STATEMENT OF UMAIR SHAH

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

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

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

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

I refer you to my full written testimony today. In the interest of time, I will touch on three main points. One, that public health truly matters, especially at the local level and in emergencies. The PAHPA reauthorization, number two, is extremely important to support our work. Number three, CDC and ASPR must appropriately be funded and getting dollars to local communities.

So public health is vital to the health of our communities. This is especially true in emergencies. Public health does all the behind-the-scenes work and is truly boots on the ground, performing dis-

ease surveillance, ensuring the safety of our environment, spraying for mosquitoes, providing immunizations, picking up dangerous animals, supporting chronic disease and mental health efforts. These are just some of what public health departments do to keep our communities healthy, protected, and safe.

I can tell you firsthand how important these roles are because I am from an impacted community. Dating back to Tropical Storm Allison in 2001, the Nation's first BioWatch had Hurricanes Katrina, Rita, and Ike, H1N1 pandemic, Ebola, and Zika and, most recently, 300-plus year floods in 3 years including Hurricane Harvey with its 1 trillion gallons of water that were dumped on Harris County.

Emergencies abound. But our story is one of a community of resilience, one that has invested in our health and response systems and understands the importance of working together to prepare, respond, and recover and that's what Texans do.

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

In the last year, our nation has seen severe weather events, ice storms, floods, hurricanes, wildfires, acts of violence, a severe flu season. This doesn't even include the issue of opioids or global health challenges that impact domestic health. Truly, two things are certain. Emergencies can and will be lurking around the next corner and public health agencies will be there to respond in kind. But we cannot do our job without the adequate resourcing and support that both public health emergency preparedness and the hospital preparedness program funding streams—PHEP and HPP—provide.

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

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

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

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

Finally, the SNS plays a critical role in preparedness regardless of its structure or location. With the proposed authority from CDC to ASPR legislative language must assure maintenance of appropriate coordination and support of state and local health departments. Public health response capabilities cannot get lost in the sea of other health care system capability needs.

Number three, we feel strongly that CDC and ASPR are agencies that are critical to support what we do on the ground. They provide

not just funding and resources, technical expertise, and advice, but they often are the response agencies that deploy at a moment's notice when necessary. We must ensure that the authorization levels of both agencies are maintained.

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

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

Since we don't invest appropriately in public health capacity, we find ourselves reactively scrambling to act when the next emergency is upon us. Decreased investment in public health leaves us more vulnerable and forces us to rob Peter to pay Paul by taking from elsewhere, and funding fluctuations also take a toll. If funding for public health is cut by 10 percent, for example, the expectations of our communities do not decrease by 10 percent in kind. We must have adequate resources to do our job appropriately.

Let me close by saying I am honored to represent the strong dedicated public health workforce that give it their all as first responders in emergencies just like fire, EMS, law enforcement, et cetera, even when themselves personally impacted.

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

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

[The prepared statement of Dr. Shah follows:]



"Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act"

Statement of

Umair A. Shah, MD, MPH

Executive Director, Harris County Public Health, TX

President, National Association of County and City Health Officials

Before the House Energy and Commerce Committee, Health Subcommittee

June 6, 2018

I would like to thank the House Energy and Commerce Health Subcommittee for inviting me to testify today on behalf of local health departments across the country that are tasked with preparing for and responding to public health emergencies in their communities. My name is Dr. Umair Shah, and I am the Executive Director for Harris County Public Health (HCPH) and the Local Health Authority for Harris County, Texas. Harris County is the third most populous county in the United States with 4.7 million people and is home to the nation's 4th largest city, Houston. I am also here today as the President of NACCHO, the National Association of County and City Health Officials. NACCHO is the voice of the nearly 3,000 local health departments (LHDs) across the country that prepare communities for disasters, respond when emergencies occur, and lend support throughout the entire recovery process.

I want to thank the Committee for taking steps to reauthorize the "Pandemic and All-Hazards Preparedness Act" which is critical to public health and health care preparedness. Public health emergency preparedness is truly national health security. Local health departments play an essential role in ensuring that people and their communities are prepared for, protected from, and are resilient to threats to health that result from all forms of disasters and emergencies. Since all disasters begin and end locally, local health departments must always be prepared to assume our role as first responders to any public health emergency. To this end, local health departments regularly host trainings and exercises to prepare staff and numerous community partners – including those in the healthcare system – for public health emergencies, to build consistent and ongoing communication amongst partners, clearly define response roles, and anticipate challenges before an emergency occurs. And when disasters arise, local health departments coast-to-coast are the "boots on the ground" responding to and helping communities recover.

Just this past year, our nation has seen a variety of large-scale emergencies and events that remind us just how important public health emergency preparedness truly is, especially at the local level. From a busy and incredibly challenging hurricane season including Hurricanes Harvey, Irma, Maria, and Nate; to wildfires in northern and southern California; to unfortunate and large-scale acts of violence perpetrated in Nevada, New York, California, Texas, Florida, and elsewhere; to an incredibly difficult influenza season of 2017-2018; one thing is certain: emergencies can and will be lurking around the next corner. And it is



our ability to prepare for, respond to, and recover from these emergencies that is expected by the American people.

I can attest to this first hand. As you will recall, in August 2017, the Texas Gulf Coast was hard hit by Hurricane Harvey. In Harris County alone, a total of 1 trillion gallons of water fell across the county's 1,800 square miles (the size of the state of Rhode Island) over a 4-day period where many areas received over 40 inches of rain with a total peak accumulation of over 51.88 inches (making Harvey the wettest hurricane on record in the contiguous United States). Harvey caused unprecedented widespread flooding, representing Harris County's third 500-year flood event in just three years. Yet according to the National Flood Insurance Program, only 15% of homes in Harris County were covered by flood insurance. Over 200,000 homes and apartment buildings were damaged, and tens of thousands of people had to evacuate; regrettably, there were 36 fatalities in Harris County.

Hurricane Harvey was but one emergency in a long line of others for our community. Dating back to 2001, Tropical Storm (TS) Allison severely damaged several buildings and hospitals in Texas Medical Center, the world's largest medical center. TS Allison was followed by the large-scale responses to Hurricane Katrina with 27,000 evacuees being sheltered at the Astrodome and then the community-wide evacuation in advance of Hurricane Rita in 2005; direct impact from Hurricane Ike in 2008 when 90% of the community was without power for days to weeks; and then the devastating floods of the last few years. These natural disasters were coupled with responses to the nation's first BioWatch hit in 2003; novel H1N1 pandemic response in 2009-10; Ebola and Zika responses of 2015 and 2016, respectively, to name but a few. Certainly, Hurricane Harvey response of 2017 culminated in all that our community learned through these disasters of yesterday.

While Hurricane Harvey was incredibly impactful for our community and our residents, there were numerous other communities impacted all across Texas – both large and small. I am proud of the work that Texas LHDs put in to respond to what occurred in their communities. In fact, the Texas Association of City & County Health Officials (TACCHO) – an associated affiliate of NACCHO representing approximately 45 LHDs across Texas – played a role in coordinating work in various LHDs across Texas. But though things were busy enough in Texas, communities across the United States faced their own unique challenges with the myriad emergencies that came their way this past year. A common thread seen across these catastrophic events was that people of all economic backgrounds found themselves stripped of their homes and life-long possessions; hospitals faced personnel, supply, and medicine shortages; many residents were found suffering from the traumatic events resulting in ongoing mental health issues; and older and disabled populations as well as children and those with functional needs were found to be especially vulnerable. In emergencies like these, local health departments, healthcare providers, emergency responders, emergency management, and the whole of local government all work together in a unified response to exact immediate action and minimize loss of life and property.

In the case of Hurricane Harvey, our public health response was integral to the overall incident command structure and response activated by the Harris County Office of Homeland Security & Emergency Management led by Harris County Judge Ed Emmett and Harris County Commissioners Court. Tens of thousands of people took refuge in a community shelter somewhere, including the 10,000 people



cumulatively who stayed at the NRG Center, the mega-shelter set up by Harris County. The other mega-shelter, the George R. Brown Convention Center, was set-up by the City of Houston (supported by our public health partner, the Houston Health Department) and provided shelter for an additional 10,000 persons. Additionally, within 24 hours and in partnership with healthcare system partners, HCPH set up a Functional Needs Medical Refuge unit (FNMR) at NRG Center. Though mass sheltering gets the attention, public health has response roles behind the scenes throughout a community's response.

HCPH activated its emergency management plan and reassigned departmental assets and resources to disaster relief efforts across the broader community. HCPH monitored for communicable diseases in other community "pop-up" shelters, simultaneously while deploying a fleet of mobile response RV units across over 30 events within just six weeks of Harvey's landfall. When our community was not mobile, we became mobile for it – bringing "public health to the public" and ensuring residents had access to basic provisions such as food and water, immunizations (flu and tetanus), veterinary/animal services, health and safety education, and clinical services.

Additional response activities included: working with 9,000 local businesses to ensure food was safe to eat, drinking water inspections, assessments of area environmental, toxicology and chemical risks, "door-to-door" surveys using the Centers for Disease Control and Prevention's Community Assessment for Public Health Emergency Response (CASPER) tool, as well as enhanced county-wide mosquito control efforts (including aerial spraying) in collaboration with the Texas Department of State Health Services (DSHS) and the U.S. Air Force. It was truly an "all-public health" response to a singular, massive event.

Indeed, no one was spared from the impact of Hurricane Harvey. Our own staff members – as those of many local health departments in the region impacted by Harvey – were personally devastated by losing homes, having water and flood damage, children displaced from schools and loved ones impacted throughout the community. Yet despite it all – and true the nature of public health professionals across this noble field nationally – our staff members still came to work, came early, worked late, did not go home, and worked days and weeks on end, to serve the needs of our devastated community. I would be remiss if I did not recognize three individuals in particular who helped lead our department's response: Mr. Les Becker, our Deputy Director/Director of Operations, Mr. Michael "Mac" McClendon, Director of the HCPH Office of Public Health Preparedness and Response (OPHPR), and his OPHPR Deputy, Mrs. Jennifer Kiger, who was 8 ½ months pregnant but still responded to what our community needed. When asked to go home, Mrs. Kiger refused and stated emphatically, 'this is my community and I want to be here to serve it'. I am incredibly humbled by the dedication of our HCPH team and the nationwide network of public health professionals who act as first responders and yet often are not recognized as such.

Passion and dedication aside, it is clear that without resources from the Centers for Disease Control and Prevention (CDC) and the Assistant Secretary for Preparedness and Response (ASPR) during Hurricane Harvey, our preparedness, response, and recovery efforts and impacts would have been far less robust. This was not just from the acute response phase that went into play during the event but the years of planning in advance of events such as Hurricane Harvey. **In order to meet preparedness and response needs of communities such as ours, CDC and ASPR must have adequate support and authorization levels along with commensurate funding** to ensure local health departments are equipped to prepare and



Public Health
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respond to the variety of local disasters, whether natural, man-made, pandemic, bioterrorism, or otherwise.

Summarizing the often-invisible nature of public health, I would ask you to consider public health as the offensive line of a football team protecting the quarterback. Most everyone knows who Nick Foles is on the Super Bowl-winning Philadelphia Eagles is, but can they name any member of the offensive line of that Eagles Championship team? Very doubtful. In the case of football, when any football team has a successful year, does that mean that they will be putting in a second string offensive line the next year? No, they will by and large keep that offensive line strong in the hopes of being successful and winning again. In public health, unfortunately, the opposite happens as we do not continue to invest in the invisible offensive line for a community's health, security and well-being. Since FY2003 when the Public Health Emergency Preparedness (PHEP) program was appropriated at \$1 billion, we have since seen a precipitous decline in funding year after year, and it is the concern of local health departments that soon cracks will show and forces will penetrate and overwhelm the offensive line that protects the public's health.

The programs authorized by the *Pandemic and All-Hazards Preparedness Act* are vital to local health departments. The proposed bill "Pandemic and All-Hazards Preparedness Act of 2018" authored by Representative Susan Brooks (R-IN) is an important step in ensuring local health departments can protect the health and safety of their communities in the event of an emergency. I firmly believe that the funding PAHPA has provided saved lives in each major 2017 disaster, as well as small and other large-scale emergencies over the years in local communities across our country. NACCHO's recommendations on the provisions in the draft "Pandemic and All-Hazards Preparedness Reauthorization Act of 2018" are as follows:

Public Health Emergency Preparedness (PHEP)

NACCHO strongly supports the reauthorization of the Public Health Emergency Preparedness Program (PHEP) grants through 2023. By authorizing the PHEP Cooperative Agreement, PAHPA has enabled local health departments to hire personnel, develop and exercise critical response plans, and stockpile medicines and supplies. Since 2002, PHEP has provided more than \$11 billion to health departments enabling them to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. It is important to note that 55% of local health departments rely solely on PHEP funding to support their preparedness activities.

However, as noted previously, there have been dramatic decreases in funding for PHEP since its inception. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BT Act), P.L. 107-188, which initially established PHEP and HPP in 2002 authorized \$1.08 billion for PHEP and \$520 million for HPP. Subsequently PAHPA (which replaced the BT Act) authorization levels for PHEP dropped to \$824 million in FY2007 and \$642 million for each fiscal year from 2014 through 2018. As authorization levels dropped, so did appropriations. At its highest point in 2003, Congress appropriated nearly \$1 billion for PHEP. After austere cuts, PHEP appropriations have been stagnant at \$660 million for the past several years, with a slight increase to \$670 million in FY2018.

These drastic cuts reduce local health department capacity to prepare for all-hazards and consequently impact the ability of communities throughout the nation to be resilient when disasters strike. Many local



health departments, such as HCPH, have been able to reallocate resources from other areas to cover the gaps created by the continual cuts to PHEP funding levels and even this is a stop-gap strategy that is not sustainable. Unfortunately, not all health departments can even do this as many do not have the luxury to “borrow from Peter to pay Paul.” This creates an inequitable environment for public health preparedness, disproportionately impacting smaller jurisdictions such as those in rural and frontier areas. Therefore, **NACCHO recommends the Committee increase the authorization level from \$670 million to \$824 million, which is the level authorized in 2006.**

Hospital Preparedness Program (HPP)

NACCHO strongly supports the reauthorization of the Hospital Preparedness Program (HPP) through 2023. HPP and PHEP are complementary programs with different purposes. While PHEP supports local health departments and their response to public health threats and helps to build resilient communities; HPP enables health care systems to save lives during emergencies that exceed day-to-day capacity of health and emergency response systems. Both programs work hand-in-hand for overall community response in the midst of an emergency or disaster.

More than \$5 billion has been provided to HPP to expand capabilities that will allow healthcare systems to meet acute needs and more rapidly expand capacity when there is a surge in the demand for medical care and emergency services in the aftermath of a disaster. As such, HPP is a distinct and complementary program that supports the broader public health and emergency response system as a whole. HPP has helped to improve emergency communication and coordination among hospitals, ancillary medical facilities and public health officials; facilitate patient tracking in mass casualty events, such as the horrific concert mass-shooting in Las Vegas in 2017; sustain operations in the midst of an event; track medical resources and assets including available hospital beds; and establish systems to reunite family members following an event.

HPP funding has been cut in half from a maximum investment of \$515 million in FY2004 to only \$264 million in FY2018. Funding has since stayed relatively level annually since being cut by a third in FY2014. Despite the progress made with early investments, austerity has taken its toll. Funding cuts have resulted in staffing reductions, forced staff to fill multiple roles and hindered the ability to maintain existing or build new partnerships between public health and the healthcare sector. Therefore, **NACCHO urges the Committee to increase the authorization for HPP from \$264 million to \$474 million** to ensure that ASPR can support the on-going robust country-wide health system preparedness infrastructure that is equally necessary. Even in response to Hurricane Harvey, HCPH worked closely with our HPP regional partners through the healthcare coalition convening partner, the Southeast Texas Regional Advisory Center (SETRAC), to respond to health and medical needs of the residents of Harris County as well as 24 other surrounding counties. SETRAC coordinated a wide arrange of medical activities including 1,544 patient movements, 24 hospital evacuations, and 20 nursing home evacuations. Their regional healthcare preparedness coalition also assisted in efforts to ensure that patients on dialysis, for example, who were trapped in their homes or relocated to evacuation centers could continue to receive treatment.

Medical Reserve Corps

The Medical Reserve Corps (MRC) program is a national, community-based corps of medical and non-medical volunteers that strengthen public health, emergency response, and community resiliency. MRC



volunteers contribute to building a strong public health system, capable of responding to any emergency, be it manmade, a weather-related natural disaster, or an emerging infectious illness, to better respond to emergencies. MRC units support and supplement existing emergency and public health resources in the community. These volunteers are critical emergency response resources to address public health challenges more quickly and efficiently. These trained volunteers are members of the community they work to protect.

Local MRC's were vital to the Hurricanes Harvey, Maria, Irma, and Nate responses as well as other emergencies throughout our country such as the wildfires on the West Coast. For the hurricanes, in total, 100 MRC units were dispatched in local communities with over 5,000 volunteers, totaling 106,354 hours of volunteer service for an estimated total economic value of almost \$4 million.

Funding for the MRC program continues to dwindle as it is currently funded at \$6 million, a cut of \$5 million or 45% since FY2010. The bill cuts the authorization for MRC from \$11 million to \$6 million. Without this funding, communities will be at greater risk in emergency situations, without the necessary human resources for emergency response. Staff will be pulled from other public health functions, which can endanger the health and safety of the public. **NACCHO urges the Committee to maintain the authorization level for MRC under current law.**

Public Health Emergency Fund

A standing rapid response fund to provide bridge funding between base preparedness funding and supplemental appropriations for acute emergencies and emerging threats is necessary. NACCHO appreciates that the bill strengthens existing authorities for the Public Health Emergency Fund (PHEF). However, there is concern about the 1% transfer authority to infuse the fund when a public health emergency is declared. The transfer authority will take vital dollars away from other public health programs in the midst of a funding cycle. Furthermore, there are timing challenges if a disaster occurs at the end of the federal fiscal year when most funding will have been obligated and distributed. In addition, as we experienced in 2017, there can be multiple public health emergencies in a given year and these can be even spread over far-reaching geographies across the United States (consider Harvey in Texas and Irma in Florida while wildfires were burning in California, as an example).

NACCHO and Harris County can both attest to the impact of cuts in the midst of a fiscal year to pay for an emergency. In 2016 during the Zika response, in the absence of supplemental funding, CDC redirected \$44 million in Public Health Emergency Preparedness funds from state and local health departments. NACCHO surveyed local health departments on the impact of the cuts to their preparedness programs and found that the cuts were disruptive impacting planning, staffing, exercising, and coordination with partners. In the case of Ebola in 2015, more broad "all-hazards" funding for public health emergency response was instead funneled to Ebola response activities. While this may have been necessary given the context at that time, it must be remembered that while our nation may be dealing with a specific accentuated response for a single threat at any one time, the reality is that multiple emergencies can occur at once. Thus, taking away from overall preparedness and response funding to handle a potential singular emergency such as Ebola is a strategy with significant limitations.



Further, it is imperative that emergency fund dollars be used to jumpstart the response to emergency events such as the Zika outbreak in 2016 or Ebola in 2015. Due to the cost of recent public health emergencies – especially those requiring development of new medical countermeasures – the PHEF, as proposed to be funded through transfer authority, will likely be insufficient to pay for the entire response. The PHEF as proposed would not eliminate the need for supplemental funding for large scale emergencies. Nor does it eliminate the need for robust funding for ongoing preparedness. **NACCHO believes strongly that it is essential Congress appropriate funds for the PHEF without transferring money away from existing public health and preparedness resources.**

Public Health Emergency Medical Countermeasure Enterprise

NACCHO supports the codification of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE Strategy and Implementation should require that state and local health departments be involved in all phases of the medical countermeasures (MCM) enterprise including in initial investment; research and development of vaccines, medicines, diagnostics and equipment for responding to emerging public health threats; and distribution and dispensing of countermeasures.

NACCHO recommends that state and local public health departments have a permanent place in the PHEMCE membership to ensure that all decisions that will affect state and local health functions are vetted by public health authorities. Membership should include a state public health authority and a local public health authority.

Strategic National Stockpile (SNS)

Current funding, support, and expertise provided to state and local health departments for the SNS must be maintained regardless of the infrastructure or location of the SNS – it is too vital to this country's ability to respond in the midst of a variety of large-scale emergencies. However, there are potential vulnerabilities to this with the proposed transfer of authority for the SNS from CDC to ASPR at the beginning of FY2019. **NACCHO believes there should be language that assures the maintenance of appropriate coordination and support for state and local public health departments.** Under no circumstance can public health response capabilities be lost in the sea of other health care system response capability needs. This cannot and must not happen. As proposed, operational and logistical functions that would be transferred to ASPR would essentially be separated from programmatic and support functions already in place at the CDC. If not handled well, such a transfer may introduce added complexity, poor coordination and less expediency as it pertains to the national, state and local operational readiness to distribute and dispense medical countermeasures from the stockpile where the healthcare-public health interface is critical.

BARDA and the BioShield Special Reserve Fund

NACCHO supports the authorization level of BARDA and the BioShield Special Reserve Fund and at no less than \$710 million annually for BARDA and \$7.1 billion over 10 years for the Fund. BARDA has been highly successful in bringing vaccines, drugs, and diagnostic to fruition for which there has been little commercial market. Since 2007, there have been 34 products approved or licensed. Yet the challenges facing the nation are greater than ever, including emerging infectious diseases and other global threats. The recent reemergence of Ebola in the Democratic Republic of Congo underscores the importance of this capability in real-time today.



Pandemic Influenza and Emerging Infectious Diseases

NACCHO appreciates the Committee's acknowledgement that pandemic influenza and other emerging infectious diseases are under the umbrella of BARDA's mission. Recent years have demonstrated that infectious diseases from around the globe are a threat to our national health security. Truly global health and domestic health are tied ever more so than before. Recent global health threats such as the novel H1N1 pandemic, Ebola, and Zika, as well as others that are climate and environmental in nature, have shown us just this. A true "One Health" notion of ensuring human health, animal health, entomology (insects) and environmental health, is leveraged and absolutely critical to robust multi-sectoral response. This was underscored in the CDC's 2018 *Vital Signs* report that highlights the tripling of vector-type infectious diseases – often zoonotic in origin – in the U.S. from 2004-2016. Such threats remind us of how important collaboration across the One Health spectrum truly is and provides a glimpse of public health of tomorrow. With these threats in mind, **NACCHO supports the Committee's authorization of additional appropriations for these new strategic initiatives.**

Cybersecurity

NACCHO appreciates that the bill highlights the importance of cybersecurity as part of national health security. As people use electronic health data more widely and increasingly rely on networked computer technology to deliver efficient healthcare and public health services, the need to protect public health information and public health infrastructure increases. A successful cyber-attack on public health information infrastructure would severely reduce both public health emergency responses and non-emergency public health functions. It could paralyze and indeed shut down our combined public health and healthcare systems at a moment's notice. That said, however, NACCHO would urge the Committee to be cautious in expanding the scope of PAHPA without the authorization of commensurate resources to carry out new activities and initiatives.

Summary

In summary, I want to highlight the need for Congress to see dollars spent in public health as a true investment and this absolutely applies to the area of public health emergency preparedness and response. Further, funding for CDC and ASPR must not just be maintained but enhanced and used in a way to leverage these dollars to build adequate capacity at the state and local levels throughout the United States. Local health departments like Harris County Public Health are working "24-7" to save lives and address the preparedness needs of the community to respond to disasters. A ten percent, for example, cut in funding does not coincide with a ten percent decrease in responsibilities or expectations from our respective communities. These responsibilities and these expectations cannot be underscored enough for the health and security of our nation's communities. The Pandemic and All-Hazards Preparedness Act of 2018 will definitely provide support for activities that would help local health departments in their preparedness and response efforts.

As communities across the country recover from last year's devastating events, both natural and manmade, coastal communities in Florida and North Carolina have already experienced adverse impacts of Subtropical Storm Alberto, just prior to the start of the 2018 hurricane season, and a busy hurricane season is already anticipated throughout this summer and fall. In our own neighborhood, we witnessed a mass casualty event at a local high school in Santa Fe, Texas – joining the list of other impacted



communities that have seen such horrific and terrifying events play out in their schools. While LHDs will continue to prepare and respond to future emergencies at the local level, equally we need increased federal support to continue doing this work effectively and efficiently. It is truly a long-term investment in our communities.

Our community knows this all too well. If Hurricane Harvey was just the only emergency we had to deal with that would have been bad enough. However, Harvey was on the heels of multiple storms and emergencies over a decade plus that have impacted Harris County. It is clear our community has seen an emergency or two and we – like other communities – have shown that proper investment in public health and healthcare delivery is absolutely necessary for a community's safety, vitality, and well-being and that we can learn from previous events. Case in point, due to the significant investment in public health and healthcare infrastructure in our community from TS Allison forward, a storm as devastating as Hurricane Harvey caused only 10% of our area's 120 some hospitals, long-term acute care, and nursing homes to be inoperable or requiring evacuation. Lessons can be learned. Investments can pay off.

Closing

In closing, we urge Congress not only to support the PAHPA Reauthorization but also to direct efforts toward building healthy and resilient communities through appropriate and meaningful enhancements to proactive public health system capacity, including in areas of community preparedness, laboratory testing, surveillance and epidemiological investigation, emergency operations coordination, public health awareness infrastructure, and others alike. Investments in smart, forward-facing technologies and information systems are equally critical to the success of response capabilities and must also be remembered.

Such efforts will not only help communities recover faster from an emergency but will reduce the impact of that very emergency. The more resilient a community is, the better it is able to resist, respond, and recover from a disaster. The strong and incredibly important work of local health departments – the invisible offensive line of our communities – across the country should not be kept hidden but made more visible so all of us can recognize the absolute value proposition of what public health brings to the table, just like our partners in law enforcement, fire, EMS, and emergency management. With optimal and necessary support from the federal government, state and local public health partners can continue to perform the incredibly critical work that they do on a daily basis even if it remains invisible to the vast majority.

On behalf of HCPH, NACCHO, and the nearly 3,000 LHDs across the country, I appreciate again the opportunity to testify today. We join you in working toward strengthening and enhancing our nation's preparedness and response systems and look forward to continuing to work with you on this legislation as it moves forward. Thank you for all you do in building safe, healthy, and protected communities where we live, learn, work, worship, and play, across this great nation of ours.

Thank you.



Mr. BURGESS. Thank you, Dr. Shah.
Dr. Berrey, you're recognized for 5 minutes, please.

STATEMENT OF MICHELLE BERREY

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

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

I am a board-certified infectious disease and public health physician. I spent the last 20 years developing new drugs for viral diseases. I currently serve as CEO of Chimerix, a small publicly-traded biotech of 85 employees in Durham, North Carolina. We are one of many companies currently collaborating with BARDA in development of medical countermeasures against CBRN threats.

We are here today as members of the Alliance for Biosecurity as a strong supporter of reauthorization of PAHPA. Our lead candidate, brincidofovir, or brinci for short, is an anti-viral with activity against a broad range of viruses. It is in late stage development for treatment of small pox. Brinci is one of a handful of dual-use agents, meaning it is in development both as a medical countermeasure for protection of the public health and to address some of the most common viruses in patients with urgent needs for new treatments. For brinci, this is for children undergoing bone marrow transplants. It was Federal funding that allowed us to jumpstart our smallpox program and to progress to full development and our currently collaboration with BARDA.

When smallpox was eradicated in the 1970s, routine vaccinations ceased. Without broad immunity, weaponized smallpox could be devastating to the global population and thus it became an appealing potential biological weapon. It is a highly infectious easily transmitted airborne virus with at least a 30 percent mortality rate. As the first line of defence for smallpox exposure, vaccines are stockpiled by BARDA for every American including the one in five Americans who would require a next-generation or attenuated vaccine.

So why did the Institute of Medicine also recommend that the U.S. stockpile two different smallpox antivirals with different mechanisms of action? The reason that antivirals are critical is for three separate populations: one, those who remain ineligible for vaccine; two, patients with severe side effects from the vaccine; and three, those with symptomatic smallpox.

Like the flu, once symptoms begin it is too late for a vaccine. Specifically for brinci, we have completed over a dozen efficacy studies for the treatment of smallpox under the FDA's animal rule. In our largest rabbit pox study, we demonstrated 100 percent survival in animals that we began dosing at the time we confirmed infection. Our studies have also shown that brinci may also reduce transmission of smallpox by accelerating clearance of virus. This point could be critical in stopping an outbreak.

Chimerix has worked closely with our colleagues at the Division of Antivirals at the FDA to progress this challenging program. Just this morning, we received orphan drug designation from the FDA, which provides a waiver for FDUFA fees and will thus provide further savings for BARDA. Developing countermeasures as dual-use compounds allows us to stretch precious federal resources and to ensure sustainability of the enterprise.

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

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

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

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

I will be happy to welcome any your questions.

[The prepared statement of Dr. Berrey follows:]



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"Examining the Reauthorization of the Pandemic All-Hazards Preparedness Act"

Statement of
M. Michelle Berrey, MD, MPH
President and Chief Executive Officer
Chimerix, Inc.
Before the House Energy and Commerce Committee, Health Subcommittee

June 6, 2018

Introduction

I would like to thank Chairman Burgess, Ranking Member Green, and all members of the Committee for the opportunity to speak to you today in support of the reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA).

I am an Infectious Disease and Public Health physician by training. I have spent most of the last 20 years developing new drugs for viral diseases. I currently serve as CEO of Chimerix, a small biopharmaceutical company of 85 employees that is headquartered in Durham, North Carolina. Our lead product candidate, brincidofovir, is an antiviral with activity against many different viruses. This compound is in the late stages of development for the treatment of smallpox and is in concurrent development for the treatment of patients with life-threatening adenovirus infections, making it one of only a handful of "dual-use" agents.

In addition to supporting the proposed reauthorization of PAHPA, I aim to highlight the important components of a successful public-private partnership that supports the discovery and development of needed medical countermeasures.

We at Chimerix are fortunate to have received government funding to jumpstart our smallpox development program. In 2003, a grant from the U.S. National Institute of Asthma

and Infectious Diseases (NIAID) allowed us to begin research on brincidofovir for the treatment of smallpox infections and complications resulting from smallpox vaccination. By 2011, this collaboration with NIAID had enabled us to complete the early development work and we subsequently initiated a new partnership with the U.S. Biomedical Advanced Research and Development Authority (BARDA). The goal of our continuing work with BARDA is to develop brincidofovir as a medical countermeasure against smallpox.

Vaccination is intended to be the first line of defense in the event of a smallpox release. BARDA's Smallpox Vaccine Program has a stated goal of having enough smallpox vaccine for the entire Nation. This includes a vaccine for the general population, and an attenuated vaccine for the estimated 20% of Americans who may not be able to receive the live virus vaccine, including those who may be pregnant, individuals living with HIV, or the three million Americans currently taking a biologic for autoimmune or other diseases.¹

The Institute of Medicine recommends that, in addition to vaccines, the U.S. stockpile two different smallpox antivirals with different mechanisms of action. These would serve to treat those who remain ineligible for a vaccine and to treat individuals with symptomatic smallpox.

Biological Weapons Pose a Serious and Growing Threat to the United States

Unfortunately, the threat of a biological weapon impacting the United States has never been more real. This year marks the 100th anniversary of the Spanish Flu, which killed an estimated 50-100 million people worldwide. In today's interconnected world, it is difficult to overestimate the devastation that a highly infectious agent—whether natural or manmade—would wreak. Of note, smallpox, like influenza, is transmitted through

¹ MacIntyre C, Costantino V, Chen X, Segelov E, Chughtai A, Kelleher A, et al. Influence of Population Immunosuppression and Past Vaccination on Smallpox Reemergence. *Emerg Infect Dis.* 2018;24(4):646-653. <https://dx.doi.org/10.3201/eid2404.171233>

respiratory droplets and does not require contact with bodily fluids. In fact, smallpox is two to three times more infectious than the flu virus.²

Several weeks ago, the Johns Hopkins Center for Health Security conducted a tabletop exercise simulating the spread of a novel virus across the globe. In their simulation, the failure to develop a vaccine within 20 months led to 150 million deaths globally.³ Health care systems collapsed, the U.S. stock market crashed, and the American political system was in upheaval.⁴ Exercises like these highlight the importance of PAHPA and the public-private partnership to stockpile medical countermeasures and build the expertise needed to protect our country.

The U.S. stopped vaccinating routinely against smallpox in 1971, as progress was being made toward the eradication of smallpox. The only labs in the world approved to have the virus for research are in the U.S. and Russia.⁵ For many years, national security and health experts debated the merits of eradicating these existing stockpiles. Unfortunately, recent scientific research and publications have rendered that debate moot.

In January of this year, a team of Canadian researchers published in an online open-source journal their methodology for recreating the horsepox virus from materials ordered from scientific catalogs. As suggested by the name, horsepox is closely related to both cowpox and smallpox. This confirms that standard scientific methods could be utilized to synthetically create smallpox *de novo*. This new synthetic smallpox could be altered slightly to have a higher mortality rate than the estimated 30% of naturally-occurring smallpox from *Variola major* (last reported in 1975⁶), or to be resistant to currently stockpiled vaccines or antivirals. Perhaps even more concerning, the project cost only about \$100,000 and took a small team about six months.⁷ This is not only achievable for

² Gani R, Leach S, "Transmission potential of smallpox in contemporary populations." *Nature*. 2001 Dec 13;414(6865):748-51.

³ Lena Sun, "This mock pandemic killed 150 million people. Next time it might not be a drill," *Wash. Post*, May 30, 2018.

⁴ *Id.*

⁵ CDC, "Bioterrorism: Smallpox," <https://www.cdc.gov/smallpox/bioterrorism/public/threat.html> (Dec. 19, 2016).

⁶ *Id.*

⁷ Noyce RS, Lederman S, Evans DH, "Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments." *PLOS ONE* (Jan. 19, 2018), available at <https://doi.org/10.1371/journal.pone.0188453>

state actors like North Korea—which may already have a stockpile of smallpox—but for highly motivated rogue actors.

If weaponized, smallpox could be devastating. Since this virus is most commonly transmitted person-to-person via respiratory droplets, a single sneeze or cough could release thousands of viruses into the air where they could be inhaled or land on mucous membranes in the eye, nose, or throat. Smallpox has an initial prodromal period, very much like Ebola, during which the individual has no symptoms and is not infectious.⁸ By the time someone begins to have a fever and rash—a time when they would be very infectious—and presents at an emergency room or clinic, they could have spread this virus to their immediate family, to those on public transportation, or to other patients in an ER waiting room. Compounding the problem, very few physicians practicing in emergency rooms today have ever seen smallpox, or would think to test a patient with a new rash for smallpox. Consequently, it would be very difficult to trace smallpox infections and the disease could rapidly spread across the globe.⁹

Importantly, brincidofovir meets all U.S. Government requirements for a second antiviral for the SNS:

- Dosed orally, with a short course of therapy;
- Clinical experience in more than 1,500 patients, including relevant populations of immunocompromised patients through our adenovirus and cytomegalovirus research programs, and importantly, clinical safety and efficacy data for other viruses in pediatric patients;
- High barrier to resistance;
- Strong efficacy in animal models, meeting the FDA's criteria of "reasonably likely to predict benefit in humans"; and
- A development path to approval agreed upon with the FDA.

⁸ WHO, "Smallpox," <http://www.who.int/biologicals/vaccines/smallpox/en/> (Jan. 14, 2014).

⁹ *Id.*

We are committed to completing the development program for brincidofovir as quickly as possible so we are able to offer a much-needed second treatment option for smallpox to the SNS.

Brincidofovir Development Program

To date, we have completed over a dozen efficacy studies of brincidofovir for the treatment of smallpox under the FDA's Animal Rule. This rule allows for efficacy testing in animal models in diseases that are not ethical or feasible to study in humans. Because smallpox was successfully eradicated, there is no existing population of patients for testing.

We are proud of the progress we have made in the brincidofovir development program in smallpox, demonstrating improved survival rates following confirmed orthopoxvirus infections in multiple animal models. Our studies also show that brincidofovir may reduce transmission of smallpox by accelerating clearance of virus. This component could be critical in stopping an outbreak.

Chimerix recently reached agreement with the FDA for a general study design for a final rabbitpox study, which will be conducted in parallel with a registrational mouse study this year. We anticipate that results will be available in early 2019 for both studies. Chimerix plans to submit regulatory applications in both the U.S. and Europe for approval of brincidofovir for smallpox in 2020.

Conducting studies to determine a medicine's efficacy under the Animal Rule is complex and provides a less-than-straight path to approval. Establishing rigorous animal models requires a great deal of planning, analysis, and ultimately, trial and error. These efforts demand significant resources and investment. Reauthorizing PAHPA ensures that there is dedicated funding ahead for stockpiling this is critical as there is no existing commercial marketplace for an antiviral for smallpox. We are developing a solution for a problem that we all hope never presents itself, but *not* being prepared for a smallpox event is *not* an option.

Brincidofovir is also in clinical development for emerging life-threatening viral diseases in patients that do not have an intact immune system, making it a "dual use" compound. We are currently pursuing what would be our first commercial indication for the treatment of adenovirus in pediatric stem cell transplant recipients.

As a small, clinical-stage company focused on transforming survival rates in these pediatric patients, we face specific challenges in advancing both commercial and government research programs for brincidofovir in adenovirus and smallpox, respectively. For example, the safety and tolerability of the compound in different populations is important to understand. We would recommend that additional guidance be provided within the current Animal Rule for dual-use compounds such as ours.

Because a majority of the adenovirus patient population are children, we have optimized an oral suspension that does not require refrigeration, an important characteristic for medicines in the SNS. Independent of our BARDA collaboration, we also identified the need for an intravenous (IV) formulation for hospitalized patients with active viral infection who may not be able to be treated with an oral medicine. BARDA has expressed interest in exploring the utility of the IV formulation of brincidofovir for potential utility in patients with active smallpox infection. Thus, the dual-use development of brincidofovir maximizes the application of federal monies and taps into the recognized innovation of the American biotechnology sector.

Lessons Learned From Partnership With BARDA

Our private-public partnerships over the last seven years, particularly with BARDA, have been critical to the survival and progression of our smallpox program. BARDA's leadership and staff are committed to improving our nation's preparedness for a biological attack, and we are deeply appreciative of their service and grateful for the opportunity to serve as private-sector partners. Our experience has underscored the importance of ongoing and

transparent communication between companies and government organizations engaged in biodefense research. The unpredictable nature of government funding, however, makes it challenging to maintain momentum. Without a guaranteed government marketplace, capital to maintain the necessary research and development programs is difficult to secure.

Reauthorizing PAHPA Is Critical for Our Nation's Preparedness

With its passage twelve years ago, PAHPA created a series of public-private partnerships that have been remarkably successful. The passage of the Project BioShield Act and then PAHPA created a market for medical countermeasures for the first time. This provided the incentive for companies like ours to take the risk of partnering with the government and devoting substantial time and resources to developing these therapies.

Mass media outlets sometimes give the false impression that if a novel biological threat reaches the U.S., scientists would quickly be able to develop and deploy a countermeasure. The reality is that science takes time. Our company is a prime example of the fact that researching and developing a medical countermeasure takes years of sustained investment. Another recent example is Siga Technologies' development path, from its founding in 1995 to the FDA approval for its smallpox antiviral which is expected later this year.

In BARDA's objectives, the agency has specified stockpiling two different antivirals in the SNS with activity for smallpox. This is not only important in the case of viral resistance, but potentially, as a form of combination therapy. As we have seen in other infectious diseases, combination therapy, or "cocktails," can be much more effective than a single drug, and this could potentially be an option when treating an active smallpox infection.

Stockpiling of medical countermeasures is critical because manufacturing sufficient quantities of product to reach affected populations cannot happen overnight. By facilitating product development and stockpiling quantities of medical countermeasures, Project BioShield and PAHPA provide a critical bulwark against potential biological threats.

The impact of these programs has been undeniable. According to ASPR, since the passage of PAHPA, 34 medical countermeasures have been approved or licensed by the FDA and 14 have been placed in the SNS. Twenty-seven medical countermeasures are currently supported by Project BioShield, and more than 200 candidates are in the development pipeline. Moreover, PAHPA has created a community of scientists, academics, and policymakers focused on cross-collaboration and preparedness. This network will be vitally important if and when the U.S. is faced with a biological threat.

We commend the Committee for the bipartisan collaboration on the PAPHPA reauthorization. In particular, we appreciate inclusion of the ten-year advance appropriation for the Project BioShield Special Reserve Fund. Companies like ours rely on the existence of a government market for medical countermeasures to sustain the long-term investment in researching and development of these therapies. Under the annual appropriations process we have had in place in recent years, this government market guarantee has become uncertain.

In fact, a recent report by the Bipartisan Policy Center found that since Project BioShield reverted from its original ten-year advance appropriation to annual appropriations, the dollar value and scope of awards have been significantly reduced, creating uncertainty for the private sector and raising questions about the sustainability of the medical countermeasure enterprise.¹⁰ Returning to a ten-year advance appropriation would provide increased certainty that will allow emerging companies like ours to continue this partnership and hopefully, encourage other innovative companies to enter this space.

Conclusion

We are proud of our partnership with BARDA and our role in contributing to the United States' preparedness for a biological attack. We encourage the Committee to reauthorize

¹⁰ Bipartisan Policy Center, Budgeting for Medical Countermeasures: An Ongoing Need for Preparedness 4, 9 (Feb. 2018).

PAHPA and build on the successes of the past twelve years to help sustain this vital public-private partnership for the years ahead.

Mr. BURGESS. Thank you, Dr. Berrey.
Mr. Decker, you're recognized for 5 minutes, please.

STATEMENT OF ERIK DECKER

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

I am the Chief Security and Privacy Officer for the University of Chicago Medicine. I also serve as the Chairman of the Advisory Board for the Associations of Executives and Health Care Information Security, otherwise known as AHIS.

AHIS is an association that represents more than 850 senior security leaders within health care. Lastly, I serve as the Industry Lead and Co-chair of a public private partnership task group sponsored by the Department of Health and Human Services for establishing cybersecurity best practices within the health care sector. This group is the result of a legislative imperative of the Cybersecurity Act of 2015, Section 405(d) and authorized under the National Infrastructure Protection Plan.

We are organized under the joint cybersecurity working group within the Healthcare Sector Coordinating Council and the Government Coordinating Council. We support the reauthorization of PAHPA. Specifically, we support the inclusion of cybersecurity as an identified hazard and the need to designate a sector-specific agency such as ASPR to interface with the health care industry.

Over the last decade, the health care sector has witnessed the evolution of cyber-attacks against our health systems. Today's cyber-attacks have become more numerous and sophisticated from the establishment of underground markets for the exchange of stolen sensitive information to the creation of a "hacking as a service industry." In the hyper-connected world of health care, the digital footprint has exploded, creating more points of entry than ever for attacks to be successful.

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

We need a system of prevention and response that is similar to the disease prevention and infection control practices within the health care industry. This system should encourage and incentivize the adoption of standard cyber hygiene practices, as our clinicians do with washing their hands, and that is capable of coordinating large-scale emergency response to cyber threats as HHS has done with the Ebola and Zika outbreaks.

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

I would like to offer a few methods that ASPR could deploy to achieve these outcomes. Number one, encourage the adoption of a

cybersecurity framework and a soon to be released top ten cybersecurity best practices within health care.

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

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

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

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

[The prepared statement of Mr. Decker follows:]

Testimony before the United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on “Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act”

2123 Rayburn Office Building

June 6, 2018

Statement of Erik Decker

Chief Security and Privacy Officer, University of Chicago Medicine

Advisory Board Chairman, Association for Executives in Healthcare Information Security

Industry Co-Chair, Cybersecurity Act of 2015 Section 405(d) Task Group on Aligning

Cybersecurity Best Practices to the Health and Public Health Sector

Summary of Testimony

Thank you, Chairman Burgess, Ranking Member Green and members of the subcommittee. It is an honor to testify on behalf of the Association for Executives in Healthcare Information Security (AEHIS), concerning the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA.)

Speaking on behalf of my colleagues, we support the reauthorization of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018. I appreciate the opportunity to discuss the need for maturing healthcare's cybersecurity resiliency and response across our nation.. We believe it is imperative that we continue to establish, modernize and mature the industry's resilience, and response, to these evolving cybersecurity threats. Specifically, we feel this reauthorization of PAHPA will address the following challenges:

1. The digital transformation of the healthcare industry that requires complicated technical platforms to achieve desired clinical outcomes;
2. The identification of modern day cybersecurity threats, and how these threats can cause significant harm to the Healthcare and Public Health Sector, and this digital platform;
3. The need for maturation of cybersecurity resiliency and capability within the industry, specifically relating to cyber programs and medical device security;
4. By leveraging ASPR as the Sector Specific Agency, encourage the coordination and deconfliction of best practices, guidance and enforcement expectations amongst the various U.S. Department of Health and Human Services (HHS) operating divisions such as OCR, FDA, CMS, and ONC; and
5. The need for further incentivization to the industry for adopting cybersecurity best practices.

TestimonyWitness Background

AEHIS is an organization that represents more than 850 Chief Information Security Officers (CISOs). Launched in 2014 under the auspices of the College of Healthcare Information Management Executives (CHIME), AEHIS provides education and professional development for senior IT security leaders in healthcare. CHIME and AEHIS members, the nation's Chief Information Officers and Chief Information Security Officers, take very seriously their responsibility to protect the privacy and security of patient data and devices networked to their systems.

In addition to serving as chairman of the AEHIS Advisory Board, I am the Chief Security and Privacy Officer at the University of Chicago Medicine. UChicago Medicine is an academic health system based in Chicago whose tripartite mission involves providing medical care to patients and the community, educating and training the next generation of physicians, and advancing medicine through innovation and scientific research.

Lastly, I serve as the co-chair and industry lead for the joint Healthcare Sector Coordinating Council (HSCC) and Government Coordinating Council (GCC) Task Group formed to improve cybersecurity in the Healthcare and Public Health sector, as required under the Cybersecurity Act of 2015 405(d) ¹.

¹ <https://www.congress.gov/bill/114th-congress/senate-bill/754>

Current State of Digital Health

The healthcare industry is undergoing significant digital modernization and with that the methods clinicians practice medicine is changing. New innovations, techniques and capabilities have been introduced to improve health outcomes, such as precision medicine, digital health strategies, telemedicine and continued development of clinical decision support processes. With this evolution the role of the clinician is also changing; they are becoming more reliant on availability of key critical information at the moment of care.

This critical information is presented through the use of new technology platforms. As the healthcare professional has specialized, so are the technology stacks that support them. From primary to quaternary care, no longer are there single monolithic systems that provide support for all aspects of the healthcare system. Today in healthcare there are large teams that directly support the patient through diagnostic, therapeutic, revenue cycle and care management services. Indirectly, operational teams support the clinicians and the system's ability to operate, such as supply chains, operations, legal, environmental and patient transport services, clinical/biomedical engineering and of course information technology.

The modern healthcare system is hyper connected to support these healthcare models. From traditional technologies such as electronic health records, revenue cycle, imaging systems and enterprise resources planning (ERP) to the connected medical devices, specialty applications, and the cloud, all of these systems are involved in the care for the patient. Additionally, providers must be able to interoperate and share common patient information between various care providers, through health exchanges. There is increasing reliance on these data being

available, and confidential, to support these nuanced clinical workflows. With the adoption of this technology, the technical ecosystem has exploded in complexity.

Current State of Cybersecurity Threats:

The healthcare industry has faced threats to the privacy of our patients' data since the inception of digital systems. In the recent past, these threats have evolved to include additional targets, namely the threats disrupting these highly interconnected digital systems and extorting the organization through ransom, and the threats to patient safety introduced through vulnerabilities in connected medical devices. Within the last year the healthcare industry has faced some significant cybersecurity attacks. Attacks like WannaCry in May of 2017 have demonstrated the necessity to being prepared for a national cybersecurity attack against our healthcare industry. The digitization of personal health information and the sharing of data encouraged by the Medicare and Medicaid EHR Incentive Program, has also led to an increase in the number and types of cybersecurity threats facing healthcare providers. Meanwhile, providers with limited resources, struggle to balance the ever-increasing demands for cybersecurity and information risk management programs.

One facet to the increase in cybersecurity attacks are due to introduction of new types of attackers. The sophistication of these attackers has dramatically shifted over the last several years, such as:

- organized crime has developed underground markets and exchanges of sensitive information and services (such as 'Hacking-as-a-Service'),

- sophisticated hacking groups who determined how to encrypt and lock up a systems digital environment and hold it for ransom,
- terrorist organizations who have a willingness to cause disruption and harm, and
- nation states interested on the theft of intellectual property for national economic advantages.

We can no longer think of preparedness relative only to natural disasters or pandemics; it's imperative that we acknowledge the criticality of cybersecurity threats levied against the nation's healthcare system.

Public-Private Collaboration

Many healthcare providers are under-resourced and need assistance navigating this new threat environment. Even those organizations who are better resourced can find the threat environment challenging. Therefore, many healthcare organizations look to their partners in the federal government for guidance to enhance preparedness and seek assistance in the event of an incident.

When the industry experienced the wide-scale attacks known as "WannaCry", the Department of Health and Human Services (HHS) acted rapidly. This response was spearheaded by the ASPR and the Healthcare Cybersecurity and Communications Integration Center (HCCIC.) The HCCIC rapidly disseminated information about the world-wide threats and hosted calls often lasting several hours open to the industry for the purpose of information sharing. The speed at which HHS acted and their inclusive approach of healthcare delivery organizations of all types and sizes should be commended. However, the HCCIC has since been the source of confusion

for providers. Specifically, confusion exists regarding the purpose of the HCCIC, the Department of Homeland Security (DHS) run National Cybersecurity and Communications Integration Center (NCCIC), and the existing industry Information Sharing and Advisory Centers (ISACs) and Information Sharing and Advisory Organizations (ISAOs).

The passage of the Cybersecurity Act of 2015² in December 2015, specifically the inclusion of section 405, marked Congressional recognition of the need to evaluate and enhance the cybersecurity posture of the healthcare industry, something strongly supported by our members.

Within section 405, provision (d) instructed HHS and industry to “align health care industry security approaches” and develop “a common set of voluntary, consensus based, and industry-led guidelines, best practices, methodologies, procedures, and processes,” that are scalable and cost-effectively reduce risks for a range of healthcare organizations. In May of 2017, the so-called 405(d) task group was formed consisting of over 100 industry and government experts. The membership of this task group covers a large spectrum of our industry, from small practice providers, to large health system chief security officers, as well as a contingent of government agency representation from within HHS, DHS and the National Institute of Standards and Technology (NIST.)

As co-lead of this task group, I am please to report we have developed a series of cybersecurity best practices for small, medium and large healthcare organizations which will help mitigate the top cybersecurity threats we face today. We expect to provide the best practices to the Secretary

² <https://docs.house.gov/billsthisweek/20151214/CPRT-114-HPRT-RU00-SAHR2029-AMNT1final.pdf>

for dissemination to the industry before the end of 2018. This effort has been a fantastic example of public-private partnerships and what is possible with an inclusive approach, leveraging the expertise of representatives from across the industry, with the backing of the federal government.

A separate directive from the Cybersecurity Act of 2015 was a mandate for HHS to issue a clear statement defining “the official within the Department of Health and Human Services to be responsible for leading and coordinating efforts of the Department regarding cybersecurity threats in the health care industry.” Today, AEHIS members cite confusion about who leads HHS’ cybersecurity programs and the correct way to communicate with the Department concerning cybersecurity-related issues. Additionally, AEHIS members cite concern about sharing information that might elicit an enforcement action from the regulatory arm of HHS. However, in this modern age of cybersecurity attacks, the need to share this information is vital for protecting our industry. We feel PAHPA clarifies the intent of creating a Sector Specific Agency that can work proactively and reactively with the Healthcare industry and help to coordinate and deconflict issues relating to regulation, guidance and best practices issued by the various HHS operating divisions. By example, having an impartial agency, such as ASPR, coordinate the intersection of cybersecurity challenges relating to medical devices and two regulatory bodies (FDA and OCR) would be incredibly beneficial for the industry. Navigating the guidance gaps and intersections today hinders the ability for industry to be nimble at its protection and response.

We agree that cybersecurity threats are just another type of hazard that must be managed. As such, we feel ASPR is well situated to be the appropriate operating division to coordinate these

necessary national responses, as well as interfacing with regional and local public health departments as necessary, in the event of such a large-scale cybersecurity event. We do believe for ASPR to be successful in preparedness and response that specific cybersecurity expertise will be necessary, as well as the supporting financial resources.

These efforts should not duplicate existing successful industry practices, such as information sharing which should continue through the information sharing and analysis centers (ISACs) and information sharing and analysis organizations (ISAOs). The ISACs and ISAOs are the preferred method for disseminating and sharing technically relevant cybersecurity threat and mitigation details. We believe ASPR, HCCIC or NCCIC, with the right authority, would be well suited for coordinating activities and leveraging existing resources, as needed.

Medical Devices

Given healthcare has entered an era of ubiquitous connection, and the internet of things (IoT) is transforming healthcare along with the world's economy, our members continue to worry about the threats to patient safety the cybersecurity attacks pose. Tens of thousands of medical devices can be used throughout large healthcare systems, many of which are connected directly to the patient or serving to provide information to inform clinical decision making. Wearables and medical devices are being directly connected to electronic health record (EHR) systems, which generates additional data for clinical decision making but also increases the threat surface. Just in healthcare alone, the growth of IoT connections from 2014 to 2015 increased by 26 percent.³

³ *State of the Market: Internet of Things 2016*,
<https://www.verizon.com/about/sites/default/files/state-of-the-internet-of-things-market-report-2016.pdf>

And, since a typical hospital bed has between 10-15 devices connected to it, the footprint to infiltrate a healthcare system and risks to patient safety are increasing.

With cyberattacks like Petya and WannaCry showing just how vulnerable some network connected devices can be, action must be taken to secure the healthcare industry. Viewing security as a component of safety and efficacy of device functions, and embracing “security by design”, are necessary to keep pace with these variable threats. A secure healthcare system will ultimately enable greater consumer confidence and will spur better care coordination, enhanced information exchange and improved patient care.

Incentives

To further enhance proactive collaboration, we believe it important to incentivize the industry for the adoption of these cybersecurity practices. Incentives could come in many forms, such as monetary subsidy or safe harbors from enforcement actions. This will encourage the investment into cybersecurity from the providers in an age when it is understood no organization can prevent all cybersecurity attacks. Specifically, we encourage HHS offer enforcement flexibility for those providers who: 1) demonstrate adoption of the NIST Cybersecurity Framework; and 2) adopt the relevant best practices being delivered through the CSA 2015 405(d) Task Group.

The Committee’s interest in this topic is timely, and efforts to enhance the cybersecurity of our nation’s healthcare system are to be commended. On behalf of AEHIS and my colleague healthcare CISOs, I sincerely thank the Committee for allowing me to speak regarding the reauthorization of the Pandemic and All-Hazards Preparedness Act. I look forward to answering your questions.

Mr. BURGESS. And I thank all of our witnesses for their testimony. We will proceed into the question and answer portion of the hearing. I will recognize myself 5 minutes for questions.

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

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

[The information appears at the conclusion of the hearing.]

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

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

Dr. SHAH. Thank you, Mr. Chairman.

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

Initially, it was you have a hit, it is an act of intent and you have to launch an all public health response to it. That has now shifted, fortunately, in a way that it is a laboratory confirmation—a sensor positive that doesn't necessarily mean that it's a public health positive, and this is the difference between the science of public health and the art of public health where we have to put all the other epidemiologic data, all the other environmental health data, all of the other factors in so we can make a determination whether this is truly a terrorist attack or a terrorist threat, and that, I think, is the way to go. But what that really implies is that we have to make sure that the technology is as strong as it can be, it's as certain as possible to give us the right result.

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

Mr. BURGESS. So if I could ask, what is the state of the art? The level of precision that is now technically available is—obviously, you can work with that at the local level?

Dr. SHAH. Yes, we can. There are some challenges with the proposed some technologies that were there.

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

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

Mr. BURGESS. Thank you for that answer.

Dr. Berrey, I referenced I went to medical school in Houston. It was a number of years ago. The New England Journal of Medicine back in 1974 or 1975 or 1976 talked about the fact that smallpox was going to be eradicated from the face of the earth. As I sat in my study cubicle that day in the mid-1970s I thought it was until I arrived here a number of years later as a member of Congress and found out that it wasn't.

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

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

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

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

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

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

Mr. BURGESS. Thank you for that.

My time has expired. I will recognize the gentleman from Texas, Mr. Green, 5 minutes for questions, please.

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

I know in the Houston areas that I represent we have a coordinated effort. Both our county judge, Ed Emmett in the city of Hous-

ton and Harris County and some of the responses that we've had necessitate the deployment of the national strategic stockpile.

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

With the likely transfer of SNS from CDC to ASPR, do you foresee any possible disruptions to the planning, coordination, and development of the SNS in future events, given that frequency, intensity of weather-related events will only increase?

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

What I would say is that Hurricane Harvey was the culmination and the continuation of a lot of the lessons that we have learned over the decade plus since Tropical Storm Allison. And, fortunately, we have learned those lessons and there has been an incredible amount of investment in both public health and health care. With respect to the SNS, as you heard from the earlier panel, there certainly are challenges as we think about a transfer and there's some uncertainty at least at the local level of what exactly this means when they say it's being moved from the CDC to ASPR.

The biggest concern that I would put out there is the fact that we know that ASPR is responsible for hospital readiness and health care readiness, and we also know that oftentimes public health gets drowned out by the hospitals and healthcare system. And so one of the biggest challenges we would have as moving SNS over to ASPR is to ensure that it does not get lost in all the public health activities that we at the local level and the state level, that we require from an SNS as well—from our Federal partners. And so ensuring that the legislation has that built in is absolutely critical. The other aspect of this is the federal medical station that was deployed during SNS for Hurricane Harvey response was very much about really having a field hospital that we were able to rely on.

Unfortunately, Florida and Hurricane Irma happened right afterwards and it started to move. And so one of our big challenges is to ensure that when we have multiple emergencies happening how do we really try to figure out what those Federal assets are and how we can use them locally as well as across the system. I think that's another challenge.

Mr. GREEN. Well, I appreciate it, because I know the response with Hurricane Harvey and Katrina—when the CDC came in we were treating a lot of our visitors, who are now Texans, from Louisiana. CDC can bring other resources, including the public health service, and I just didn't want to disrupt some of the good things we had.

If you have any suggestions on how we may make sure that that process will not lose the success we have now, I would be glad to see what we can do when we are marking up the bill, because that's my concern—the change from CDC to ASPR, which is a great agency, but I don't want to lose that effort.

Dr. Shah, one of the other concerns I have is we spent some today discussing the importance of well-funded public health infrastructure for preparedness and response.

A related discussion in the provision of the bill would allow the secretary to transfer 1 percent of any appropriation to the public health emergency response fund. The intent of the fund is to provide a source of extra funding for responding to public emergencies like Katrina or Harvey.

However, in your written testimony, you indicated that you had significant concerns about the transfer authority. Specifically, you mentioned that the authority will take away vital dollars from other public health programs.

And my question is from the perspective of the local public health officials on the ground can you describe the challenges that would occur from allowing the secretary to transfer 1 percent of HHS funding to the public health emergency response in case of a public health emergency declaration?

Dr. SHAH. Thank you again for that question.

What I would say is that we recognize the importance of having a fund because in the midst of an emergency you have to have that funding ready right then. You cannot wait months or some period of time to get those dollars back into the system.

The challenge that we have is that while we were looking at what happened during Zika, we started to go back and pull dollars from Ebola. But Ebola was still a threat while we were also trying to find the dollars over to Zika.

And at our own health department, for example, we had hired a physician for chronic disease prevention for diabetes and high blood pressure and immediately because we did not have those funds we had to move that physician over to be part of the response system for Zika.

And so I think it's a real challenge that we have to remember that there are multiple challenges and issues the public health departments at the local level are facing all the time. What we don't want to have happen is in mid-cycle dollars are shifted from one place to another and you now start to lose infrastructure in that existing area that is equally important.

And we also have to remember that multiple emergencies can happen at the same time. So yes, those are our concerns, Congressman, that we are interested in discussing.

Mr. GREEN. Thank you. I know I am out of time but that's another issue we'll look at because I still have my constituents waiting for FEMA assistance 10 months now since Harvey and I would not like to have our public health have to wait that long because then we could end up with epidemics.

Thank you, Mr. Chairman.

Dr. SHAH. When you wait for dollars that can cost lives, and so that's very important. Thank you.

Mr. BURGESS. The chair thanks the gentleman.

The chair recognizes the gentlelady from Indiana 5 minutes for questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman.

Dr. Berrey, in 2004 Congress passed the Project BioShield Act, which created the special reserve fund of \$5.6 billion made avail-

able over a 10-year period to help create stability and ease concerns from companies about the likelihood of—help them decide about whether or not to get into the market for medical countermeasures. That has traditionally been unprofitable, and once this initial funding expired, Congress reverted to appropriating for the program on an annual basis, which I understand has created less long-term certainty.

Do you agree that recommitting to a multi-year funding approach for medical countermeasures development and procurement would help strengthen our nation against biological threats and could you please talk about whether or not it's incentives or how can we better prioritize our existing funding for medical countermeasures?

Dr. BERREY. Absolutely. Thank you, Congresswoman Brooks, and I want to thank both you and Congresswoman Eshoo for sponsoring this bill.

I will say without question that having Federal moneys available for support of these long-term research and development projects is absolutely critical. We know that the private sector does not establish the same value—does not support those programs, especially these longer-term programs, and thus it is critical that we have federal moneys available.

We've seen the impact in other small and large companies that are committed to this space. But without a multi-year authorization have seen the dollar value and the size of those procurement contracts decrease because BARDA does not have that capability of having the security of a longer-term multi-year commitment there. Having that dedicated fund is absolutely critical. We believe in dual use and both the economic and the medical benefits that dual-use compounds can bring.

We've seen benefits to our medical countermeasure program that have been exclusively paid for through our private sector dollars. One specific example is optimization of our pediatric suspension. We now have a suspension that has no need for refrigeration, which is ideal for the SNS, and because we are treating children through our clinical program for adenovirus, we have real-world data that can support the dosing information specific for pediatric use in the event of a smallpox outbreak.

I believe that both the long-term funding and continued support through PAHPA reauthorization are critical for that but, secondly, I wanted to make the point that I do believe dual-use compounds, even though they do bring additional challenges, have additional economic benefits.

Mrs. BROOKS. Thank you.

Mr. Decker, the Blue Ribbon Study Panel on Biodefense called for the development and implementation of a government-wide security strategy for stored pathogen data that incorporates deterrent and enforcement measures, oversight, and inspection.

Would you be willing or interested in contributing to such a process and do you believe a strategy like this would improve the security of sensitive public health information?

Mr. DECKER. Well, certainly, I think that focusing any amount of preparation and effort on securing sensitive information is going to be important.

I am not familiar with that particular provision so I am happy to take that back and provide an answer to you, if you'd like.

Mrs. BROOKS. Are you familiar with the Blue Ribbon Study Panel on Biodefense and recommendations they made?

Mr. DECKER. No, I am not.

Mrs. BROOKS. OK. Well, we would welcome the opportunity to work with you on that and to get your further thoughts on what they recommended.

And finally, Dr. Shah, if we could just go in a little bit with respect—can you help us understand the role that CDC—we've certainly had quite a debate and discussion this morning about CDC's role and what would you say?

Are there any additional tools CDC needs that—or resources that they need that we ought to be providing as we explore what their role is, going forward, relative to ASPR's?

Dr. SHAH. Yes, that's a tough one. Thank you for that question.

That's a tough one only because there are a number of needs that public health in general has at the Federal, state, and local level. And so I could really have a nice—

Mrs. BROOKS. That's a huge lecture. I understand that.

Dr. SHAH. Yes. Yes. Exactly. Exactly.

That said, I do think that outside of supply chain logistics and those kinds of things that, obviously, and ASPR would be very good at doing, there would be an opportunity really to be looking at the real consultation and the technical assistance—

Mrs. BROOKS. Right.

Dr. SHAH [continuing]. And the support that's given to local and state health departments. Really, that's what CDC is really, really good at—technical assistance and really being able to pick up a phone and call and/or even deploy in if you need help and assistance and want to make sure that that consultation piece is available.

But also the real piece about the support that is given to local health departments as they're doing their work. If this shifts over to ASPR and that piece is not so strong then at the end of the day the last mile is really the most important piece about SNS is how do you get medications into the mouths of people and you want to make sure that local health departments have the support to be able to get that done well and that, obviously, would mean that we would continue to have that support from whomever is going to be providing it.

So those guardrails really need to be in place.

Mrs. BROOKS. Thank you. I agree. I yield back.

Mr. GUTHRIE [presiding]. The gentlelady yields back and I will recognize myself for 5 minutes to ask questions, and thank you all for being here today.

And Dr. Shah, this is for you. During an Ebola outbreak in West Africa—the Ebola outbreak in 2014, much was made about the lack of standards and guidelines for the use of personal protective equipment in hospitals that were treating infected patients.

What are your thoughts on establishing reasonable personal protective equipment guidelines and requirements for emergency medical service personnel in advance of a biological event based on existing research and lessons learned?

Dr. SHAH. Thank you for that question.

I would say, first of all, there are a few things about Ebola. I think Ebola and Zika and H1N1, the pandemic, teach us that global health is very much connected with domestic health and we have to keep that in mind.

So, really, the way to be able to interrupt the transmission or get to zero risk for the American people is to be able to interrupt transmission in global communities, for example, in West Africa in 2014 or in the case of Zika in Latin American and Caribbean countries.

That also, obviously, is a concern now with the Democratic Republic of Congo with DRC because the concern now is does this get into an urban environment that potentially you could get spread and get on a plane and you can now get to North America and here we are, we are back and playing for years later a very similar situation.

So we work very closely with our environmental health folks. The environmental health field is amazing when it comes to really helping us as well as the occupational health field when it comes to those personal protective equipment and those environment changes that need to be made and we really believe with a disease like Ebola, because it's so meticulous that you have to use personal protective equipment every single time, we have to recognize the absolute importance of ensuring that we are working with our private sector that are designing these suits, designing those gloves, designing those masks, designing all those materials but we also train local practitioners so they know what they're doing, how they're doing it, how they're putting it on, how they're using it so they are meticulous.

One example I will give you is from Hurricane Harvey. We have J.R. Atkins, who was an EMS responder, who volunteered. He was meticulous about using personal protective equipment except one time where he was bitten by a mosquito—it was a spider, most likely, and he wound up having necrotizing fasciitis, a flesh-eating bacteria, and we wound up going to the operating room three to five times.

So we have to be meticulous when it comes to infectious disease control and we certainly support that.

Mr. GUTHRIE. OK. Thank you very much.

And this for you but anybody on the panel that would like to address it—the public health emergency preparedness cooperative agreement is an annual source of direct funding for state and local public health systems.

Can you speak about the importance of these agreements in terms of capability to address biological threats and how do state, local, and territorial public officials leverage the Federal support and how does it help prepare the country for the next outbreak?

Dr. SHAH. Thank you again for that question.

What I would say is that we recognize that there is a lot of capacity already at the local and state level. There is a lot that's already being done with the resources that we have in state and local communities.

But it would be important to say that public health emergency preparedness funding—that 55 percent of local health departments are actually relying on those dollars for their preparedness work.

It is so critical to many of our local health departments, especially the smaller local health departments, the more frontier local health departments. We have to make sure that those dollars are available and that they can support and really augment what's already happening at the local level.

The other piece around the biologics is that we want to make sure that there is improved recognition of quicker digital systems and recognition of surveillance systems that really allow us to do disease pattern recognition.

The final point that I would make in the interest of time is the fact that we have to really be thinking about where the risk is, where the threats are, and really ensuring that those dollars are going not just to certain areas of a community but all of a community to make sure that those dollars are really reaching those local health agencies that are boots on the ground to ensure that they can do the work that they're doing.

Mr. GUTHRIE. Thank you.

Anybody comment? I know that's more his area but anybody want to comment on that as well?

Dr. BERREY. The only additional point that I would make is as we look back on smallpox and as Chairman Burgess noted earlier that we haven't seen smallpox since the 1970s. So when you think about the physicians that are currently staffing emergency rooms, it's very unlikely that any of the physicians who are currently serving in those first response settings have actually seen smallpox.

So a big component not just in diagnosis is first to think about this could be a bioweapon, could be a chemical weapon, reflect recently on coverage of the nurses who was treating the Russian spy and his daughter who entered into the emergency room considered it was mostly likely an opioid overdose, and only an hour later as the police officer was brought in with similar symptoms did they realize that this was not in fact an opioid overdose.

So we really have to go back to thinking about those zebras. When you hear hoof beats, don't always think of zebras, but today might be the day for us to begin remembering those zebras. We can be educating our physicians to think about early diagnosis and give them the tools to make sure that diagnosis can occur rapidly.

Mr. GUTHRIE. Thank you. My time is expired.

I will recognize the gentleman from Missouri, Mr. Long, for 5 minutes for questions.

Mr. LONG. Thank you, Mr. Chairman.

Mr. Decker, did you participate in the industry calls that HHS led during the WannaCry cyber-attack?

Mr. DECKER. Yes, I did.

Mr. LONG. Did you find them valuable?

Mr. DECKER. Yes, I did. What was valuable was getting the information out to all the health systems so that we could understand what was happening—if we were being impacted. Having a sort of a pulse on what was going on in Europe and the U.K. at the time and if that was coming over across the pond was important.

There was some confusion on some of the calls—some information that came out of those calls that was technical in nature and it was not necessarily related to the actual technical nature of the

attack that was occurring. But the coordinated and facilitation effort of what those calls were doing was highly useful.

Mr. LONG. So I am assuming that you did find it valuable to interact with HHS in real time?

Mr. DECKER. Absolutely.

Mr. LONG. Do you think that if another WannaCry attack took place today HHS would be able to serve a similar kind of function?

Mr. DECKER. I think they would stand up a similar type of activity—an incident response function like that. I think it would be beneficial for the preparedness of that response to be a little more coordinated.

The means by which HHS is facilitating the process versus the means by which information sharing and analysis centers facilitate technical and distribute technical information down to the health systems, I think there's some better coordination that could occur there as well as some further monitoring of the other critical infrastructures that's occurring.

But, ultimately, you know, having HHS serve as the focal point and facilitation point and the coordination point for a national response so that we can have an open line of communication with them in case we need help is, I think, incredibly important.

Mr. LONG. If another cybersecurity incident like WannaCry were to take place, would you want to contact HHS for guidance and additional information?

Mr. DECKER. Personally, yes. I think there's also a bit of hesitancy from some of our constituents on HHS being a regulator as well as an office that provides support and resources.

I think there's a hesitancy for some to not open up the lines of communication. So I think that further bolstering the knowledge of who that sector-specific agency is, what the protection is—

Mr. LONG. Knowledge of what? I am sorry.

Mr. DECKER. Of who the sector-specific agency is and how we can communicate with them under protection is something that would help with disseminating that information.

Mr. LONG. If it did happen again, who would you want to contact at HHS and how do you know that that would be the right person to contact?

Mr. DECKER. Yes. So contacting ASPR would be on the list as well—now, ASPR would probably be the main focus point, or the MCIC within the Department of Health and Human—or DHS.

Mr. LONG. You mentioned some people might have concerns about sharing information with HHS since HHS is your regulator—

Mr. DECKER. Yes.

Mr. LONG [continuing]. In addition to your sector-specific agency. You said other people had that concern. Do you share that concern?

Mr. DECKER. Do I share that concern?

I think there is a clear line between which operating division is responsible for interfacing with industry and which is responsible for regulating the industry.

But I don't think that is common knowledge throughout all the healthcare industry. I think people see HHS as the regulator. They don't understand the intricacies inside of HHS.

So though I understand the difference between what ASPR is, what OCR, what ONC, CMS, et cetera, are, I think it's not common knowledge.

Mr. LONG. What steps could HHS take to address some of the concerns that you detail?

Mr. DECKER. A lot of focused education and awareness I think would be important. Designating a very specific agency that's going to be responsible for coordinating with the industry is, I think, very important.

Being able to facilitate the various guidance between OCR, FDA, ONC, CMS, et cetera, because all of those operating divisions produce guidance for cybersecurity for the health care industry.

But it's potentially in conflicting matters and so deconflicting the guidance that comes out and being able to really lower the barrier of entry to the cyber space I think is going to be important, especially for the smaller practice organizations like small practices, one- or two-physician practices, critical access hospitals, community hospitals where they're resource strapped and every dollar that they have, if they spend it on cyber or if they spend it on public health, or they spend it on something is something they have to consider.

Mr. LONG. With all the players involved in the soup it sounds like acronymology to me.

Mr. DECKER. It is a little bit.

[Laughter.]

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

Mr. BURGESS [presiding]. The chair thanks the gentleman. The gentleman yields back. We are just about to have votes on the floor so it looks like there are no further members wishing to ask questions.

So I want to thank our witnesses for being here with us today. Pursuant to committee rules, I will remind members they have 10 business days to submit additional questions for the record. I am going to ask witnesses to submit their response within 10 business days upon receipt of those questions.

I would also like to submit documents from the following, for the record: American Academy of Pediatrics, the American Hospital Association, the American Society for Microbiology, America's Essential Hospitals, Global Health Technologies Coalition, Healthcare Leadership Council, Infectious Disease Society of America, International Safety Equipment Association, and the Trust for America's Health statement.

Again, members have 10 business days to submit additional questions. I ask the witnesses to submit their responses within 10 business days of the receipt of those questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 1:13 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]



The NEW ENGLAND JOURNAL *of* MEDICINE

Perspective

MAY 31, 2018

SHATTUCK LECTURE

Innovation for Pandemics

Bill Gates

Over recent decades, the world has seen incredible progress in reducing child mortality and tackling infectious diseases. Thanks to better vaccines and other interventions, child mortality has

decreased by more than 50% since 1990. We are on the verge of eradicating polio. HIV is no longer a certain death sentence. And half the world is now malaria-free.

Yet there is one area where the world isn't making much progress: pandemic preparedness. This failure should concern us all, because history has taught us there will be another deadly global pandemic. We can't predict when, but given the continual emergence of new pathogens, the increasing risk of a bioterror attack, and the ever-increasing connectedness of our world, there is a significant probability that a large and lethal modern-day pandemic will occur in our lifetime.

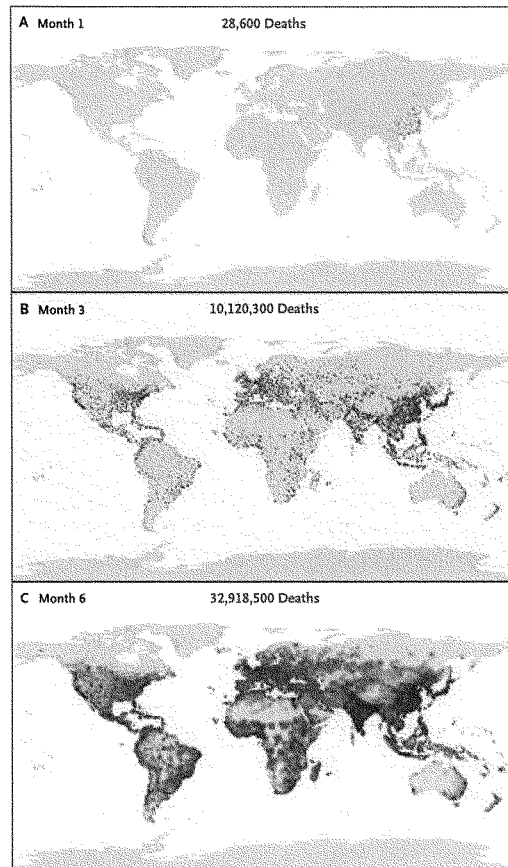
Several events in the past decade have made me pay close at-

tention to the risk of future pandemics. One was the outbreak of swine flu in 2009. Although H1N1 influenza wasn't as lethal as people initially feared, it called attention to our inability to track the spread of disease and develop new tools for public health emergencies. The Ebola epidemic in West Africa 4 years ago was another wake-up call, as the number of confirmed cases climbed, the death toll mounted, and local health systems collapsed. Again, the world was much too slow to respond. And every year, advances in science make it easier for somebody to create a biologic weapon of mass destruction.

What the world needs is a coordinated global approach to pandemics that will work regardless

of whether the next pandemic is a product of humans or of nature. Specifically, we need better tools, an early detection system, and a global response system.

This year is the centenary of the 1918 influenza epidemic, which killed an estimated 50 million people.¹ We have some better interventions than we had a century ago. We have a seasonal influenza vaccine, although it's not often fully effective, you have to get it every year, and the percentage of people who choose to get it is fairly small. We also have antibiotics that would help with the secondary infections from bacterial pneumonia. Yet despite these advances, a simulation by the Institute for Disease Modeling shows what would happen if a highly contagious and lethal airborne pathogen, like the 1918 influenza, were to appear today. Nearly 33 million people worldwide would die in just 6 months (see map).



Simulation of a Modern-Day Global Influenza Pandemic.

After 1 month (Panel A), there would be a total of approximately 28,600 deaths; after 3 months (Panel B), 10,120,300 deaths; and after 6 months (Panel C), 32,918,500 deaths worldwide. From the Institute for Disease Modeling. An animated map is available with the full text of this article at NEJM.org.



An animated
map is available
at NEJM.org

The good news is that scientific advances and growing interest by a number of actors, including some in the private sector as well as philanthropic funders, make

development of a universal influenza vaccine more likely than in the past.

Our foundation is involved in a variety of research partnerships, including a collaboration among

the Icahn School of Medicine at Mount Sinai, GlaxoSmithKline, and PATH. Their work focuses on several vaccine candidates that did well in trials in animals and are now moving to human trials. We are also supporting efforts by others, including the National Institute of Allergy and Infectious Diseases, whose vaccine candidate is expected to advance to human trials in about a year.

To broaden these efforts even further, we launched a \$12 million Grand Challenge in partnership with the Page family to accelerate the development of a universal influenza vaccine.² The goal is to encourage bold, cross-disciplinary thinking by the world's best scientists, including those who are new to the field.

However, the next threat may not be influenza at all. It may well be an unknown pathogen that we see for the first time during an outbreak, as was the case with SARS (severe acute respiratory syndrome), MERS (Middle East respiratory syndrome), and other recently discovered infectious diseases.

The world took a step to begin addressing this risk with the launch in 2017 of a public-private partnership called the Coalition for Epidemic Preparedness Innovations (CEPI). With funding commitments of more than \$630 million, CEPI's first order of business is advancing the development of vaccines for three of the priority diseases on the World Health Organization (WHO) list for public health research and development: Lassa fever, Nipah virus, and MERS.

CEPI will also be working on rapid-response platforms to produce safe, effective vaccines for a range of infectious diseases. Later

this year, the coalition will announce grants to several companies, working with a variety of technologies, including nucleic acid vaccines, viral vectors, and other innovative approaches. The goal is the capability to develop, test, and release new vaccines in a matter of months rather than years.

But vaccines can't be the only answer when we have to respond immediately to a rapidly spreading infectious disease. Not only do vaccines take time to develop and deploy, they also take at least a couple of weeks after vaccination to generate protective immunity. So we need to invest in other approaches, such as antiviral drugs and antibody therapies that can be stockpiled or rapidly manufactured to stop the spread of pandemic diseases or to treat people who have been exposed.

There has been good work on specific antivirals in the past decade. For example, in the HIV field, the quality of the antivirals is phenomenal and suggests that broader-spectrum antivirals could be developed. For influenza, the Shionogi pharmaceutical company received approval in Japan for a new antiviral, Xofluza.³ This single-dose drug inhibits an enzyme that influenza virus needs in order to multiply. Another approach, taken by PrEP Biopharm, a development-stage biopharmaceutical company, has demonstrated in challenge studies in humans that preactivating the immune response through intranasal delivery of a double-stranded viral RNA mimic can help prevent both influenza and rhinovirus.⁴ Since the innate immune response is non-virus-specific, this approach has potential for use against a range of respiratory viruses.

Over the past few decades, there has also been great progress

in monoclonal antibody therapies, leading to new products for cancer and autoimmune diseases. During the Ebola outbreak in West Africa several years ago, researchers were able to identify and test a combination of monoclonal antibodies to treat infected patients. The overall estimated effect of the treatment appeared to be beneficial, though the result did not meet the prespecified statistical threshold for efficacy. And a growing pipeline of broadly neutralizing antibodies are being discovered in some people exposed to infectious diseases. For example, in a small percentage of people infected with HIV, antibodies with both high potency and broad coverage develop, sufficient to protect against most strains of the virus. The same is true for some people infected with influenza. Various combinations of these exceptional antibodies may be able to protect against pandemic strains of a virus even if it has evolved genetically from the time of its detection and identification. It is conceivable that we could create libraries of these antibodies and produce manufacturable seed stocks that would enable us to have the antibodies ready for immediate use in an outbreak — or to scale up manufacturing if a pandemic occurs.

If we can learn how to use RNA or gene delivery effectively, we may not need to make the antibodies at all. Instead, new methods of gene delivery could enable our own cells to produce these antibodies directly. These approaches are promising because the protection comes literally within hours after the antibodies are injected into the arm.

At the Munich Security Conference last year, I asked world

leaders to imagine that somewhere in the world a new weapon exists or could emerge that is capable of killing millions of people, bringing economies to a standstill, and casting nations into chaos. If it were a military weapon, the response would be to do everything possible to develop countermeasures. In the case of biologic threats, that sense of urgency is lacking. But the world needs to prepare for pandemics in the same serious way it prepares for war. This preparation includes staging simulations, war games, and preparedness exercises so that we can better understand how diseases will spread and how to deal with responses such as quarantine and communications to minimize panic.

Earlier this year, the U.S. Congress directed the administration to come up with a comprehensive plan to strengthen global health security, both here and abroad. Such a plan could be an important first step if the White House and Congress use the opportunity to articulate a leadership role for the United States in global health security. Given the depth of U.S. scientific and technical expertise, our innovative biopharmaceutical industry, and our influence in international forums, the United States can and should play a leadership role in developing the kind of pandemic preparedness and response system the world needs.

The global community eradicated smallpox, a disease that killed an estimated 300 million people in the 20th century alone. We are on the verge of eradicating polio, a disease that 30 years ago was endemic in 125 countries and that paralyzed or killed 350,000 children per year. And today, nearly 21 million people

are receiving lifesaving HIV treatment, thanks primarily to the support of the world community.

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) was the key catalyst for world action on the AIDS crisis. It's an example of the kind of leadership that's needed for broader efforts to make the world safer from other infectious disease threats. Because of its strong bipartisan support, PEPFAR has saved millions of lives and shown that national governments can work together to address diseases.

We need a clear road map for a comprehensive pandemic preparedness and response system, because lives, in numbers too great to comprehend, depend on it.

Editor's note: This year's Shattuck Lecture was delivered at the annual meeting of the Massachusetts Medical Society as part of an educational event entitled Epidemics Going Viral: Innovation vs. Nature. Videos of the event, which included two panel discussions, the Gates lecture, and a Q&A session, are available at NEJM.org.

Disclosure forms provided by the author are available at NEJM.org.

From the Bill and Melinda Gates Foundation, Seattle.

1. Johnson NP, Mueller J. Updating the accounts: global mortality of the 1918-1920 "Spanish" influenza pandemic. *Bull Hist Med* 2002;76:105-15.
2. Bill and Melinda Gates Foundation. Ending the pandemic threat: a grand challenge for universal influenza vaccine development (<https://gchgh.grandchallenges.org/challenge/ending-pandemic-threat-grand-challenge-universal-influenza-vaccine-development>).
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Beyond Legalization — Dilemmas Physicians Confront Regarding Aid in Dying

Bernard Lo, M.D.

“What do you think about physician aid in dying?”

Because 18.2% of the U.S. population lives in jurisdictions where physician aid in dying (PAD) is now legal, physicians need to anticipate that patients may inquire about or request it. Two decades ago, when PAD was illegal throughout the United States, 18.3% of physicians reported ever having received a request for assisted suicide¹; inquiries are likely to be more frequent now. But physicians may feel unprepared, uncertain, and uncomfortable when confronting these conversations, even if they've thought through their own position on PAD legalization.

Physicians can start by clarifying what patients are asking and why. Some ways in which patients might raise the topic of PAD are listed in the box. Not every question about PAD is a request for assisted suicide. Patients might

be seeking information, talking through concerns, expressing distress, or trying to ascertain the physician's views. To clarify the patient's motivation, physicians might say, “I'll be glad to answer that question, but first please tell me what led you to ask.”

Next, physicians can explore patients' concerns and identify and address their palliative care needs,² regardless of the physicians' own views or the legal status of PAD where they practice. Discussions could cover patients' physical symptoms; psychosocial, existential, and spiritual suffering; hopes and fears; and goals of care. All options for end-of-life care should be discussed, including palliative and hospice care and palliative sedation.

It's also important for physicians to think through what actions they're willing to take. Both physicians who support PAD and those who oppose it should try

to relieve patients' multidimensional concerns and distress. After comprehensive palliative care is intensified, 46% of patients who have requested PAD change their minds.³

Physicians who support PAD face several decisions regarding patient inquiries. First, are they willing to assist any patient who meets the legal requirements for PAD, or will they participate only in certain circumstances? Physicians are most likely to support PAD in cases of unremitting pain.⁴ Many physicians who support PAD legalization may have cases of refractory physical suffering in mind. But perceived loss of autonomy and dignity is now a more common reason for requesting PAD than inadequate pain control.⁵ Some physicians may decide they aren't comfortable assisting in a patient's death in such circumstances.⁶

Responses may also be influ-

June 5, 2018

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
Committee on Energy and Commerce
2336 Rayburn House Office Building
Washington, DC 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
2470 Rayburn House Office Building
Washington, DC 20515

The Honorable Susan W. Brooks
1030 Longworth House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
241 Cannon House Office Building
Washington, DC 20515

Dear Chairman Burgess, Ranking Member Green, and Representatives Brooks and Eshoo:

As organizations that care deeply about the health and well-being of children, we thank you for your bipartisan commitment to reauthorizing the *Pandemic and All-Hazards Preparedness Act*. As the *Pandemic and All-Hazards Preparedness (PAHPA) Reauthorization Act of 2018* moves forward, we urge you to address the ongoing gaps in our nation's preparedness and response for children by including two provisions supported by our organizations. Recent natural disasters such as Hurricanes Harvey, Irma and Maria have demonstrated that our nation still is not fully prepared to respond to the medical and mental health needs of children.

First, while we appreciate that the discussion draft for the *Pandemic and All-Hazards Preparedness (PAHPA) Reauthorization Act of 2018* extends the HHS National Advisory Committee on Children and Disasters (NACCD) for five years, we urge you to add additional expertise to the NACCD including non-federal experts in pediatric mental or behavioral health, pediatric infectious disease, children's hospitals, children and youth with special health care needs, among others. It is essential that the NACCD be adequately funded and required to meet at least once in person.

The NACCD was established to provide advice and consultation to the Department of Health and Human Services (HHS) Secretary and the Assistant Secretary for Preparedness and Response (ASPR) on issues related to the medical and public health needs of children before, during, and after disasters. The NACCD has completed several reports in recent years focused on youth leadership, surge capacity, and the provision of human services. Their expertise has been invaluable in ensuring that children are protected during public health emergencies and disasters. We hope you will include our recommendations for modest improvements to the NACCD in the *Pandemic and All-Hazards Preparedness (PAHPA) Reauthorization Act of 2018*.

Second, we urge congress to authorize the Children's Preparedness Unit (CPU) at the Centers for Disease Control and Prevention (CDC) as part of PAHPA reauthorization. The CPU provides the CDC and its grantees with critical technical assistance, training, and consultation to improve preparedness and response capabilities for children. The CPU has proven to be an invaluable resource to the CDC, the pediatrician community, schools, and other child-serving institutions during recent emergencies such as

Ebola and Zika. It is a model for public-private collaboration between pediatrics and the public health sector and enhances efforts to safeguard and improve the health of our nation's children.

Children are not little adults. They have specialized needs that must be considered when planning for, responding to, and recovering from a disaster. This includes having a strong, well-funded public health and medical system. We thank you for your consideration and urge the inclusion of our recommendation as the *Pandemic and All-Hazards Preparedness (PAHPA) Reauthorization Act of 2018* advances. For further information and draft language for these provisions, please contact Tamar Magarik Haro (tharo@aap.org) in the American Academy of Pediatrics Washington Office at 202-347-8600.

Sincerely,

American Academy of Pediatrics
 Child Care Aware® of America
 Children's Hospital Association
 Family Focused Treatment Association
 National WIC Association
 Public Advocacy for Kids
 Trust for America's Health



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June 6, 2018

The Honorable Susan W. Brooks
United States House of Representatives
1030 Longworth House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
United States House of Representatives
241 Cannon House Office Building
Washington, DC 20515

Dear Representatives Brooks and Eshoo:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Energy and Commerce Committee Subcommittee on Health's discussion draft, titled the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2018."

We appreciate the Subcommittee's willingness to engage stakeholders as the work toward reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA) proceeds. Our member hospitals and health systems play a critical role in all types of disasters and public health emergencies, and we share the Subcommittee's goal of improving our nation's preparedness and response capabilities and capacities. In light of our shared goals, the AHA offers the following recommendations regarding the PAHPA reauthorization discussion draft.

SEC. 202. AMENDMENTS TO PREPAREDNESS AND RESPONSE PROGRAMS

The Hospital Preparedness Program Should Be Authorized at a Sufficient Level. America's hospitals and health systems play a critical role in disasters and public health emergencies. Congress recognized that role in PAHPA by creating the Hospital Preparedness Program (HPP), the primary federal funding mechanism for health care system emergency preparedness. Since 2002, the HPP has provided critical funding and other resources to aid hospitals' response to a wide range of emergencies. These investments have contributed to saving lives during many disasters and emergencies.

However, funding for the HPP has not kept pace with the ever-changing and growing threats faced by hospitals, health care systems and their communities. Indeed, authorized funding levels and annual appropriations for the HPP have significantly declined since the program began. In particular, HPP's highest level of appropriation was \$515 million, yet program funding has eroded to only \$265 million, a vastly insufficient level given the task of preparing the health care system for a surge of patients, continuity of operations, and recovery.



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 The Honorable Ann Eshoo
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The lessons of the many catastrophic emergencies and disasters in 2017 alone – including the hurricanes in Texas, Florida and Puerto Rico, the mass shooting in Las Vegas and the wildfires in California – as well as the threats posed by possible chemical, biological (including emerging infectious diseases), radiological and nuclear events support the need for a much more significant investment in health care system preparedness. Other threats continue to challenge the nation – currently, America's health care system is again focused on the issue.

We are, therefore, extremely concerned that the Subcommittee has proposed an annual HPP authorization of only \$264.6 million, a significant reduction from the program's current authorized funding level of \$374.7 million and an amount we believe will be inadequate to ensure that the health care delivery system is ready to respond to the ever-changing and growing threats that hospitals, health care systems and communities face. **Instead, we urge the Subcommittee to increase the HPP's authorization level to at least \$515 million for each of fiscal years 2019 through 2023, an amount representing a more appropriate level of investment in emergency preparedness as threats and risks continue to emerge.**

We note that the Subcommittee's discussion draft would expand the scope of the HPP beyond preparedness to include response activities, including medical surge for public health emergencies. Further, Sec. 401 of the draft would expand the activities for which the HPP awardees would be responsible to prepare and respond to include cybersecurity threats. **We believe that \$515 million in authorized funding for HPP would better reflect Congress' commitment to funding this expansion in scope.**

Broadening the Definition of Eligible Awardees under the HPP. **The AHA supports the Subcommittee's intention to broaden the types of entities that would be eligible to be HPP awardees to include health systems, state hospital associations and health care coalitions.** We believe that introducing such competition into determining HPP's awardees would permit the Assistant Secretary for Preparedness and Response (ASPR) to fund innovation and improve the nation's health security. **We urge the Subcommittee to also explicitly include academic medical centers and metropolitan and regional hospital associations as entities that would be permitted to compete to be the awardee for their jurisdiction.** Doing so will allow the HPP to award funds to those entities that present the most innovative approaches to health care delivery system readiness in their communities. A second benefit of introducing competition is the potential to address the misalignment between HPP's health care mission and its current awardees' public health mission. While most of the HPP's public health department awardees work well with their private-sector health care delivery system counterparts to enhance preparedness and response, others struggle to work collaboratively with the private health care system that they also regulate. Through this change, private health care entities hospital associations; and health care coalitions that have the organizational capacity and initiative to lead sector-wide preparedness and response activities would also be able to compete for HPP funds for their state or jurisdiction, not just health departments.

Therefore we recommend that text on page 12, line 19-20 be amended to read: "be a health coalition, State, regional or metropolitan hospital association, academic medical center or a health system; and".

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However, we are concerned that, although the Subcommittee's purpose seems to be clear, the actual amendments made to Sec. 319C-2(b)(1)(A) include drafting errors that render the section unclear. **In addition to the expanding the competition to academic medical centers and metropolitan and regional hospital associations, the AHA urges the Subcommittee to review and correct the amendments made on page 12, lines 12-20 in the discussion draft to ensure that the intentions are unambiguous.**

In particular, we believe that the following changes may be called for on page 12:

- Line 12, change "Section 319C-2(b)(1)(A)" to "319C-2(b)(1)(A)(iii)".
- Line 15, change "(ii)" to "(II)"
- Line 16, change "(iii)" to "(III)"
- Line 19, change "(iv)" to "(IV)"

Preparedness Programs Should Remain Distinct. The HPP and the Public Health Emergency Preparedness Program (PHEP) should continue to be aligned and coordinated but should be maintained as separate, distinct programs. The two programs serve a different but complementary purpose. PHEP, administered by the Centers for Disease Control and Prevention (CDC), builds the capacity of state and local health departments to prevent, detect and respond to emergencies. HPP, administered by ASPR, prepares the health care delivery system to provide essential care to patients by ensuring surge capacity and continuity of care during disasters. Both programs are needed to save lives and protect the public from emergency-related illnesses and injuries, and each should remain under the jurisdiction of the agency that currently oversee its administration.

We urge the Subcommittee to amend the discussion draft to formalize ASPR's relationship to the HPP and the CDC's relationship to PHEP by amending Sec. 319C-2 and Sec. 319C-1 to ensure that each program remains under the authority of its respective agency. Such language was included in S. 2852, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPAI), approved by the Senate Health, Education, Labor and Pensions (HELP) Committee.

SEC. 201. PUBLIC HEALTH EMERGENCIES

Sec. 201 amends the authorities of the Public Health Emergency Fund to rename it to the "Public Health Emergency Response Fund" and specifies uses for the fund. It also would permit the Secretary to transfer to the fund up to one percent from any discretionary appropriations.

The AHA supports the concept of a pre-approved standing fund of emergency resources that would speed the public health response to disasters. We support the following principles for such an immediate response fund for public health emergencies. Such a fund should:

- supplement and not supplant existing, base public health and preparedness funds;
- not preclude supplemental emergency funding based on the scope, magnitude and duration of the emergency at hand;

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- come with a mechanism to automatically replenish its funds;
- be used in the short-term for acute emergencies that require a rapid response to save lives and protect the public; and
- be administered by the Secretary of Health and Human Services (HHS), with congressional oversight, to ensure relevant agencies receive dollars when needed for response.

That said, we have concerns about the fund as described in the discussion draft. **First, we are opposed to using transfers from other HHS discretionary programs to finance the fund.** This approach would be disruptive and harmful for other critical health care and public health programs, as we learned during the Zika outbreak. Instead, we urge the Subcommittee to create a mechanism to replenish the fund without drawing down from other programs and to work with the Appropriations Committees to ensure it receives new funding as necessary.

Second, we are concerned that the fund's stated purposes would allow it to be used in the absence of a declared or even potential public health emergency. In particular, we would not support using the fund for developing and procuring medical countermeasures in the absence of a declared or potential public health emergency. At a minimum, we recommend that the Subcommittee amend the language on page 8, lines 21-24 of the discussion draft to limit this use to a declared public health emergency or if the Secretary determines there is a significant potential for a public health threat or emergency to occur. Ideally, the AHA prefers the "uses" language included in rapid response fund section of the Senate HELP Committee's PAHPA Reauthorization bill. Section 206 of S. 2852 includes appropriate guardrails for when an emergency fund could be used. It also would permit other critical uses in a public health emergency or potential public health emergency, such as for facilitating coordination between public health and private health care entities, strengthening bio surveillance capabilities and laboratory capacity, and supporting initial emergency operations and assets for intermittent disaster response personnel.

SEC. 401. CYBERSECURITY

Last year's global WannaCry ransomware attack underscored the cybersecurity risks that hospitals and health systems continue to encounter. Given that the United States faces relentless cybersecurity threats from other nation states, it is not reasonable to expect individual health care and public health entities to be the front line of defense. Although hospitals and health systems are taking many steps to secure their systems, the AHA supports strong national cyber defenses to aid them in those efforts. **Therefore, we generally support this section's designation of ASPR as the lead agency responsible for ensuring that the health care sector is capable to provide continuity of care during cybersecurity incidents and the addition of cybersecurity responsibilities to a number of existing public health, health care and biodefense programs within ASPR.** We further agree that, as part of the National Health Security Strategy, the Secretary should promote strategic initiatives to advance countermeasures to diagnose, mitigate, prevent or treat harm from any cybersecurity threat.

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However, adequately strengthening the health care and public health sector's cyber defenses will be a resource-intensive and costly endeavor, and we urge the Subcommittee to authorize additional funding to carry out these new cybersecurity responsibilities in each of the impacted programs.

SEC. 103. NATIONAL ADVISORY COMMITTEE ON CHILDREN AND DISASTERS

The AHA supports this section, which would reauthorize the National Advisory Committee on Children and Disasters (NACCD) through 2023. The NACCD, which was established to provide expert advice and consultation to the HHS Secretary on the medical and public health needs of children in disasters and public health emergencies, is an important resource for the Secretary. However, the AHA urges the Subcommittee to revise the discussion draft to clarify that federal representatives should be ex officio, non-voting members, and that the committee should incorporate additional expertise such as mental and behavioral health, children with special health care needs, and emergency medical services for children. Further, the AHA recommends that the Subcommittee reauthorize the National Preparedness and Response Science Board (previously called the National Biodefense Science Board) as well as the CDC's Children's Preparedness Unit.

We thank you for the opportunity to submit comments on the PAHPA reauthorization discussion draft and look forward to continuing to working with you on as this important legislation advances. If you have questions or would like further information, please feel free to contact me or have a member of your team contact Robyn Bash, vice president, government relations and public policy operations, at rbash@aha.org or 202-626-2672.

Sincerely,



Thomas P. Nickels
Executive Vice President



**Written Testimony Prepared by the American Society for Microbiology
Examining the Reauthorization of the
Pandemic and All-Hazards Preparedness Act**

Submitted to the
Subcommittee on Health
Energy and Commerce Committee

United States House of Representatives
June 6, 2018

The American Society for Microbiology (ASM) appreciates the opportunity to submit this statement in support of reauthorization of the Pandemic and All-Hazards Preparedness Act.

ASM is the largest single life science society, composed of more than 30,000 scientists and health professionals. Our mission is to promote and advance the microbial sciences, including programs and initiatives funded by the federal government departments and agencies, by virtue of the pervasive role of microorganisms in health and society.

This year marks the 100th anniversary of the Great Influenza pandemic, which killed between 50 and 100 million people worldwide, reminding us that we must be prepared to rapidly respond to declared and potential public health emergencies, including infectious disease epidemics.

Among the most consequential issues facing world is antimicrobial resistance. According to the Centers for Disease Control and Prevention (CDC), each year in the United States at least two million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections. Furthermore, these infections result in an additional \$20 billion per year of excess costs to our health care system.

The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) was created under a 2014 Executive Order and has twice been continued, most recently in 2017. The Advisory Council is set to expire on September 30, 2019 unless there is another continuation by Executive Order. Considering the danger posed by antibiotic-resistant bacterial infections remains high, ASM encourages this Subcommittee to put PACCARB into law which will ensure that PACCARB can continue its mission to produce reports and recommendations that influence federal combating antibiotic-resistant bacteria activities, home and abroad. A guarantee of

PACCARB's continuance also sustains the One Health partnerships — the integration of human, animal, and environmental domains — that have been formed since PACCARB's inception.

To date, PACCARB has issued a report on the progress of the federal government toward fulfilling the National Action Plan on Combatting Antibiotic-Resistant Bacteria (CARB) and has made a series of recommendations, to which Federal agencies have been responsive. Importantly, there has been, as a result of PACCARB, improved efforts at coordination of federal CARB efforts. PACCARB also issued a report on incentives for the development of new antibiotics. Whether addressed through PAHPA reauthorization or other mechanisms, an end-stage business model for private sector involvement and commitment is critical to antimicrobial and vaccine development and their successful deployment.

We believe PACCARB is having an effect on the larger antimicrobial resistance discussion and plays an important role in oversight of federal activities. We hope you will agree that PACCARB has made substantial progress since 2015 and that its important work and influence should continue well into the future as part of the federal government's all-hazards approach to protecting our nation.

ASM is hopeful that Congress will complete work on PAHPA reauthorization this year. We appreciate the Subcommittee's commitment to reauthorization and offer a few closing remarks on the PAHPA reauthorization discussion draft.

Reauthorization of PAHPA is the opportunity to include a specific authorization for the pandemic influenza program under the Biomedical Advanced Research Development Authority (BARDA). ASM is not only pleased to see inclusion and authorization of a Pandemic Influenza Program included in the discussion draft, but is also extremely grateful that the Subcommittee also recognizes the importance of a separate Emerging Infectious Disease Program and corresponding authorization. The Ebola and Zika pandemics did not originate within our borders, but traveled here quickly. There is no question that there will be another threat. The only questions are when and where in the world it will originate. We ask that provisions creating and authorizing funding for these two programs be retained as the legislation is finalized for introduction.

ASM also appreciates the recognition by this Subcommittee of the need for a Public Health Emergency Response Fund that allows the federal government to provide an initial response to a public health crisis until Congress can fulfill its fiduciary responsibilities. ASM supports that the legislation strengthens existing authorities for the Public Health Emergency Fund and attempts to create guardrails for the use of those funds. It is important, as specified in the discussion draft, that any amounts in such Fund supplement, not supplant, existing public health and preparedness grants and funding. ASM holds the position that dedicated funding is needed for such a fund and urges this Subcommittee to not lose sight of this critical need.

ASM appreciates the opportunity to submit this statement in support of reauthorization of PAHPA and looks forward to working with the Subcommittee to advance reauthorization legislation this year.



**Statement for the Record
Committee on Energy and Commerce
Subcommittee on Health**

Examining the Reauthorization of the
Pandemic and All-Hazards Preparedness Act
June 6, 2018

Thank you for the opportunity to submit a statement for today's hearing on the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) and, specifically, funding for the Hospital Preparedness Program (HPP).

Our more than 325 member hospitals are on the front lines of public health emergency response in their communities. They also provide a disproportionate share of the nation's uncompensated care and devote about half of their inpatient and outpatient care to Medicaid or uninsured patients. Members of America's Essential Hospitals form a critical part of the nation's emergency health care infrastructure by providing trauma services, teaching disaster readiness, coordinating preparedness efforts, and offering specialty services, such as poison and burn care centers. Therefore, it is paramount that Congress provide adequate and sustained funding for our essential hospitals to function as first responders and facilities well-positioned for a coordinated regional response during public health emergencies.

Since its inception under PAHPA, the HPP has provided critical funding and support for hospitals during public health crises. When the program was created, its appropriated funding level was at its highest: \$515 million per fiscal year. Since then, HPP funding authorization has dropped drastically to just \$255 million per fiscal year.

The current House proposal, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018, calls for nearly a 30 percent cut in authorized funding for the HPP. This further reduction in funding would pose a significant threat to our hospitals' capabilities and responsiveness during public health emergencies. **We encourage the committee to support H.R. 4776, the Hospital Preparedness Reauthorization Act of 2018, introduced by Rep. Debbie Dingell, which would restore the HPP's authorized funding to \$515 million for fiscal years 2019 through 2023.**

essentialhospitals.org

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Funding shortfalls pose consistent and significant obstacles for essential hospitals. Our members operate with an average margin less than half that of other U.S. hospitals, and they often do not recoup the costs associated with their response to emergencies that directly affect not only their hospital, but also the surrounding communities. Adequate funding for the HPP and other preparedness programs, and the prioritization of HPP grants to essential hospitals, is necessary.

Essential hospitals work tirelessly to ensure that America's safety-net remains strong and is equipped to serve communities during public health crises. We urge the committee to provide adequate and sustained funding for our hospitals as they care for patients facing financial hardships and deliver trauma care, emergency preparedness, health care workforce training, and other communitywide services.

Thank you for your prompt attention to this vital issue.



advancing innovation to save lives

June 4, 2018

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Walden and Ranking Member Pallone:

As members of the Global Health Technologies Coalition (GHTC)—a group of more than 25 organizations working to save and improve lives by encouraging the research and development of essential health technologies to bring healthy lives within reach for all people—we write in support of the reauthorization of the Pandemic All-Hazards Preparedness Act (PAHPA).

GHTC strongly supports the Biomedical Advanced Research and Development Authority (BARDA) playing a robust role in the advanced development of medical countermeasures (MCMs) to address naturally occurring threats with pandemic and epidemic potential. As you consider the U.S.'s biodefense needs and emerging threats in reauthorizing PAHPA, we ask that you ensure BARDA has ample resources and authority to address emerging infectious diseases (EIDs), pandemic influenza (PI), and drug-resistant infectious diseases. Specifically, we ask that you consider the creation of a separate line item with authorization for a minimum \$300 million to fund BARDA's work on EIDs to prepare and maintain platform technologies as rapid-response architecture as, to date, BARDA's work in this area has only come through emergency funding. We also ask that in light of the growing risk of these threats, you formalize the workstream for antimicrobial resistance (AMR) at BARDA and require reporting on BARDA's work in EIDs, PI, and AMR.

While BARDA is authorized to advance MCMs for EIDs, robust work in the space is lacking and previous efforts have primarily advanced only through emergency funding for response to the Ebola and Zika virus crises. As BARDA has a unique and unmatched ability to mobilize diverse stakeholders and industry to advance late-stage development of critical MCMs, we urge the Committee to include a dedicated funding for EIDs within BARDA as these unpredictable threats need our greatest attention.

We also encourage the Committee to consider strengthening BARDA's AMR work to include a focus on the threat of drug-resistant infectious diseases with pandemic and epidemic potential. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) "High-Priority Threats" list includes only one multi-drug resistant biological threat (MDR anthrax) and a catchall category of EIDs. The PHEMCE Strategy notes that PHEMCE leadership may include specific emerging pathogens if leadership determines they have the potential to affect national health

security. AMR is a clear health security threat for the U.S. and projections indicate that drug-resistant tuberculosis (DR-TB) is the single largest driver of AMR deaths globally.

We additionally request that the Committee consider including requirements for the Assistant Secretary of Preparedness and Response's (ASPR) five-year annual budget to report on priorities relative to EIDs, PI, and AMR so that BARDA's decision-making gains insight on the threats and ensures that the PHEMCE is adequately weighing the needs in these areas relative to other priorities for MCM development.

We stand ready to work with you to advance US leadership in MCM research and development, particularly for naturally occurring threats with pandemic and epidemic potential and those which face growing antimicrobial resistance. On the heels of the Ebola and Zika crisis, Congress has a unique opportunity to ensure our country is better prepared for the next outbreak.

Please do not hesitate to contact GHTC Director Jamie Bay Nishi at jnishi@ghtcoalition.org or (202) 540-4379, if you have questions or need any additional information.

Sincerely,



American Society of Tropical Medicine & Hygiene



AVAC



Global Health Technologies Coalition



International AIDS Vaccine Initiative



Infectious Diseases Society of America



PATH



RESULTS



Sabin Vaccine Institute



Treatment Action Group

Treatment Action Group



TB Alliance



June 6, 2018

The Honorable Michael Burgess, M.D.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Ranking Member Green:

The Healthcare Leadership Council (HLC) is writing to urge you to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), which is set to expire at the end of the 2018 fiscal year. Passed into law in 2006, PAHPA aims to "improve public health, medical preparedness, and response capabilities for emergencies, whether deliberate, accidental or natural." This act established the office of Assistant Secretary for Preparedness and Response (ASPR), whose mission is to strengthen our national health security and protect the public from 21st century health security threats, such as naturally occurring disease outbreaks, emerging infectious diseases, extreme weather events, and cybersecurity attacks on our healthcare delivery system. ASPR plays a crucial role in mobilizing a "coordinated national response" in emergencies to protect the public's health and our national security.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach. Through this diversity, HLC develops a coordinated perspective on the impact of any legislation or regulation affecting the nation's medical infrastructure and the public's health.

PAHPA provides funding for coordination across the Department of Health and Human Services (HHS) federal agencies, such as the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and Substance Abuse and Mental Health Services Administration (SAMHSA), as well as local, state and territorial health entities, to prepare and respond to emergencies and disasters. Under PAHPA, ASPR works to organize, train, equip and mobilize "federal public health and medical personnel" in public health emergencies at state and local levels.

The Hospital Preparedness Program (HPP), a key initiative under the umbrella of ASPR, consists of cooperative agreements between states, and local entities, and focuses on funding coordinated hospital coalitions collaborating in an area with emergency medical systems and public health departments. Funding for this program has decreased significantly from \$515 million in 2004 to \$254 million in 2017. According to a 2017 Trust for America's Health report, "over half of states scored five or lower out of ten on emergency preparedness." We cannot expect states to combat the healthcare threats of our time with half of them ill-prepared to handle a public health emergency. To meet the challenges of 21st century threats to our nation's health security, increased funding is needed to develop and implement regional disaster programs, such as HPP, to improve our healthcare infrastructure and national readiness. 21st century infrastructure includes more sophisticated informatic approaches to identifying diseases, greater sharing of information to supply more sophisticated analytics, a greater understanding of the genetic components of disease, and a willingness to consider more expansive models of disease detection.

HLC strongly supports the authorization and an increase in funding to implement a "Regional Disaster Health Response System," a key priority for Assistant Secretary Kadlec, M.D. In addition to the current challenge of responding to disasters, this new tiered regional approach will enable cross-jurisdictional preparedness for 21st century threats that may cause mass casualties, including building specialized regional capabilities and coordinating capacity to care for a large influx in patients. We recommend that Congress authorize ASPR to fund demonstration projects to implement this new model using increases in HPP funds. ASPR is also required to address the complex needs of patients with chronic conditions during a disaster, many of whom rely on healthcare technologies for treatment. The Regional Disaster Health Response System would direct grants to state and local governments (without requiring a request from the federal government) to distribute to healthcare coalitions, academic medical centers and other entities. This approach will help address the unique needs of patients with chronic conditions during a disaster, accelerate response, increase physician capacity and access to medical specialists in emergencies. Additionally, the supply chain will be able to redirect needed medical products to the providers treating the population affected by the public health event.

ASPR oversees research, development and acquisition of medical countermeasures, such as vaccines, medicines, and other pertinent medical supplies. ASPR carries out and manages these functions through three key programs: The Biomedical Advanced Research and Development Authority (BARDA), Project Bioshield, and the Public Health Emergency Medical Countermeasures Enterprise. BARDA, a critical medical countermeasure enterprise, has partnered with the National Institutes of Health (NIH), HHS, and biotechnology and pharmaceutical companies to develop 34 medical countermeasures approved or licensed by the FDA. BARDA has also assisted with the development of 27 medical countermeasures to combat national health security threats identified by the Department of Defense (DoD) and Department of Homeland Security (DOH), such as smallpox, anthrax, botulinum, and radiologic and chemical events, through Project Bioshield. BARDA has aided in the development of 23 influenza vaccines, antiviral drugs, devices and diagnostics to confront the risk of pandemic influenza. While this progress is laudable, there is still a lack of progress in the development of critical new and novel antibacterial therapies to tackle the threat of Antimicrobial Resistance (AMR). As such, it is important that new incentives, including post-market incentives, are put in place to help provide the economic certainty needed to bring these vital medicines to market.

The 21st Century Cures Act also provides a Medical Countermeasures Innovation provision (section 3084), to allow BARDA to enter an arrangement with a nonprofit entity to catalyze medical countermeasure (MCM) development and implementation. These public-private partnerships are vital to creating MCMs and highlight the importance of providing consistent public funding to ensure these partnerships can continue in the future to protect public health.

Public-private partnerships are likewise important to the healthcare supply chain in order to ensure the availability of medical products critical to any emergency, pandemic response, or following a natural disaster or public health emergency. A major "lesson learned" from the previous hurricane season that will benefit from a public-private partnership is re-entry for healthcare supply chain personnel after a disaster. Medical product distributors play a unique role in emergency preparedness, working diligently to ensure access to needed healthcare commodities for patients and providing key support to first responders during natural disasters, biological events, and other adverse emergencies. Unfortunately, during this past hurricane season, issues arose that prohibited distributors from adequately responding, thus creating barriers to accessing essential goods.

For these reasons, we would recommend ASPR establish a process to facilitate the transportation and distribution of essential healthcare goods during a presidentially declared emergency or major disaster declaration. This process should allow collaboration and input from both industry stakeholders and other federal agencies to best coordinate an appropriate process to allow these essential businesses and associated personnel to transport and distribute life sustaining medical products to a disaster area. This process should also improve communication related to fuel prioritization, hospital vacancies, law enforcement, access, and federal agency coordination.

Another example includes clinical laboratories, who are a crucial in providing information to connect healthcare stakeholders during an emergency. Clinical laboratories are the first line of detection and response to pandemic disease. The longstanding cooperation between public health, commercial laboratories, and academic research centers has been weakened by rate cuts from the Protecting Access to Medicare Act (PAMA). PAHPA provides the opportunity to strengthen diagnostic infrastructure by ensuring funding for laboratory testing and access to informatics that will allow rapid analysis of lab results across large patient datasets. PAHPA can answer the critical need to aggregate patient records across multiple institutions, providers, and states that will allow for rapid analysis of diverse lab providers.

As a multistakeholder coalition across all disciplines within healthcare, HLC strongly endorses the second reauthorization of PAHPA and the expansion of HPP funding to implement regional disaster programs. The protection of our nation's health security requires coordination and collaboration between the public and private sectors, and across multiple departments and agencies at the federal, state, and local level. Given the number of entities involved, this only underscores the complexities of current and emerging healthcare threats. Our healthcare system cannot afford to be siloed, rather, it must be integrated to successfully confront these challenges.

Thank you for your attention to this important matter. Should you have any questions, please contact Tina Grande at 202.449.3433 or tgrande@hlc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy". The signature is fluid and cursive, with the first name "Mary" being the most prominent.

Mary R. Grealy
President
Healthcare Leadership Council



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IDS

Infectious Diseases Society of America

June 5, 2018

The Honorable Susan Brooks
United States House of Representatives
1030 Longworth House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
United States House of Representatives
241 Cannon House Office Building
Washington, DC 20515

RE: Comments on Discussion Draft (g:\VHLC\053118\053118.252.xml), 5/31/18

Dear Representatives Brooks and Eshoo:

The Infectious Diseases Society of America (IDSA) thanks you for your leadership and greatly appreciates the opportunity to offer comments on your discussion draft for the Pandemic and All Hazards Preparedness Reauthorization Act of 2018 (PAHPRA). The programs and authorities contained within Pandemic All Hazards Preparedness Act (PAHPA) reauthorization provide essential leadership and resources for communities and health care facilities to prepare for, and respond to, public health threats as well as critical support for the research and development of life-saving medical countermeasures, including vaccines, diagnostics, and antimicrobial drugs.

IDSA represents over 11,000 infectious diseases physicians and scientists. Many of our members work on the frontlines of public health emergencies, including bioterror attacks, outbreaks, and natural disasters, such as hurricanes that carry significant infectious diseases risks. We support swift congressional action to reauthorize sufficient resources to safeguard our nation's health and safety. We are pleased to offer specific comments on the draft reauthorization bill and urge you to consider two additional provisions as you work toward introduction of the legislation: 1) to incent antibiotic research and development (R&D) for unmet needs, and 2) to provide loan repayment to encourage health professionals to enter the public health preparedness and response workforce. We look forward to an ongoing dialogue as you continue working on these important issues.

Sec. 104 National Disaster Medical System

IDSA recognizes the importance of the National Disaster Medical System (NDMS) that sends teams of medical personnel to support community responses to public health emergencies when local health care professionals are overwhelmed. The NDMS fills essential gaps, helping to ensure that all individuals in need during a public health emergency can receive care. IDSA appreciates that the discussion draft would authorize a \$4.7 million per year increase for this program.

Sec. 105 Volunteer Medical Reserve Corps

IDSA recognizes the importance of the Volunteer Medical Reserve Corps -- a group of medical and public health personnel who work to strengthen public health,

improve emergency response capabilities, and build community resiliency. Corps volunteers have supported vaccination clinics, emergency preparedness and response training, as well as disaster medical support. IDSA is concerned that the draft reauthorization bill would reauthorize this program at only \$6 million each year, and we urge reauthorization at the currently authorized level of \$11.2 million each year or greater. Such funding will ensure that the Corps maintains the ability to deploy volunteers as needed to support preparedness and response efforts.

Sec. 201 Public Health Emergencies

IDSA strongly supports the public health emergency response fund, but has concerns that the fund has not been adequately financed. Over the last few years, this country has repeatedly confronted public health emergencies that required swift responses. However, federal agencies experience significant delays in receiving resources necessary to respond. For example, despite bipartisan recognition of the need to address the Zika virus outbreak, additional funding took nearly eight months.

IDSA believes that a public health emergency response fund should enable federal agencies to rapidly move forward with sufficient initial efforts to contain and track the spread of infections, to treat infected individuals, as well as to launch necessary research for vaccines, diagnostics, and therapeutics.

Current law authorizes “such sums as may be necessary”, but Congress has not maintained appropriations to meet the needs of public health emergencies. IDSA is concerned that the discussion draft authorizes the transfer of funds from existing programs, rather than establishing a new source of funding for rapid responses to public health emergencies. We are concerned that the transfer mechanism would either fail to provide sufficient resources to jumpstart an emergency response (if too few funds were transferred) or would come at the expense of other existing public health activities (if too many funds were transferred). We appreciate that the discussion draft limits discretionary fund transfers to no more than one percent. However, we caution that one percent can greatly impact existing programs with lean budgets. Emergency responses are just one sector of the many critical duties performed by our public health system. Current funding of federal, state and local public health agencies is critical to protect the health of U.S. citizens through many mechanisms. Examples include providing surveillance of antimicrobial resistance, tracking foodborne illnesses and other infectious diseases, vaccine promotion, screening for transmissible diseases (such as HIV, hepatitis C, and tuberculosis) among others. Public health budgets are already stretched. We understand that there are significant pressures placed upon the federal budget, and we appreciate your mindfulness regarding new federal spending. However, given the central role of public health in securing the safety of Americans, we urge you to advance funding for the public health emergency response fund that does not divert resources from existing public health priorities.

Sec. 202 Improving State and Local Public Health Security

Local and state public health agencies provide the initial responses to infectious disease outbreaks that occur every year in this country. The year-long 2017-2018 hepatitis A outbreak in San Diego caused over 500 illnesses and 20 deaths locally and triggered outbreaks in other parts of California, Arizona, Utah, Michigan, and Kentucky. Outbreaks can only be contained by case identification and epidemiologic tracking, rapid laboratory testing, public communications about threats, and providing advice on how individuals can protect themselves, such as by offering vaccinations to those at risk. State and local health departments must be adequately funded to perform these functions and be

ready daily to assure a rapid, effective first response.

The 2014-2015 *Legionella* outbreak in Flint, Michigan demonstrates what happens when delayed health department responses occur due to diminished resources. From June 2014 to November 2015, at least 87 county residents developed Legionnaires' disease, and ten died. This stands in comparison to the 6 to 13 cases annually in the four preceding years. Adequate resources, including expert staff, are needed to rapidly identify the causes of outbreaks and take swift actions to limit the spread of infection. States and communities continue to face severe—and, at times, unexpected—threats including influenza, Zika, and the consequences of infectious diseases arising from hurricanes, floods, and other natural disasters.

Funding authorized by this provision supports laboratory response networks in state and local health departments that are responsible for investigation of suspicious specimens. When hospitals encounter an organism that may be an agent of bioterrorism (such as plague, anthrax, smallpox, or tularemia), they send samples to these specialized laboratories for identification. In addition, all white powder testing is performed at these laboratories under the direction of the Federal Bureau of Investigation (FBI). PAHPRA funding enables laboratories to test these select agents.

This provision also authorizes funding to train public health experts to respond to communicable disease events. IDSA and PIDS appreciate that the draft bill reauthorizes this provision at the 2017 appropriated level of \$670 million, rather than the currently authorized level of \$641.9 million, in part recognizing that community needs have grown. Noting that the 2006 PAHPA bill authorized \$824 million, we urge you to consider providing a higher authorization for these important activities.

Sec. 203 Partnerships for State and Regional Hospital Preparedness to Improve Surge Capacity

Federal funding to support hospital preparedness and response capabilities is essential. Hospitals must have the workforce and the resources to care for patients during public health emergencies. During such crises, hospitals may face not only their patients from communities they typically serve but also displaced patients from outside areas where healthcare facilities are over capacity or damaged by the emergencies. Hospital resources for infection prevention and control are essential, not only when the emergency is an outbreak. Any disaster event that results in significant injuries (such as wounds or burns) can present serious risks for infection.

Many hospitals were overwhelmed due to the 2017-2018 seasonal influenza season. In advance of influenza season, hospitals and health departments developed and implemented preparedness plans to help contain the spread of infection and support appropriate treatment for infected patients. Throughout the country, hospitals collaborate with health departments to coordinate influenza responses and share best practices. Without PAHPRA funding, much of this planning and coordination would not be possible, and our responses to influenza would be less robust. IDSA and PIDS are concerned that the discussion draft would authorize only \$227.2 million for hospital preparedness -- a significant cut from the current authorized level of \$347.7 million and the 2017 appropriated level of \$254 million. We note that the 2006 authorized level was \$474 million and urge you to consider increasing the authorization for these activities.

As many hospitals routinely operate at near capacity for economic survival, this inherently limits the identification and staffing of additional beds during a time of national crisis. Additional planning and resources must be directed to build contingencies to meet surge capacity needs.

Sec. 204 Revitalizing the Centers for Disease Control and Prevention

IDSA supports reauthorization of this provision and greatly appreciates the \$23.5 million increase in authorized funding to support efforts including improving national communications regarding public health emergencies, modernizing public health situational awareness and biosurveillance and enhancing telehealth capabilities to support emergency responses.

Sec. 301 Strategic National Stockpile and Security Countermeasure Procurements

IDSA supports your bill's proposed increase in authorized funding for the Strategic National Stockpile and security countermeasure procurements. These funds are essential to ensure that medical countermeasures (such as vaccines, diagnostics, and therapeutics) are available to deploy during a public health emergency.

Sec. 302 Biomedical Advanced Research and Development Authority (BARDA)

IDSA strongly supports a robust reauthorization of BARDA. We applaud the vital role BARDA has played advancing research and development of medical countermeasures. Antibiotic resistance is a severe threat to our security and therefore should be a top priority for PAHPA reauthorization. As you revisit BARDA's authority, IDSA strongly encourages the inclusion of new incentives for antibiotic R&D for unmet needs.

Antibiotic Resistance and Antibiotic Research and Development

We are particularly supportive of BARDA's broad spectrum antimicrobials program. This led to a crucial victory in 2017 when the first BARDA-supported antibiotic—Vabomere™ (meropenem/vaborbactam) from The Medicines Company—received Food and Drug Administration (FDA) approval. As you may know, most large pharmaceutical companies have retreated from antibiotic R&D. IDSA greatly appreciates the longstanding leadership by the Energy and Commerce Committee on this issue. In 2012, the Generating Antibiotic Incentives Now (GAIN) Act passed as part of the FDA Safety and Innovation Act (FDASIA). It provided an important first step to spur antibiotic R&D. In 2016, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act passed as part of the 21st Century Cures Act. This law reduced regulatory burdens to facilitate antibiotic R&D. While these efforts have yielded modest market improvements, the antibiotic pipeline remains fragile and insufficient to meet current needs, let alone needs that can arise during an emergency.

Antibiotic resistance is a serious threat to our security and should be a priority for PAHPA reauthorization. If an antibiotic resistant pathogen were weaponized and used against the U.S. population, we are ill-prepared to deal with such a crisis. Further, antibiotic resistance can significantly complicate responses to many other emergencies. For example, significant wounds and burns resulting from a terrorist attack can quickly become infected. Increasing rates of antibiotic resistance and inadequate antibiotic innovation leave us with frighteningly few options and, in some cases, no available treatment for these highly resistant infections. As another example, many influenza deaths are attributable to secondary bacterial pneumonia. Treatment of bacterial pneumonia has become increasingly challenging due to antibiotic resistance and our limited antibiotic arsenal.

Recommendation for New Antibiotic Market Entry Incentive

IDSA strongly encourages you to include a new incentive for antibiotic R&D in the PAHPA reauthorization bill. While BARDA currently supports antibiotic R&D by providing funds for costly clinical trials, private investments in antibiotic R&D are still needed. Unfortunately, because antibiotics are typically taken for a short time and must be used judiciously to protect their utility, high sales volume of any new antimicrobial drug is extremely unlikely and, in fact, would be counter to goals of restraining the inappropriate use of last-resort agents. Therefore, industry has limited or no opportunity to earn a return on investment in antibiotic R&D, making antibiotic R&D unattractive for many companies. As an example, The Medicines Company announced it would no longer pursue antibiotic R&D, just shortly after the launch of its new antibiotic Vabomere last year.

IDSA urges you to provide a new targeted antibiotic incentive in PAHPA reauthorization that will provide for a return on industry investment. Specifically, we propose a substantial market entry reward for new antibiotics that treat serious or life-threatening resistant infections that address unmet medical needs. Companies that receive such rewards should be required to commit to antimicrobial stewardship goals to slow the emergence of antimicrobial resistance to the new drug.

At a minimum, we urge you to include the following language from **Section 404 of S. 2582, the Pandemic and All Hazards Preparedness and Advancing Innovation (PAHPAI) Act**, as approved by the Senate Health, Education, Labor and Pensions Committee and authorize explicit new funding for BARDA to implement an initiative aimed at antimicrobial resistance, similar to the draft bill's approach to pandemic influenza and emerging infectious diseases programs at BARDA:

SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTIMICROBIAL RESISTANCE, AND OTHER SIGNIFICANT THREATS.

Section 319L(c)(4) (247d–7c(c)(4)) is amended by adding at the end the following:

“(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs, supporting innovative candidate products in preclinical and clinical development, to address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of, countermeasures and products, as applicable, to address areas including—

“(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.”.

Pandemic Influenza Program (p. 17-18)

IDSA recognizes the ominous threat of pandemic influenza. We commend the inclusion of a new provision in the draft bill directing BARDA to establish a pandemic influenza program and particularly appreciate the authorization of new funding to support this important effort. For your consideration, we offer suggested edits to the text of this provision to maximize the potential for innovation. In particular, we stress the fundamental need to enhance vaccine manufacturing capacity

and the ability to rapidly deliver influenza vaccine in a pandemic. Please see suggested additional language for this provision (p. 18, lines 8-21) below in red:

“(1) supports research and development activities for qualified pandemic or epidemic products (as defined in section 319F–3(i)), including improved antiviral drugs and vaccines, and by developing innovative technologies to enhance rapid response to threats relating to pandemic influenza;

“(2) ensures readiness to respond to pandemic influenza threats by improving the ability to rapidly produce vaccine in a pandemic, including improving the capacity for rapid manufacture of vaccines, supporting the development and manufacturing of influenza virus seeds, clinical trial lots, and stockpiles of novel influenza strains; and

“(3) sustains and replenishes ~~pandemic~~ stockpiles of vaccines for potential pandemic strains, including stockpiles of bulk antigen and adjuvant material, including annually testing the potency and shelf-life potential of all existing pandemic stockpiles held by the Department of Health and Human Services.

Emerging Infectious Disease Program (pp. 18-20)

IDSA strongly supports the provision in the draft bill directing BARDA to establish a program supporting research and development for emerging infectious diseases, and we particularly appreciate the authorization of new funding to support this important effort. As emerging infectious diseases present a continuously evolving threat, we must remain vigilant. Waiting until a serious outbreak occurs to initiate research and development of vaccines, diagnostics, and therapeutics dramatically hampers our ability to respond in a timely manner that leads to a clear cost of lives lost and potentially survivors maimed. **We recommend that your legislation direct BARDA to consult with infectious diseases experts to help determine which emerging infectious diseases should have priority. We further recommend that this program consider both domestic and global infectious diseases threats.** Since infectious diseases do not respect national borders, threats in other parts of the world can quickly become threats in the U.S. and our national security. Stopping a threat abroad is often the most effective way to keep a fatal pathogen from reaching our shores.

New Recommendation for Additional Provision to Strengthen the Public Health Workforce: Reinstating and Improving Loan Repayment Opportunities

IDSA urges you to take an additional step toward securing our public health workforce by providing loan repayment for the CDC Epidemic Intelligence Service (EIS) officers to make this career path more financially feasible for new physicians.

A successful response to a public health emergency depends upon skilled personnel. A sufficient number of appropriately trained individuals is necessary to ensure a ready response. The CDC's Epidemic Intelligence Service (EIS) is a two-year fellowship program in which participants receive on-the-job training to respond to infectious disease outbreaks and other public health emergencies. EIS was established in the 1950s in response to the threat of bioterror during the Korean War. Since then, EIS officers have been on the frontlines of responses to public health emergencies including the September 11, 2001 attacks, anthrax attacks, Ebola, Zika, and the 2017 major hurricanes. EIS is the state-of-the-art training ground for many of our nation's public health leaders. However, EIS continues to experience a significant decline in physician applicants, as considerable medical school debt drives many physicians to higher paying opportunities.

CDC had statutory authority, under section 317S of the Public Health Service Act (42 USC 247b-7) for establishing a student loan repayment program from FY 1995 to FY 2002. Although a program was authorized, funds were not appropriated and, therefore, the authority has never been used. Beyond the appropriation issue, this now-expired authorization required a longer three-year service agreement than the EIS fellowship itself (3 years versus 2 years), meaning that an individual taking part in two-year programs such as the CDC EIS fellowship would not be eligible for loan repayment due to the three-year service requirement.

We propose modifying the CDC student loan repayment statutory provision by reducing the three-year service agreement to two years as well as reauthorizing and funding the modified provision. The reduction in the service year agreement will allow public health trainees in the CDC two-year fellowships, such as EIS, to be eligible for student loan repayment. This reauthorization and service-year modification will allow CDC to effectively recruit physicians for critical public health preparedness and response roles. Below please see the provision with our proposed modifications.

42 U.S. Code § 247b-7 - Loan repayment program

(a) In general

(1) Authority

Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than ~~\$35,000~~ \$50,000 of the principal and interest of the educational loans of such health professionals.

(2) Limitation

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee, such an Epidemic Intelligence Service Officer, of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry for purposes of paragraph (1) for a period of not less than 2 years.

(b) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of this subchapter, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated ~~\$500,000 for fiscal year 1994, and such sums as may be necessary \$1,000,000 for each of the fiscal years 1995 2019 through 2002-2023.~~

(d) Availability of appropriations

Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

IDSA thanks you for your leadership and commitment to public health emergency preparedness and response. Protecting the public from threats such as bioterrorism and infectious diseases outbreaks is a critical federal government responsibility. IDSA stands ready to assist you in reauthorization of PAHPA. We appreciate your consideration of our recommendations. If you have any questions or we can be of any further help, please do not hesitate to contact Amanda Jezek, IDSA's Senior Vice President for Public Policy and Government Relations at 703-740-4790 or ajezek@idsociety.org.

Sincerely,



Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA

Cc: The Honorable Greg Walden
Chairman, U.S. House of Representatives Energy & Commerce Committee

The Honorable Frank Pallone, Jr.
Ranking Member, U.S. House of Representatives Energy & Commerce Committee

The Honorable Michael Burgess, MD
Chairman, Subcommittee on Health, U.S. House of Representatives Energy & Commerce Committee

The Honorable Gene Green
Ranking Member, Subcommittee on Health, U.S. House of Representatives Energy & Commerce Committee



May 31, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Susan W. Brooks
United States Representative
1030 Longworth House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
United States Representative
241 Cannon House Office Building
Washington, DC 20515

Dear Chairman Walden, Ranking Member Pallone, Representative Brooks, and Representative Eshoo,

As you craft the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), the 90-member companies of the International Safety Equipment Association (ISEA) – who are leaders in safety equipment manufacturing, testing, and application (see attached list) – ask that you make technical changes to the definitions of "covered countermeasure" and "qualified pandemic of epidemic product" to ensure all appropriate CDC-specified personal protective equipment (PPE) is covered by both the PAHPA and PREP Act. These improvements will ensure CDC-specified products are made available during the next pandemic without hesitation, even as it will facilitate improved coordination between HHS emergency planners and equipment manufacturers.

As you know, among the key provisions of PAHPA are sections that ensure appropriate forms of devices are acquired by the federal government and included in planning for public health emergencies, including pandemics and chemical, biological, radiological, or nuclear events. Unfortunately, due to a technical definitional issue, many of the forms of devices/PPE that are called upon by the Centers for Disease Control (CDC) to protect our nation's first responders during a public health emergency are not fully covered by PAHPA or the Public Readiness and Emergency Preparedness Act (PREP) Act.

Specifically, because the definitions used in these statutes for a 'covered countermeasure,' a 'security countermeasure,' or a 'qualified pandemic or epidemic product' only apply to drugs, biological products, and devices (which include PPE) that are cleared by the Food and Drug Administration (FDA), many of the devices/PPE the CDC expressly directs health care workers use during a public health emergency – such as chemical protective gloves, chemical protective garments, and many forms of respiratory protection, including Powered Air Purifying Respirators (PAPRs) that were widely deployed during the recent Ebola outbreak, or other forms of devices/PPE used for other chemical, biological, radiological, or nuclear events – are not covered by PAHPA or PREP Act.

To correct this oversight before the next national emergency hits – and with the Ebola threat again on the rise in the Democratic Republic of the Congo, including a case in a major city – a technical "fix" to the definition of a device in these statutes is needed to ensure the manufacturers of all appropriate drugs, biological products, and CDC-specified devices/PPE will receive the same narrow, time-limited, focused protection against liability when called upon in a national emergency.

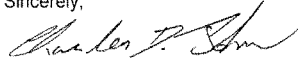
Thank you for your consideration of this request, and we look forward to working with you to correct this oversight during the upcoming reauthorization of the Pandemic and All Hazards Preparedness Act.

1901 North Moore Street, Arlington, Virginia 22209-1762 USA 703-525-1695

www.safetysystem.org • isea@safetysystem.org fax 703-528-2148

Thank you, again, for your ongoing efforts to improve public safety during the reauthorization of PAHPA – and we look forward to continuing to work with you on this issue in the coming weeks. Please contact me at 703-525-1695 or at cjohnson@safetysystem.org for more information or with any questions about this issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles D. Johnson, Jr.", written in black ink.

Charles D. "Chuck" Johnson, Jr.

Proposed legislative text is in bold red.

[NOTE: 42 CFR 84 are the regulations for respiratory protective devices, which are tested and certified by the National Institute for Occupational Safety and Health (NIOSH). Subparts H – KK are the specific test methods for each type of respirator.]

42 U.S. Code § 247d–6d(i)

(i)(1) **COVERED COUNTERMEASURE** — The term 'covered countermeasure' means—

- (A) a qualified pandemic or epidemic product (as defined in paragraph (7));
- (B) a security countermeasure (as defined in section 319F–2(c)(1)(B)); or
- (C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act; **or**

(D) a device that is:

(i) personal protective equipment certified under 42 CFR 84, Subpart H – Subpart KK; or

(ii) protective gloves and garments meeting the ASTM or other test standards designated by the Center for Disease Control and independently verified by a laboratory accredited by the Occupational Safety and Health Administration's Nationally Recognized Test Lab program; or

(iii) other personal protective devices designated by the CDC as necessary for worker protection.

(i)(7) **QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT** — The term 'qualified pandemic or epidemic product' means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) **or in section (i)(1)(D) of this Act**) that is—

- (A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—
 - (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
 - (II) to limit the harm such pandemic or epidemic might otherwise cause; or

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, ~~prevent~~, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or

(iii) authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act.

INSERT IN THE APPROPRIATE SECTION:

“When issuing a declaration or guidance on the personal protective equipment (PPE) that should be used in response to a public health emergency, the Centers for Disease Control and Prevention shall include the performance levels required for the appropriate PPE by citing appropriate standards, test methods, or materials.”

****This language would ensure the CDC provides specificity regarding the performance standards for PPE that healthcare workers should utilize in a particular emergency (for personal protection and acquisition purposes) and that HHS/ASPR can cite in any related PREP Act declaration.**

**Manufacturer Members**

3M Company
 5.11 Tactical Series
 A-Med Supply (Oliver Landon International)
 Accuform
 Ansell
 Avon Protection Systems, Inc.
 Blauer Manufacturing Co.
 Bollé Safety
 Bradley Corporation
 Buckingham Manufacturing Co., Inc.
 Bullard
 Bulwark
 Carhartt
 D3O
 Delta Plus Group
 Dräger Medical Systems, Inc.
 DSM Dyneema
 DuPont Personal Protection
 Encon Safety Products
 ERB Industries, Inc.
 Ergodyne
 Essilor of America
 FallTech

Gateway Safety, Inc.
 Gentex Corporation
 Guardian Equipment
 Guardian Fall Protection
 Global Glove
 Hammerhead Industries, Inc.
 Haws Corporation
 HexArmor
 Honeywell Industrial Safety
 Hughes Safety Showers (A Justrite Group Company)
 International Enviroguard, Inc.
 Ironwear
 KASK America
 Kimberly-Clark Professional
 M.L. Kishigo Manufacturing Co.
 Klein Tools, Inc.
 Lakeland Industries, Inc.
 Magid Glove & Safety Mfg. Co. LLC
 Majestic Glove
 Malta Dynamics
 MCR Safety
 Mechanix Wear, Inc.
 Moldex-Metric, Inc.

MSA Safety Inc.
 NASCO Industries, Inc.
 National Safety Apparel
 OccuNomix International, LLC
 ORAFOL Americas Inc.
 Pacific Safety Supply Inc.
 PAFtec Australia Pty Ltd (CleanSpace)
 Performance Textiles, div. of Brand & Oppenheimer Co.
 Petzl
 Prevor Inc.
 Protective Industrial Products, Inc.
 Pyramex Safety
 Radians, Inc.
 Rasco FR
 Safe Reflections, Inc.
 Safety Optical Service
 Scott Safety
 Superior Glove
 SureWerx
 Speakman Company
 Tingley Rubber Corp.
 Ty-Flot
 Werner Co.
 West Coast Corporation
 World Fibers, Inc.



June 6, 2018

Chairman Michael Burgess
Energy & Commerce Health Subcommittee
2125 Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Congresswoman Susan Brooks
1030 Longworth House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Ranking Member Gene Green
Energy & Commerce Health Subcommittee
2322A Rayburn House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Congresswoman Anna Eshoo
241 Cannon House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Burgess, Ranking Member Green, and Representatives Brooks and Eshoo:

On behalf of Trust for America's Health (TFAH), I am pleased to offer comments for the record on the discussion draft of the Pandemic & All-Hazards Preparedness Reauthorization Act of 2018 (PAHPRA) for today's legislative hearing. TFAH is a non-profit, non-partisan organization that promotes optimal health for every person and community and makes the prevention of illness and injury a national priority. We do not accept any government funding or represent any groups that benefit from the programs authorized in this legislation. As such, we strive to be an independent voice on behalf of strengthening America's public health and preparedness systems. While we look forward to working with your staff with more detailed recommendations, we offer the following comments on several provisions within the legislation:

Public Health Emergency Medical Countermeasures Enterprise (Sec. 102): We support codification of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). However, the PHEMCE should encompass the medical countermeasures (MCM) process from research and development through distribution and dispensing. Having appropriate medicines and vaccines are useless without the capacity to dispense those products to the right patient at the right time. If products are developed without an understanding of the supply chain management capabilities, the populations being targeted, and the capabilities of the health departments and others that will oversee distribution, there will be a tremendous loss in terms of resources and lives. We urge the authors to add "distribution and dispensing" to the functions of PHEMCE in sec. 102 to ensure the product can reach the patient.

Public Health Emergency Response Fund (Sec. 201): While we support the concept of an emergency response fund ("Fund"), we have several concerns with this section as currently written. First, we object to resourcing the Fund through transfer from other programs. We

learned during the Zika outbreak that reducing programs by up to 1 percent can have immediate consequences and harms the nation's health security. In a survey of local health departments following the redirection of all-hazards preparedness funds to support the Zika response, respondents reported negative impacts on pre-event readiness, supplies, staffing and other areas.¹ These are capabilities not easily backfilled with short-term funds.

Second, we are concerned with language in this section that seems to make funds available for the Secretary to develop and procure MCMs under any circumstances, not just in emergency situations (p. 8 lines 21-24). At a minimum, this paragraph should be re-lettered to clarify that MCM development is an appropriate use of the Fund if the other circumstances described in the establishment clause are met. We strongly urge the authors to either delete this paragraph or to include a more complete list of appropriate uses of the Fund, including public health, biosurveillance and medical response activities. Third, because the Fund should be a bridge between preparedness and other response funds, we ask that language be added to the "Supplement not supplant" section that clarifies that funds should also not supplant other emergency appropriations allocated to respond to the identified crisis. Finally, we urge the Committee to require the Secretary to plan for expedited distribution of funds to appropriate entities and agencies under this section.

Improving State and Local Public Health Security (Sec. 202): We are strong supporters of the Public Health Emergency Preparedness (PHEP) cooperative agreement, which is the main source of funding to enable health departments to prevent, contain and respond to emergency health threats. We are concerned that the authorization levels in this section are too low to rebuild the program from a nearly 30 percent cut over the past 15 years. PHEP should be authorized at least at \$824 million, the levels authorized in the PAHPA legislation of 2006. In addition, we urge the Committee to add language clarifying that the PHEP cooperative agreement should continue to be administered through the Centers for Disease Control and Prevention (CDC). Since the inception of the PHEP program, CDC has served effectively as the lead agency for developing public health capacity with state, territorial and local health departments. CDC's expertise and relationship with health departments has created a valuable partnership that has contributed to the nation's overall health security.

Partnerships for State and Regional Hospital Preparedness to Improve Surge Capacity (sec. 203): We are concerned that the authorized levels for the Hospital Preparedness Program (HPP) in this section are very low. HPP's highest level of appropriation was \$515 million, yet the program has eroded to only \$267 million, a vastly insufficient level given the task of preparing the health care system for a surge of patients, continuity of operations, and recovery. HPP should be authorized at least at \$474 million, the level authorized in the PAHPA

¹ *Impact of the Redirection of Public Health Emergency Preparedness (PHEP) Funding from State and Local Health Departments to Support National Zika Response*. ASTHO, NACCHO, APHL and CSTE, 2016. <https://www.naccho.org/uploads/downloadable/resources/Impact-of-the-Redirection-of-PHEP-Funding-to-Support-Zika-Response.pdf>

legislation of 2006. As the Centers for Medicare & Medicaid Services (CMS) emergency preparedness rule goes into effect, the U.S. Department of Health and Human Services (HHS) expects as many as 50,000 health care facilities to seek inclusion in health care coalitions. The legislation appropriately adds “response” to the mission of HPP, which would not be possible to achieve without additional funding. This level would allow rebuilding of the program as it transitions from capacity building to operationalizing health care coalitions for response.

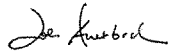
Strategic National Stockpile (Sec. 301): We support the funding levels in this section. However, we are concerned with the paucity of detail on how a transfer of the Strategic National Stockpile (SNS) from CDC to the Assistant Secretary for Preparedness and Response (ASPR) would improve the program and health security. It is important to remember that the SNS is not simply a procurement or stockpiling program; it is also a public health program and system of distribution and dispensing. CDC offers several SNS capabilities that would need to be considered, even beyond the Divisions of SNS (DSNS). For example, DSNS works with the Division of State and Local Readiness (DSLRL) to help PHEP awardees prepare to receive, distribute and dispense materiel from the stockpile. In fact, MCM distribution and dispensing is a key capability of the PHEP grants. The committee should ensure the transfer does not harm the existing cooperation and resources between DSNS and DSLRL to develop health department MCM capabilities and address gaps. In addition, the DSNS currently has access to expertise across CDC. In the midst of the Zika outbreak, for example, experts in vector-borne diseases, birth defects and maternal health, sexually transmitted infections, emergency preparedness and response, blood safety and others all populated the CDC Emergency Operations Center. If you move ahead with this transfer, we urge the Committee to include provisions requiring ASPR to develop strategies to ensure that SNS can continue to access this expertise and by explicitly giving CDC an ongoing role in the SNS enterprise.

Cybersecurity (sec. 401): While we understand the problem that cyber threats pose to the security of our nation’s health care and public health systems, we question adding cybersecurity to the responsibility of the Assistant Secretary for Preparedness and Response, the PHEP awards, and the PHEMCE without additional funding. Cybersecurity is an enormous and technical task, and the ASPR and public health staff have little existing expertise or capacity to address the threat without significant new resources. We urge the Committee to take a step back and hold additional hearings to consider options for the role of HHS in cybersecurity before legislating.

Workforce: We are concerned that the legislation does not address gaps in the public health, environmental health and epidemic response workforce. For example, we recommend the legislation include a provision to provide loan repayment to help the CDC recruit individuals to serve as Epidemic Intelligence Service (EIS) officers. We also urge the Committee enable CDC to hire informatics professionals to address modern biosurveillance needs of the agency.

Thank you for the opportunity to offer our comments for today's hearing. We look forward to continuing to work with the Committee on this important legislation.

Sincerely,

A handwritten signature in black ink, appearing to read "John Auerbach". The signature is fluid and cursive, with the first name "John" being more prominent.

John Auerbach, MBA
President & CEO

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641
June 26, 2018

Dr. Robert Kadlec
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

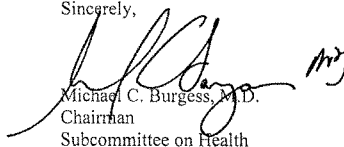
Dear Dr. Kadlec:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 11, 2018. Your responses should be mailed to Daniel Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to daniel.butler@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health
Attachment

Questions for the Record

Robert Kadlec, MD

U.S. Department of Health and Human Services
Assistant Secretary for Preparedness and Response

House Energy and Commerce Subcommittee on Health

"Reauthorizing the Pandemic and All-Hazards Preparedness Act"

Wednesday, June 6, 2018

Rep. Burgess:

- 1) **It is my understanding that HHS established a goal to provide domestic manufacturing surge capacity that makes first doses of pandemic influenza vaccine available within 12 weeks of a pandemic declaration. This goal was profiled in HHA's 2017 Pandemic Update and HHS investments to achieve this goal go back at least to 2011. Have HHS and private sector investments yield that capacity? Does HHS maintain this timeline as a goal?**

Rapid, large scale domestic manufacturing capacity for pandemic influenza vaccines is a critical component of pandemic preparedness to make vaccine available for everyone as soon as possible after emergence of a pandemic virus. Using previous supplemental appropriations, ASPR, through BARDA, has made significant gains in pandemic influenza vaccine preparedness over the last 10 years. For example, BARDA's partnerships with industry have led to the licensure of faster, more flexible cell-based, recombinant and adjuvanted influenza vaccines, as well as modernized and expanded domestic manufacturing capabilities. Specifically, these partnerships have increased domestic influenza vaccine projected manufacturing capacity – from 60 million dose capacity a decade ago to up to 600 million bulk antigen dose capacity, which can now be produced within 6 months after a decision is made to begin large scale manufacturing. However projected timelines for vaccine (finished product) availability depend on many factors, including manufacturing yields and fill/finish capacity.

Building on these successes, and to ensure vaccine is available within 12 weeks of a pandemic declaration, BARDA has established a multifaceted strategy.

- First BARDA is partnering with companies to support the development of novel technologies that rely less on viral growth properties (e.g. eggs) to improve the speed and robustness of vaccine production. For example, BARDA supported the development of the first FDA licensed recombinant influenza vaccine (Flublok®, manufactured by Protein Sciences), and BARDA continues to fund other recombinant vaccine-related technologies, moving away from the production of vaccine in eggs.

- Second, BARDA is supporting domestic production capabilities to ensure vaccines are available for everyone across the country if necessary.
- Third, BARDA is supporting further development of recombinant and cell-based vaccines through comparative efficacy clinical studies to demonstrate and validate the expand use indications of these vaccines for a broad range of high-risk and vulnerable populations.
- Fourth, BARDA is continuing to improve adjuvant capabilities and capacity which is crucial for a rapid response. BARDA continues to support efforts to obtain licensure and expand the approved age ranges for influenza adjuvanted vaccines. In addition, BARDA is supporting development of new adjuvants for pandemic influenza vaccines that will have improved characteristics, such as improved effectiveness, decreased sustainability costs, or are faster to produce, and could also improve seasonal vaccine efficacy.

2) As biological threats arise internationally, it creates a domestic risk and surveillance is necessary in the United States to provide a warning and an opportunity for an early intervention to prevent the transmission of disease. Is there a mechanism to detect infected persons entering the country that may be a risk? What authorities and protocols does ASPR, in coordination with CDC have to detect and detain infected patients?

Early warning and detection of an infectious disease entering a community is critical for mounting a rapid, effective response. ASPR relies heavily on other parts of HHS and the federal government, such as CDC and Department of Homeland Security, to provide this early warning.

Under the Public Health Service Act (42 U.S.C. 264) and regulations at 42 CFR parts 70 and 71, CDC's Division of Global Migration and Quarantine (DGMQ) has broad authority to undertake public health measures to prevent the introduction, transmission, and spread of communicable disease into and within the United States. DGMQ uses a number of risk mitigation strategies to address public health risks posed by ill travelers entering the United States, such as:

- With federal and local partners, evaluating sick travelers arriving at US Ports of Entry and, when necessary, doing contact investigations to determine if public health follow-up is required for ill and for exposed travelers
 - For example, the Ebola entry risk assessment and risk management program evaluated all travelers arriving from countries with Ebola outbreaks in West Africa during 2014-2016.
- Regulatory requirements for airlines and other conveyances coming to the United States to report travelers (passengers or crew) with certain signs and symptoms of illness and deaths.
- If an individual presents at a port of entry and is known to be infected with, or suspected of having been exposed to, a communicable disease for which federal public health orders are authorized, by statute CDC may apprehend, detain (i.e.

isolate or quarantine), or conditionally release individuals to prevent introduction, transmission, or spread.

- This list of diseases is provided by Executive Order of the President (Executive Order 13295: Quarantinable Communicable Diseases April 4, 2003, amended by 13375 on April 1, 2005 and by 13674 on July 31, 2014).
- CDC strives to use the least restrictive means to achieve public health goals, and generally individuals voluntarily comply with public health recommendations for further medical assessment or movement restrictions, so issuance of federal public health orders are rare.

CDC and the Department of Homeland Security (DHS) operate the Public Health Do Not Board/Border Lookout tool. If an individual meets certain criteria, CDC works with DHS Transportation Security Administration (TSA) to include the individual on the Do Not Board list, which prevents an individual who presents a public health risk during travel from being able to obtain a boarding pass for air travel to or from the United States. Simultaneously, a Border Lookout record is created with DHS Customs and Border Protection (CBP) to prevent an individual from trying to enter the United States via land or sea.

Rep. Bilirakis:

- 1) As I mentioned in my opening statement, Florida is bracing for the “next big one” each hurricane season and its implications—especially with significant population growth over the last few years, a sizable portion aged 55 and older. Disaster Medical Assistance Teams (DMATs) are tremendously important to states like mine because medical care stemming from disasters can quickly overwhelm our healthcare system. To what extent does ASPR ensure that DMAT members are mission-ready?**

DMATs are a component of ASPR’s National Disaster Medical System (NDMS). ASPR ensures all DMAT members have up to date credentials. This year, ASPR began increasing the training provided to NDMS members – increasing frequency of training for personnel from once every five years to once every three years, and ensuring the training they receive includes information on treating chemical, biological, radiological and nuclear injuries. In addition, when DMAT teams are activated for national special security events, such as the State of the Union, Peace Officer Memorial, or 4th of July celebration, they participate in just-in-time trainings to refresh skills.

Specific NDMS training includes DMAT 101 and DMAT 201. DMAT 101 provides training and practice on fundamental knowledge and skills to ensure NDMS personnel are able to provide basic healthcare needs to a community impacted by disaster. Specifically, the course includes basic training on use of equipment (e.g. ventilators, defibrillators, etc.), providing a controlled environment where personnel are able to practice with equipment that is configured and organized as it would be deployed during a public health and medical emergency.

In DMAT 201, teams simulate a deployment and are required to set up their Base of Operations (Western Shelter canvas tent and supporting components to include ventilation system, water purification system, generator power, etc.) while simultaneously providing care to patients using only the equipment and supplies that would be deployed with them during an actual event. This training requires the team to function independently, similar to how they operate on an actual deployment.

1.b) Last season, DMATs experience a staffing shortage. What barriers still exist to filling this gap and does this bill provide ASPR with the necessary authority to address this challenge?

The standard U.S. government hiring process, to which NDMS is subject, takes an estimated 6-9 months from start to finish. The Bipartisan Budget Act of 2018 provided NDMS with 270 days of direct hiring authority. Direct hire authority means the usual hiring process can be expedited – reducing the 6-9 month timeline significantly.

Using this direct hire authority, NDMS is working to fill as many vacancies as possible before the authority expires in November, 2018. Currently, there are approximately 4000 vacancies within the NDMS system. ASPR projects 1000 vacancies will be filled by November, leaving 3000 vacancies. Included in the Department's PAHPA reauthorization technical assistance was a request for direct hire authority for a one to two year period to ensure NDMS is fully staffed and ready for future public health emergencies. The bill introduced in the House for PAHPA reauthorization includes direct hire authority for three years (expiring September 30, 2021).

1.c) What barriers still exist for recruiting the best medical professionals into DMATs?

NDMS personnel deploy and support public health and medical emergencies side-by-side other responders. Currently, NDMS personnel are not eligible for death benefits paid out through the Public Safety Officer Benefit (PSOB) Program, yet other responders, like FEMA personnel, are eligible should they die while supporting a response operation. Limiting coverage for NDMS personnel may have impacted recruitment and retention for NDMS.

Included in the Department's PAHPA reauthorization technical assistance was a request to align NDMS benefits with the same coverage afforded to other federal responders under the PSOB Act. Expanding this program to include NDMS personnel could support recruitment and retention of qualified personnel. The bill introduced in the House for PAHPA reauthorization includes PSOB coverage for NDMS personnel.

- 2) Resiliency is vital to preparedness and ultimately response and recovery. The stockpile of drugs, vaccines, and other medical products and supplies, known as the Strategic National Stockpile is critical to our ability to respond and recover from catastrophic events. Reliable storage and delivery of these lifesaving medicines is**

also important in terms of patient safety and cost. In what ways is your agency working with industry to extend the shelf life and improve resiliency of the Strategic National Stockpile?

Improving the resiliency of the Strategic National Stockpile by working with industry is a priority. CDC has engaged industry by forming partnerships with major industry trade associations specifically - Health Industry Distributors Association (HIDA), International Safety Equipment Association (ISEA), Healthcare Distribution Alliance (HDA), National Association of Chain Drug Stores (NACDS), and Healthcare Supply Chain Association (HSCA). These partnerships improve the resiliency of the Strategic National Stockpile through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to personal protective equipment (PPE);
- Improved public access to medical countermeasures; and
- Redundant distribution of medical countermeasures, information, and materiel.

The resiliency of the Strategic National Stockpile is closely linked to the resiliency of the commercial supply chain. Recognizing that private industry relies on accurate forecasting of demand when determining manufacturing priorities, CDC held three pre-solicitation conferences (or bidder conferences) for potential vendors and stakeholders in January 2018. These conferences, which focused on three requirements being developed for the SNS, were intended to improve the quality and accuracy of future requests for proposals in the requirement areas, as well as enabling the vendors to submit better proposals.

In addition to the important work done with private industry, CDC seeks to maximize the value of the SNS appropriation in collaboration with FDA through the Shelf Life Extension Program (SLEP). Some pharmaceuticals, if stored in accordance with the manufacturer's recommendations, may be viable beyond the manufacturer's labeled expiration date and allow for deferment of drug replacement costs. CDC works with FDA to test stability of drugs approaching labeled expiry through SLEP. If SLEP testing confirms that the product is viable and safe to use beyond the established expiration date, FDA will typically provide an additional 12 to 24 months of extended shelf life. For some products not eligible for the SLEP program, including biological products such as vaccines and immune globulins, SNS contracts with the manufacturers for annual potency testing to try to extend the shelf life of the stockpiled products.

Rep. Mullin:

1) Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?

Included in the Department's PAHPA reauthorization technical assistance was a request to authorize a 10 year advance appropriation for the Project BioShield Special Reserve

Fund, consistent with the FY 2018 Addendum to the President's Budget, which supports advanced development and initial procurement of medical countermeasures, which often have no commercial market.

BARDA utilizes many of the innovative authorities authorized by the Pandemic and All-Hazards Preparedness Act of 2006 to support advanced development of medical countermeasures. Authorities like Other Transaction Authorities mean BARDA can enter into innovative, more flexible agreements with companies. In addition, direct hire authority allows BARDA to recruit and hire personnel with the specific expertise to ensure medical countermeasure development initiatives are efficient and scientifically sound.

1.a) Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?

BARDA has utilized its authority to establish flexible Other Transaction Authority (OTA) agreements with companies for portfolios of products to address many threats, including antimicrobial resistant pathogens. The first BARDA OTA agreement was within the broad spectrum antimicrobial program and currently three out of six BARDA OTA agreements are focused on development of antimicrobial products. BARDA has also utilized CARB-X – an innovative public-private partnership – to address the threat of antibiotic resistant bacteria. CARB-X involves seven partners in the U.S. and U.K. and is backed with \$500 million in funding from several different organizations. In addition, CARB-X funded companies have been able to leverage that investment to secure significant additional private equity funding. A total of \$70 million in BARDA CARB-X investment resulted in nearly \$500 million in private equity follow on investment. The partnership has 28 different companies making novel antibacterial drugs, vaccines, and diagnostics, including eight new classes of antibiotics.

Existing statutory authorities do not prevent BARDA from working with companies to develop medical countermeasures to counter the increasing threat of antibiotic/antimicrobial resistant pathogens.

1.b) Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?

Existing statutory authorities do not prevent BARDA from working with companies to develop medical countermeasures to counter the increasing threat of antibiotic/antimicrobial resistant pathogens.

Rep. Carter

- 1) I recently met with Dr. Redfield and am very confident in his leadership and the work of all the experts at the CDC. Given their deep technical knowledge and expertise, how will you ensure that the CDC experts have the opportunity to stay involved in medical countermeasure development and employment after the Strategic National Stockpile (SNS) is moved to ASPR in October? How will you continue to engage CDC state-based mechanisms in this process and ensure that the transfer is not overly disruptive for state and local agencies?**

ASPR recognizes and appreciates the tremendous expertise of CDC subject matter experts including on infectious diseases, other public health threats, epidemiological surveillance, as well as working directly with state and local public health departments. To increase collaboration between ASPR and CDC, ASPR has invited and instituted a new senior CDC liaison who is working within the ASPR Immediate Office.

CDC is a core member of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which is led by ASPR and provides a venue for sharing information across Federal agencies with a role in medical countermeasures requirement setting, research, development, regulatory review, procurement, stockpiling, distribution and use. CDC subject matter experts will remain an active participant in all PHEMCE workgroups and committees.

In order to ensure a smooth Strategic National Stockpile transition on October 1, 2018, with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate and plan for all aspects of the program transition. We would be pleased to provide a full briefing for your staff at any time before the end of the fiscal year.

There will be no changes to the CDC's relationship with state and local public health agencies. Additional transition details are still under discussion between CDC and ASPR.

ASPR is dedicated to improving federal support in the final distribution and dispensing of products contained in the SNS by providing robust operational support to states and locals.

- 2) Your extensive experience has given you a rare look into the classified threat assessments facing our country. Do you think the United States government is doing enough to prevent and mitigate the threat of a biologic attack here at home or to our key interests abroad? In your view, will the reforms laid out in this reauthorization bill work to improve the biodefense enterprise?**

ASPR believes more can be done to prevent and mitigate the threat of biological as well as chemical and radiological threats here at home. As outlined in the Administration's technical assistance with respect to reauthorization of PAHPA, encouraging ASPR to coordinate with the Director of National Intelligence and Department of Homeland Security to assess current national security threats would further strengthen our emergency preparedness and response framework. ASPR's priorities for building readiness for 21st century health security threats are:

1. Providing strong leadership,
2. Building a regional disaster health response system,
3. Sustaining robust and reliable public health security capabilities, and
4. Advancing an innovative medical countermeasures enterprise.

All of the Administration's PAHPA reauthorization proposals will assist in improving our biodefense capabilities.

3) How will the transition from the SNS to ASPR occur and what will that mean for changes in staffing in Atlanta?

The SNS Director will report to ASPR leadership in Washington, DC, but all Division of SNS staff in the Atlanta area will remain there, and staff employed at warehouse locations across the country will also not be physically moved.

In order to ensure a smooth Strategic National Stockpile transition with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate all aspects of the program transition. We would be pleased to provide a full briefing for your staff at any time before the end of the fiscal year.

4) What is the estimated cost of the transition from SNS to ASPR?

SNS transition details are currently under discussion between CDC and ASPR.

5) Will any of the regional stockpiles be moved to the Washington region as a result of the transition?

There are no plans to relocate or move any of the existing stockpile warehouses from their current locations.

6) Will any personnel be shifted from Georgia to the Washington area?

7) ASPR has no plans to shift SNS staff from Georgia to Washington, DC. Have you reviewed the possibility of having ASPR co-located in Atlanta with the CDC to ensure that HHS and the CDC can build off existing knowledge and ensure increased efficacy? If so, what would be required, regarding staffing and financing, to make that a reality?

The transition of the Strategic National Stockpile from CDC to ASPR will not result in staff physically moving from Atlanta to Washington, or vice versa.

Rep. Pallone:

The Strategic National Stockpile (SNS) is a key line of defense against natural and manmade threats. The SNS is not just a stockpile of medications, antidotes, and medical supplies, but also consists of logistical infrastructure capable of deploying products in the event of a public health

emergency. Currently, the Prevention to the Assistant Secretary for Preparedness and Response (ASPR) is primarily responsible for managing the Hospital Preparedness Program (HPP), the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). ASPR is required to carry out drills and operational exercises to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response. ASPR is required to develop, and update each year, a five-year budget plan for medical countermeasures enterprise strategy and implementation plan. The proposed bill, H.R. ____, the Pandemic and All-Hazards Reauthorization Act of 2018 would transfer the SNS to ASPR from the Centers for Disease Control (CDC), expand the role of ASPR in responding to public health emergencies and our national response. The transfer of the Strategic National Stockpile (SNS) from the Centers for Disease Control (CDC) and Prevention to the Assistant Secretary for Preparedness and Response (ASPR) raises a number of concerns about the stability and coordination of the SNS and ultimately, how the departmental changes could affect our national readiness and ability to respond to a public health emergency.

1) Please describe ASPR's past role in responding to public health emergencies and how ASPR coordinates with the CDC in preparation for and deployment of SNS items?

ASPR's mission is to save lives and protect Americans from 21st century health security threats. ASPR was created by PAHPA to lead and coordinate the Department's medical and public health emergency preparedness activities and to collaborate across the federal government, including with CDC, to bring unified medical and public health response capabilities to support state and local authorities during public health emergencies, in accordance with the National Response Framework, Emergency Support Function (ESF) #8 (Public Health and Medical Services).

Since ASPR was established in 2006, there have been 39 declared public health emergencies. For example, ASPR coordinated the response across the Department to the unprecedented 2017 hurricane season and the 2015-2016 Zika Virus Outbreak. During the 2017 hurricane season, ASPR's National Disaster Medical System (NDMS) deployed thousands of medical professionals from across the country to aid communities in Texas, Florida, Puerto Rico and the U.S. Virgin Islands. Collectively, HHS medical responders – from NDMS and the U.S. Public Health Service Commissioned Corps – saw more than 36,000 patients between the three major hurricanes and spent months deployed. Through daily ESF-8 coordination calls, ASPR maintained situational awareness of the impact of the storms, the health needs of the impacted communities, and coordinated the federal medical and public health assets deployed to assist those communities, including deployment of SNS contents such as Federal Medical Stations. During the Zika virus outbreak, ASPR supported development of medical countermeasures (MCM), augmented community preparedness via the Hospital Preparedness Program, supported interagency coordination calls and meetings, and provided consolidated reporting and situational awareness to senior leaders on a daily basis.

In addition to response capabilities, BARDA has partnered with the private sector to develop medical countermeasures (MCM) to protect Americans from chemical, biological, radiological, and nuclear threats; pandemic influenza; and emerging infectious diseases, leading to 38 FDA approvals, licenses or clearances.

2) What training, drills and operational exercises does ASPR conduct to ready the national response for public health emergencies?

ASPR plans, conducts and supports annual training and exercises for National Disaster Medical System (NDMS) Teams, Incident Response Coordination Teams, Federal Health Coordinating Elements, and the ASPR Emergency Management Group.

This year, ASPR began increasing the training provided to NDMS members – increasing frequency of training for personnel from once every five years to once every three years, and ensuring the training they receive includes information on treating chemical, biological, radiological and nuclear injuries. In addition, when DMAT teams are activated for national special security events, such as the State of the Union, Peace Officer Memorial, or 4th of July celebration, they participate in just-in-time trainings to refresh skills.

Specific NDMS training includes DMAT 101 and DMAT 201. DMAT 101 provides training and practice on fundamental knowledge and skills to ensure NDMS personnel are able to provide basic healthcare needs to a community impacted by disaster. Specifically, the course includes basic training on use of equipment (e.g. ventilators, defibrillators, etc.), providing a controlled environment where personnel are able to practice with equipment that is configured and organized as it would be deployed during a public health and medical emergency.

In DMAT 201, teams simulate a deployment and are required to set up their Base of Operations (Western Shelter canvas tent and supporting components to include ventilation system, water purification system, generator power, etc.) while simultaneously providing care to patients using only the equipment and supplies that would be deployed with them during an actual event. This training requires the team to function independently, similar to how they operate on an actual deployment.

In addition to the annual NDMS trainings, ASPR conducts a series of exercises designed to test and assess capabilities and readiness to respond to a variety of public health emergencies. These drills and exercises include:

- HHS Noble Lifesaver Exercises designed to test our capability to evacuate and move patients from health facilities;
- HHS Nimble Challenge and Nimble Response exercises designed to focus on an identified capability or need and include both announced and no-notice exercises and/or drills;
- HHS Plan Validation Exercises designed to test and validate new or updated plans before they are finalized; and,

- HHS Emergency Management Group exercises designed to test and evaluate the HHS response to various public health emergency scenarios.

3) Will the transfer of the SNS to ASPR affect the funding and conduction of these preparatory sessions?

The transfer of the SNS to ASPR will not affect funding or conduct of trainings, drills, or exercises.

4) The President's FY 2019 budget requested the transfer of the SNS from the CDC to ASPR.

Yes, the FY19 President's Budget proposes to transfer the SNS from CDC to ASPR. At a time when the U.S. threat environment is becoming more complex and dangerous, this change will improve the efficiency of emergency responses, strengthen and streamline the medical countermeasures enterprise, and leverage synergies in supply chain logistics.

5) What is the main motivation behind the transfer of the SNS?

At a time when the U.S. threat environment is becoming more complex and dangerous, the transition of the SNS to ASPR will improve the efficiency of emergency responses, strengthen and streamline the medical countermeasures enterprise, and leverage synergies in supply chain logistics.

ASPR was established in 2006; the CDC first received appropriations to support the SNS in 1998, before ASPR was authorized. Operational authority for the SNS was subsequently split between HHS and DHS, but it was unified at HHS in 2004 and maintained in CDC. While placing the SNS at CDC made historical sense, the creation and maturation of ASPR provides an opportunity to align the direct oversight and management of SNS under ASPR.

When disasters occur, ASPR leads the National Response Framework, Emergency Support Function #8 as delegated by the Secretary, thereby coordinating federal public health and medical responses, including assets from CDC as well as contents of the SNS, such as Federal Medical Stations (FMSs) which are 250-bed medical centers set up during a disaster to care for an affected community.

ASPR has a robust medical logistics capability that supports the National Disaster Medical System (NDMS), moving medical personnel, equipment, and supplies across the nation within hours. ASPR works closely with state and local emergency management professionals, clinicians, healthcare facilities, public health officials and NDMS response teams who may be called upon to dispense SNS medical products. Shifting operational control of the SNS to ASPR, while continuing to leverage CDC's established relationships with public health agencies, will increase the effectiveness and efficiency of emergency responses.

In addition, making this change will strengthen and streamline the entire medical countermeasures (MCM) enterprise. ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes senior representatives from all agencies involved in the medical countermeasures enterprise. The PHEMCE oversees setting MCM requirements, developing and procuring new products through the Biomedical Advanced Research and Development Agency (BARDA) and Project BioShield. Congress established BARDA and Project BioShield to encourage companies to develop medical countermeasures the government needs to keep Americans safe from national security threats, by creating a government market where there is usually not a commercial incentive and to enable public-private partnerships for such advanced research and development.

When MCMs for DHS-identified national security threats are in late stage development, BARDA can procure them using the Project BioShield Special Reserve Fund. After these MCMs are approved or licensed by FDA, procurement responsibility may then shift to SNS.

6) What issues may arise by moving the SNS from CDC to ASPR?

To support a smooth transition with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate and plan for all aspects of the program transition.

7) Will any issues the ASPR currently faces be resolved by this transfer?

As mentioned in question 5, at a time when the U.S. threat environment is becoming more complex and dangerous, the transition of the SNS to ASPR will improve the efficiency of emergency responses, and strengthen and streamline the medical countermeasures enterprise.

8) How does ASPR and the CDC currently coordinate on SNS and other public health emergency response efforts?

ASPR and CDC coordinate regularly in a number of areas, for example:

- On behalf of the Secretary, ASPR leads the federal medical and public health responses to emergencies and disasters under the National Response Framework ESF #8. CDC is a key public health component of a coordinated federal response.
- ASPR manages the Secretary's Operations Center (SOC) in Washington, DC, which coordinates communication flow with the CDC's Emergency Operations Center in Atlanta.
- ASPR's Regional Emergency Coordinators collaborate with CDC field staff located in the 10 HHS Regional Offices, as well as with state and local health officials in their respective regions.

- ASPR's Hospital Preparedness Program coordinates regularly with CDC's Public Health Emergency Preparedness Program on grant requirements, timelines, capabilities, and communications with state and local health officials.
- ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes senior representatives from all agencies involved in the medical countermeasures enterprise. CDC is an active participant in all PHEMCE working groups and executive committees.

9) How does ASPR and the CDC plan to ensure continued coordination after the transfer of the SNS?

ASPR recognizes and appreciates the tremendous expertise of CDC subject matter experts including on infectious diseases, other public health threats, epidemiological surveillance, as well as working directly with state and local public health departments. All of the methods of coordination identified in question 8 will continue to happen after the SNS transfer. To further increase collaboration, ASPR has invited and instituted a new senior CDC liaison who is working within the ASPR Immediate Office.

10) How does ASPR currently coordinate with state and local health departments? How will this relationship with state and local health departments continue if the SNS is transferred to ASPR?

ASPR's Regional Emergency Coordinators currently coordinate with state and local health officials. ASPR also maintains extensive coordination with state and local emergency management officials, as well as public and private healthcare and emergency medical services leaders. With the transfer of the SNS, all previous relationships with state and local officials at ASPR and CDC will be maintained. State and local officials will continue to engage and communicate with their existing points of contact.

11) How does the Hospital Preparedness Program (HPP) improve local and state health system preparedness and public health emergency response systems?

The \$3 trillion healthcare delivery system in this country is a largely private sector, highly competitive enterprise. The Hospital Preparedness Program (HPP) helps to prepare the nation's healthcare system to save lives during emergencies and disasters by supporting the development of healthcare coalitions (HCCs) that facilitate collaboration before disaster strikes. It is the only source of federal funding for healthcare system readiness. HCCs are groups of healthcare, emergency management and response organizations that collaborate to prepare for and respond to a large influx of injured or ill patients. HCCs incentivize diverse and often competitive healthcare organizations to work together.

HCCs have supported communities' healthcare systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other healthcare partners—throughout the nation during past response operations. For example, as Hurricane Harvey made landfall in Houston Texas, the Southeast Texas

Regional Advisory Council (SETRAC), an HPP-supported HCC, coordinated all of the Houston region's healthcare response for Hurricane Harvey. SETRAC support, in part, enabled the 9,600-bed Texas Medical Center to remain operational throughout the storm and the flooding that ensued. The HCC also ensured that patients from other facilities that needed to be evacuated were transported to appropriate facilities safely. To do so, they utilized response equipment and communications and emergency management systems, financed by HPP, to coordinate across the entire region's healthcare delivery system.

Other recent examples where HCCs were successful in supporting community healthcare system needs during emergencies include responses to the Ft. Lauderdale airport shooting and to Hurricane Matthew in Georgia. When a shooter opened fire on January 6, 2017, at the Fort Lauderdale-Hollywood International Airport, killing five people and injuring many more, the Broward County HCC was ready to respond. The HCC and the airport have been close partners since 2007, conducting multiple disaster drills together every year. Thanks to years of exercising together, the HCC and airport have formalized plans, placing representatives at both the airport's Emergency Operations Center (EOC) and in local hospitals, greatly enhancing information sharing during a response. This shared coordination enabled effective, real-time communication between healthcare responders, transit authorities, and law enforcement as the incident unfolded. Within seven minutes of shots being fired, the HCC EOC liaison at the airport was coordinating patient distribution with first responders on the scene, while providing real-time updates to local hospitals and HCC members. As a result, local hospitals were able to suspend scheduled surgeries and accommodate over 50 incoming patients. One HCC member reflected that "...the response felt like an organized symphony. Without our HCC, we would not have had the established relationships or communication channels that enabled us to efficiently transport and treat so many unexpected patients and, ultimately, save lives."

Related to Hurricane Matthew, the HCC in coastal Georgia had a strong coastal evacuation plan developed from lessons learned through years of HPP-funded exercises, as well as numerous agreements with healthcare and other partners essential for moving patients across Georgia. These formalized, cross-functional partnerships enabled shared understanding of staffing, capacity, and resource availability before and during the response. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 patients – some just out of surgery – without any loss of life. The HCC turned to its strong partnerships, including with law enforcement, to ensure all patients were relocated around the state using appropriate transportation, which included helicopters from neighboring states to evacuate the most critical patients to safety. One HCC member shared that "HPP enables critical partnerships to be formed and tested before a disaster. By exercising and planning together, our HCC ensured that everyone knew their role during the response. We would not have successfully evacuated over a thousand patients – some in extremely vulnerable condition – in 24 hours without our HCC and HPP." HCCs are critical in supporting communities before, during, and after emergencies and are proving their ability to support needs during disaster.

As of June 30, 2017 (the most recent data available), over 31,000 healthcare facilities and community organizations were participating in 476 HCCs nationwide. This is an increase in HCC membership of 92 percent since June 2012. The diverse membership of HCCs also contributes to their success in preparing a community to respond to a wide variety of incidents that impact public health. Medical evaluation and treatment of incident victims require coordinated activities that extend beyond hands-on medical care. By building and sustaining HCCs, information can be collected, analyzed, and managed to support rapid patient distribution to appropriate facilities, patient tracking, family support, information coordination, and resource and transportation management. HCCs also disseminate knowledge of the range of injury and illness to inform response and timely requests for additional resources. The coordination processes and healthcare capabilities promoted by HPP's coalitions are designed to limit community morbidity and mortality after exposure to a hazard.

12) Specifically, how could the HPP be improved?

As included in the Department's PAHPA reauthorization technical assistance, there are four key modifications that could strengthen HPP to better support preparedness and response efforts and capabilities at the local level and better utilize existing resources. These include:

- Expand the use of HPP awards from preparedness to preparedness, response, and medical surge activities. This change helps ensure HPP funds can also be used to respond to local emergencies.
- Making clear that HPP partnerships can include coalitions and other entities in addition to those currently listed in the statute, and that such partnerships must include emergency medical service organizations and emergency management organizations.
- Add the option to deviate from 62 formula-based cooperative agreement awards, in order to make awards to jurisdictions with the highest risk (based on risk scores).
- Expand the withholding period for failure to reach certain benchmarks and performance metrics from one year to two years.

Further, combating modern threats requires innovative solutions to train, equip, organize, and incentivize our healthcare systems in ways that make our local communities, and our nation, more resilient. ASPR is developing two demonstration projects that address healthcare preparedness challenges, establish best practices for improving disaster readiness across the healthcare delivery system, and show the potential effectiveness and viability of a Regional Disaster Health Response System (RDHRS). The proposed system aims to leverage established investments in healthcare preparedness and trauma systems, including HPP. The proposed regional disaster health response system aims to expand the involvement of trauma centers, burn centers, pediatric hospitals, public health labs, outpatient services, and Federal facilities like Veterans Affairs clinics to better meet the healthcare needs of the public in a disaster.

13) What level of funding is required to enable the HPP to achieve its mission and respond to a regional disaster?

The President's FY19 Budget requests \$255 million, which is \$2 million above the FY 2018 Appropriations Act, for ASPR's Hospital Preparedness Program. The healthcare delivery system across the country is a \$3 trillion, highly competitive industry.

14) How does ASPR plan to improve HPP-supported healthcare coalitions into integrated entities capable of responding to severe public health emergencies such as that caused by Hurricane Harvey?

Combating modern threats requires innovative solutions to train, equip, organize, and incentivize our healthcare systems in ways that make our local communities, and our nation, more resilient.

In addition to the PAHPA reauthorization technical assistance submitted by the Department, and utilizing a portion of the increase in appropriations in FY18 for HPP, ASPR released a funding opportunity announcement, inviting applicants to develop demonstration projects that address healthcare preparedness challenges, establish best practices for improving disaster readiness across the healthcare delivery system, and show the potential effectiveness and viability of a regional disaster health response system.

15) How does ASPR currently address cybersecurity threats within the healthcare industry and public health emergency system?

The healthcare and public health systems of the U.S. rely on a complex network of staff, supplies, systems, and space to provide care. Americans rely on that critical infrastructure every day. ASPR's Critical Infrastructure Protection (CIP) program enhances the security and resilience of the nation's healthcare and public health (HPH) critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. ASPR's partners work together to mitigate risk from all hazards, including physical and cyber threats. The program analyzes infrastructure risks; prioritizes actions to mitigate those risks; and shares information related to risk management with private sector, state, local, tribal, and territorial partners during steady-state and incident response periods.

In December 2015, the Cybersecurity Act of 2015 (P. L. 114-113, Div. N) was enacted. The Act, as well as PPD-21 ("Critical Infrastructure" which designates the Department of Homeland Security and Resilience") and PPD-41 ("United States Cyber Incident Coordination") as the central point for cyber threat information sharing into the government, recognizes the unique challenges facing cybersecurity across the nation's critical infrastructure. These authorities, include provisions on HPH Sector preparedness reporting and information-sharing protocols that are led by the Department of Homeland

Security. The Act called for the creation of a federal advisory committee, the Healthcare Industry Cybersecurity Task Force, to make recommendations on HPH cybersecurity issues. In 2016, CIP established the Task Force, and supported it through the release of the Task Force's report to Congress in June 2017. The Task Force developed recommendations on cybersecurity challenges and barriers in the Sector, and how to achieve near real-time sharing of actionable threat information at no cost to businesses. On June 29, 2018, ASPR convened a workshop to highlight progress made on healthcare cybersecurity and initiated a set of public and private sector task groups to address the recommendations of the Task Force.

16) What best practices or guidance does ASPR provide regarding cybersecurity of electronic health records (EHRs) and medical devices?

ASPR defers to the relevant HHS components to address specific technical, programmatic, and/or regulatory issues related to cybersecurity. In the case of medical devices, ASPR defers to the guidance developed by the Center for Devices and Radiological Health at the Food and Drug Administration. For electronic health records, ASPR defers to the guidance developed by the HHS Office for Civil Rights and Office of the National Coordinator for Health Information Technology. ASPR promotes materials from these organizations and others in the cybersecurity and electronic health records space on the ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) website.

17) Does ASPR coordinate with the Department of Homeland Security or any other departments or agencies on cybersecurity threats?

Under Presidential Policy Directive 21, Critical Infrastructure Security and Resilience, DHS provides strategic guidance, promotes a national unity of effort, and coordinates the overall Federal effort to promote the security and resilience of the Nation's critical infrastructure. HHS is the Sector-Specific Agency for the healthcare and public health (HPH) sector. The HHS Critical Infrastructure Protection (CIP) program within ASPR coordinates HHS's role as the Sector-Specific Agency. The healthcare and public health systems of the U.S. rely on a complex network of staff, supplies, systems, and space to provide care. Americans rely on that critical infrastructure every day. The CIP program enhances the security and resilience of the nation's HPH critical infrastructure through a voluntary public-private partnership between all levels of government and the private sector. ASPR's partners work together to mitigate risk to the HPH sector from all hazards, including physical and cyber threats. The program analyzes HPH infrastructure risks; prioritizes actions to mitigate those risks; and shares HPH information related to risk management with HPH private sector, state, local, tribal, and territorial partners during steady-state and incident response periods.

In 2017, the healthcare and public health critical infrastructure sector continued to be a target for cyber-attacks with two major international cyber incidents. In May and June 2017, the WannaCry and NotPetya ransomware incidents brought together a coordinated federal effort across all sectors to respond to the attacks. As the SSA, HHS assessed

impacts to the Sector's ability to provide continuity of care across the country. Because of the foresight of HHS and HHS/ASPR leadership, the full resources of HHS's ESF 8 response capabilities were brought to bear in the response to the ransomware attacks, in partnership with HHS and DHS cybersecurity leadership. As a result, HHS, in coordination with DHS, was able to assist the overall Federal incident response effort by engaging with its private sector partners and providing them with vital guidance for remediation and information from DHS on the cyber attacks.

18) What lessons did ASPR learn from the Wannacry attacks and how can HHS' cybersecurity response be improved?

The coordinated Federal Government response to WannaCry validated the importance of the public-private sector partnership structure for responding to nationally significant cyber threats under the guidance of Presidential Policy Directive 41. Early alerting and regular communication with private sector partners helped them have the information they needed to take steps to keep their systems secure. It also allowed HHS to understand better the impact of WannaCry on the private sector and their needs. WannaCry also demonstrated the importance of coordination throughout the Department and the rest of the Federal Government. ASPR relied on subject matter experts throughout the Department and the Federal Interagency to provide the technical information and analysis.

In response to the lessons learned from WannaCry, ASPR has coordinated a series of exercise and planning activities with HHS partners. Through these activities ASPR and HHS partners have addressed issues such as assessing the significance of individual cyber incidents, coordinating communication with private sector partners, and coordinating incident management activities.

19) What resources does ASPR currently have to be successful in addressing cybersecurity risks in the health system?

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20) Given that it is FDA that approves medical devices, how does ASPR foresee leading cybersecurity guidance related to medical devices?

ASPR does not lead development of medical device cybersecurity guidance. ASPR does however work in close coordination with FDA on medical device cybersecurity matters. FDA currently serves as co-chair of the Healthcare Sector Government Coordinating Council, which is the primary organization for coordinating ASPR's critical infrastructure protection activities with government partners.

Rep. Engel:

- 1) **In regard to Dr. Kadlec's response on AMR and specifically drug resistant TB, BARDA, and CARB-X have unfortunately never offered funding opportunities to product developers working on MDR-TB medical countermeasures, including drugs, diagnostics or vaccines, and while NIAID does some work on TB research, it is not focused on product development for new TB tools, which is really what we need now to address a potential epidemic. Will BARDA and CARB-X include MDR-TB – the world's leading infectious killer and a rising global health security threat – in the scope of its funding opportunities in 2019 beyond?**

ASPR, through BARDA, invests in the development of products to address antimicrobial resistance. BARDA has largely focused on the research and development of novel antibiotics to stem the tide of antimicrobial resistant infections in both hospitals and in communities across the United States. These antibiotics are typically derivatives of existing classes of antibiotics that overcome known drug resistance mechanisms while also targeting one or more of the bioterrorism agents BARDA is tasked with addressing as part of its core mission. Additionally, the overall strategy is to leverage the development of products for routine clinical use as a means of having products "at the ready" in the event of a bioterrorism event.

Unfortunately, many of the products that would be developed to prevent or treat TB do not possess the dual purpose of also addressing a bioterrorism pathogen. For example, bedaquiline, the most recently approved TB drug, is not predicted to have any activity against the five bioterrorism bacteria (anthrax, plague, tularemia, glanders, melioidosis) for which BARDA is tasked with developing medical countermeasures.

In regard to CARB-X, TB is not currently in the scope of CARB-X. However, in addition to substantial research investments by NIAID, there are other important groups with particular expertise addressing this challenge, including the Bill and Melinda Gates Foundation and TB Alliance.

Rep. Matsui:

- 1) **One of the main issues that we will be discussing is the Strategic National Stockpile—a stockpile of supplies that can be deployed in case of a variety of types of emergencies. One of the conversations we will be having is about whether it is appropriate and necessary to transfer some SNS functions from CDC to the Assistant Secretary for Preparedness and Response (ASPR). I am interested to hear your thoughts on this topic.**

However, I want to ask a specific question related to safety of products stored in the stockpile. I understand that vaccines and other injectable drugs can be contaminated by glass because their glass containers may break, crack, delaminate, or contain glass particles. In some cases, these glass failures have resulted in recalls because they pose a potential threat to patient safety. Do you have concerns about the impact of these glass failures on the safety, security, or sterility of countermeasures in the stockpile?

FDA works closely with the CDC and manufacturers to ensure that the Strategic National Stockpile is managed very carefully and that products stored there are safe, effective, and ready for use. FDA did issue an advisory to drug manufacturers regarding the potential formation of glass lamellae (i.e., tiny glass particles that shed from the surface of glass) in injectable drugs filled in small-volume glass vials in 2011. Along with the advisory, FDA issued guidance to industry which includes recommendations to help prevent the formation of glass lamellae.¹ A subsequent analysis (using surveillance data from FY 2008 – FY 2017) by FDA did not identify any new or increasing safety signals since the advisory was issued. For glass lamellae, the number of recalls has dropped substantially since FDA issued the advisory and guidance in 2011. Glass containers are a very stable and often preferable container type for long-term storage, particularly for sterile products. Manufacturers can choose from a variety of glass container compositions depending on suitability for their specific product and storage conditions.

FDA will continue to monitor drug quality, evaluate and assess incidents involving quality issues, and respond with appropriate actions when information suggests a need to correct an issue with drug safety or availability.

- 2) **Cyberattacks represent an immediate and growing threat to public health, especially when attacks involve health care providers or health care devices. While ASPR has some role in cybersecurity preparedness, cybersecurity has not traditionally been a part of the PAHPA conversation. I think Congress and HHS both need to pay more attention to cybersecurity and health care. Big hospital systems and other health care stakeholders make efforts to ensure that their health care data is protected, but that is not always possible for smaller entities. And, the more that our health data is connected...as it should be to enhance patient care..the more vulnerable we are. That is why I work with my colleague Rep. Billy Long on the HHS Cybersecurity Modernization Act, as a first step in the direction of enhancing agency leadership on cybersecurity. Can you speak to ASPR's current role in cybersecurity preparedness?**

¹ <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124780.htm#11>

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3) Are there ways that we can better coordinate across HHS and other agencies to ensure health data both within the agency and in the health care sector is protected?

ASPR coordinates on cybersecurity matters with HHS partners through the HHS Cybersecurity Working Group. This working group reports to the Deputy Secretary of HHS, who is the identified lead official within the Department for cybersecurity. ASPR also coordinates on cybersecurity matters with government partners outside of HHS through the Healthcare and Public Health Sector Government Coordinating Council. This Council, established by the Department of Homeland Security's Critical Infrastructure Partnership Advisory Council. This Council, which convenes under DHS authorities, includes HHS, Federal Interagency, and state and local government partners.

Rep. Dingell:

The National Health Security Preparedness Index has found that our healthcare delivery readiness lags behind our preparedness in other areas. Despite this fact, the Hospital Preparedness Program has received about half the funding it once did. Giving the growing threats, it seems that we need to provide more resources not less.

- 4) **How could increasing funding for the Hospital Preparedness Program improve preparedness across the health care system? At its highest level the HPP program was appropriated at \$515 million, yet today the program has eroded to about half of what it once was. From climate change and extreme weather events to pandemic influenza and cybersecurity, now is the time to robustly fund this important preparedness program.**

The nation's healthcare delivery infrastructure is a \$3 trillion, highly competitive enterprise. ASPR's Hospital Preparedness Program (HPP) has supported over 31,000 healthcare facilities and community organizations participating in 476 healthcare coalitions (HCCs) nationwide. HCCs are groups of healthcare, emergency management and response organizations that collaborate to prepare for and respond to a large influx of injured or ill patients. HCCs incentivize diverse and often competitive healthcare organizations to work together.

HCCs have supported communities' healthcare systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other healthcare partners—throughout the nation during past response operations. For example, as Hurricane Harvey made landfall in Houston Texas, the Southeast Texas Regional Advisory Council (SETRAC), an HPP-supported HCC, coordinated all of the Houston region's healthcare response for Hurricane Harvey. SETRAC support, in part, enabled the 9,600-bed Texas Medical Center to remain operational throughout the storm and the flooding that ensued. The HCC also ensured that patients from other facilities that needed to be evacuated were transported to appropriate facilities safely. To do so, they utilized response equipment and communications and emergency management systems, financed by HPP, to coordinate across the entire region's healthcare delivery system.

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had the established relationships or communication channels that enabled us to efficiently transport and treat so many unexpected patients and, ultimately, save lives.”

Related to Hurricane Matthew, the HCC in coastal Georgia had a strong coastal evacuation plan developed from lessons learned through years of HPP-funded exercises, as well as numerous agreements with healthcare and other partners essential for moving patients across Georgia. These formalized, cross-functional partnerships enabled shared understanding of staffing, capacity, and resource availability before and during the response. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 patients – some just out of surgery – without any loss of life. The HCC turned to its strong partnerships, including with law enforcement, to ensure all patients were relocated around the state using appropriate transportation, which included helicopters from neighboring states to evacuate the most critical patients to safety. One HCC member shared that “HPP enables critical partnerships to be formed and tested before a disaster. By exercising and planning together, our HCC ensured that everyone knew their role during the response. We would not have successfully evacuated over a thousand patients – some in extremely vulnerable condition – in 24 hours without our HCC and HPP.” HCCs are critical in supporting communities before, during, and after emergencies and are proving their ability to support needs during disaster.

However, combating modern threats requires innovative solutions to train, equip, organize, and incentivize our health care systems in ways that make our local communities, and our nation, more resilient. ASPR is developing two demonstration projects that address healthcare preparedness challenges, establish best practices for improving disaster readiness across the healthcare delivery system, and show the potential effectiveness and viability of a Regional Disaster Health Response System (RDHRS). The proposed system aims to leverage established investments in healthcare preparedness and trauma systems, including HPP. The proposed regional disaster health response system aims to expand the involvement of trauma centers, burn centers, pediatric hospitals, public health labs, outpatient services, and federal facilities like Veterans Affairs clinics to better meet the healthcare needs of the public in a disaster.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
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June 26, 2018

Rear Admiral Stephen Redd, M.D.
Director
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Centers for Disease Control and Prevention
1600 Clifton Road
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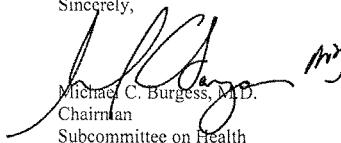
Dear Admiral Redd:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 11, 2018. Your responses should be mailed to Daniel Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to daniel.butler@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

**Response of Dr. Steve Redd, Centers for Disease Control and Prevention,
to Questions for the Record:
June 6, 2018 hearing on the Pandemic and All Hazards Preparedness Act,
House Energy and Commerce Committee, Health Subcommittee**

Rep. Bilirakis

Resiliency is vital to preparedness and ultimately response and recovery. The stockpile of drugs, vaccines, and other medical products and supplies, known as the Strategic National Stockpile is critical to our ability to respond and recover from catastrophic events. Reliable storage and delivery of these lifesaving medicines is also important in terms of patient safety and cost.

1. In what ways is your agency working with industry to extend shelf life and improve resiliency of the Strategic National Stockpile?

Response: Improving the resiliency of the Strategic National Stockpile by working with industry is a priority. CDC has engaged industry by forming partnerships with major industry trade associations specifically - Health Industry Distributors Association (HIDA), International Safety Equipment Association (ISEA), Healthcare Distribution Alliance (HDA), National Association of Chain Drug Stores (NACDS), and Healthcare Supply Chain Association (HSCA). These partnerships improve the resiliency of the Strategic National Stockpile through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to personal protective equipment (PPE);
- Improved public access to medical countermeasures; and
- Redundant distribution of medical countermeasures, information, and materiel.

The resiliency of the Strategic National Stockpile is closely linked to the resiliency of the commercial supply chain. Recognizing that private industry relies on accurate forecasting of demand when determining manufacturing priorities, CDC held three pre-solicitation conferences (or bidder conferences) for potential vendors and stakeholders in January 2018. These conferences, which focused on three requirements being developed for the SNS, were intended to improve the quality and accuracy of future requests for proposals in the requirement areas, as well as enabling the vendors to submit better proposals.

In addition to the important work done with private industry, CDC seeks to maximize the value of the SNS appropriation in collaboration with FDA through the Shelf Life Extension Program (SLEP). Some pharmaceuticals, if stored in accordance with the manufacturer's recommendations, may be viable beyond the manufacturer's labeled expiration date and allow for deferment of drug replacement costs. CDC works with FDA to test stability of drugs approaching labeled expiry through SLEP. If SLEP testing confirms that the product is viable and safe to use beyond the established expiration date, FDA will typically provide an additional 12 to 24 months of extended shelf life. For some products not eligible for the SLEP program, including biological products such as vaccines and immune globulins, SNS contracts with the manufacturers for annual potency testing to try to extend the shelf life of the stockpiled products.

Rep. Mullin:

1. Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?
 - a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?
 - b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?

Defer to ASPR/BARDA

Rep. Carter:

1. How can ASPR ensure that the transfer is not overly disruptive for state and local health departments?

Response: CDC has a 70-year history of working directly with public health agencies during public health responses as well as routine day-to-day operations, providing guidance, funding, and strategic direction for any public health threat. CDC will continue to work with state and local health departments to improve readiness to deploy SNS items by providing them with guidance, trainings, evaluation tools, performance metrics, and targeted technical assistance and subject matter expertise. Since 2004, CDC has provided dedicated medical countermeasure (MCM) funding via the Public Health Emergency Preparedness (PHEP) cooperative agreement to 72 of the largest metropolitan statistical area across the country— covering over 60% of the U.S. population. This funding supports the Cities Readiness Initiative, an initiative for these metropolitan areas to develop and exercise plans to rapidly dispense MCMs to their entire populations in response to large public health emergencies.

The PHEP cooperative agreement sets requirements and standards for state and local public health preparedness and response programs. PHEP recipients develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response. MCM distribution and dispensing are two of the public health preparedness capabilities that must be integrated with the other 13 planning areas (including surveillance, responder safety and health, risk communication, public health emergency operations) to ensure a successful response. This work will continue after the SNS transfer.

The Department is dedicated to improving the final distribution and dispensing of products contained in the SNS by providing robust operational support to states and locals. ASPR is working with CDC and other federal agencies to build upon the work CDC has done to date to continue to explore options.

To ensure a smooth Strategic National Stockpile transition on October 1, 2018, with no degradation of operational capability, ASPR and CDC have set up several joint transition workgroups to evaluate and plan for all aspects of the program transition. CDC and ASPR also

have established a new senior CDC liaison who is working within the ASPR Immediate Office. CDC will continue to be a core member of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), which is led by ASPR and provides a venue for sharing information across HHS agencies with a role in medical countermeasures requirement setting, research, development, regulatory review, procurement, stockpiling, distribution and use. CDC subject matter experts will remain active participants in all PHEMCE workgroups and committees.

2. **This past year was a very serious flu season and we learned that the virus had not changed dramatically from the previous year. With a universal flu vaccine still years away, do you think that learning more about stopping the spread of infections in doctors' offices and hospitals would be a good step in reducing the impact of the flu and other serious communicable diseases?**

Response: Effective infection control and prevention practices require consistent and ongoing refresher training by the healthcare professional and the healthcare systems that they work in. Consistent infection control practices across all U.S. healthcare settings can help prevent future outbreaks of influenza/flu and other serious emerging infectious diseases like Ebola, MERS, and SARS. Since the 2014 Ebola outbreak, CDC has provided support to state health departments through the CDC Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement to perform infection control assessments and provide feedback and guidance to healthcare facilities across the country. CDC also provides educational resources, guidelines, and tools for healthcare professionals, healthcare facilities, and the public on CDC's infection control website: <https://www.cdc.gov/infectioncontrol/index.html>. Healthcare-associated influenza infections can occur in any healthcare setting and are most common when influenza is also circulating in the community. Therefore, the influenza prevention measures outlined by CDC (<https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm>) should be implemented in all healthcare settings. Supplemental measures may need to be implemented during influenza season if outbreaks of healthcare-associated influenza occur within certain facilities, such as long-term care facilities and hospitals. A combination of infection prevention and control strategies is recommended to decrease transmission of influenza viruses in healthcare settings. These include source control (immediately putting a surgical mask on patients being evaluated for respiratory symptoms), promptly placing suspected influenza patients in private rooms, ensuring that influenza vaccination is provided to all healthcare personnel, and having healthcare personnel wear personal protective equipment (PPE) when caring for patients with suspected influenza. Healthcare personnel should wear gloves, an isolation gown, and face protection (either a face shield, or eye protection and a mask) for entry into an influenza patient isolation room. A mask should be worn by infectious patients any time they leave the isolation room.

Through the CDC-funded Prevention EpiCenters Network, CDC collaborates with academic medical centers to address important scientific questions and find new ways to improve healthcare quality and patient safety. This work includes innovative research on preventing the transmission of viral and bacterial pathogens within healthcare settings, enhancing healthcare

worker safety, and understanding the role of the healthcare environment in disease transmission to further establish effective infection control strategies and novel interventions.

- 3. The Ebola outbreak highlighted a successful public-private partnership between CDC and Emory University; all 4 patients that were treated in Emory's Serious Communicable Diseases Unit recovered from this highly contagious infectious disease. Building off this model partnership and the lessons learned by researchers and providers, would you be supportive of applying this knowledge to future pandemics that could affect thousands of Georgians like avian flu?**

Response: CDC continues to learn from previous outbreak investigations and uses them to inform the science, data, and safe healthcare practices going forward. To prevent highly contagious infectious diseases and outbreaks from spreading widely, CDC works closely with state and local health departments, healthcare systems/facilities, and other state and local partners before, during and after an emergency to enhance infection control capacity and further identify gaps in infection control practices to help mitigate outbreaks, epidemics and pandemics in the future. CDC has also leveraged strategic partnerships with professional organizations, healthcare partners, and academic groups to provide infection control training to clinicians, patients and healthcare workers (HCWs) through live training events, web-based resources, webinars, conference calls, and mobile device apps. To better establish prevention strategies and improve infection control practices, CDC is supporting innovation and research through CDC cooperative agreements and collaboration via the CDC Prevention EpiCenters network and other professional groups. These groups continue to work with CDC to identify and validate infection control strategies and novel interventions that effectively prevent transmission of infectious viral or bacterial pathogens in healthcare settings.

The linkages between CDC and Emory University, as well as with the University of Nebraska Medical Center and Bellevue Hospital Center, are effective public-private partnership models and have contributed to the development of the ten regional treatment facilities for Ebola and other highly infectious diseases to help prepare for future pandemics.

- 4. The Hospital Preparedness Program is an important tool for our regional health care system preparedness. Emory University has been a recipient of funding to explore innovated ways to increase hospital readiness during local or national emergencies. In partnership with GA Tech, they have developed new tools including using virtual reality to keep healthcare workers trained and up to date on best practices to help improve patient outcomes and provider safety. Do you believe this program has been helpful in getting our nation more prepared for the next epidemic?**

The \$3 trillion healthcare delivery system in this country is a largely private sector, highly competitive enterprise. The Hospital Preparedness Program (HPP) helps to prepare the nation's health care system to save lives during emergencies and disasters by supporting the development of healthcare coalitions (HCCs) that facilitate collaboration before disaster strikes. It is the only source of Federal funding for health care system readiness. HCCs are groups of health care, emergency management and response organizations that collaborate to prepare for and respond to a large influx of injured or ill patients. HCCs incentivize diverse and often competitive health care organizations to work together.

HCCs have supported communities' health care systems—including hospitals, long term care facilities, emergency medical services agencies, public health departments and other health care partners. Specific to infectious disease preparedness, HPP used supplemental funding to establish a regional treatment network. This network balances geographic need and differences in institutional capabilities, and accounts for the potential risks of care. Through HHS investments, the U.S. health care system has achieved marked progress in the development of a regional network of tiered hospitals. HPP's collection and analysis of annual performance and impact data indicate that supplemental Ebola funding provided through the cooperative agreements has been instrumental in enhancing awardees' tactical facility- and system-wide capacity to respond to an Ebola-like threat. HPP's cooperative agreement funding strategy and performance measures for Ebola encouraged a rapid buildup of key response capabilities at each facility tier. HPP requires awardees to engage in operational planning, tactical coordination across states and regions, workforce training, intentional purchase of necessary equipment, and exercises that promote skill-building. From the purchase of personal protective equipment (PPE) by facilities on the frontline to acquiring incinerators to handle contaminated waste at regional Ebola and other special pathogen treatment centers, hospitals at each tier used HPP's year-one funds to purchase equipment and infrastructure required to fulfill their response roles moving forward. Also in the initial funding year, nearly 7,000 rostered staff in the Ebola treatment centers and regional Ebola and other special pathogen treatment center tiers were pre-identified and trained to provide Ebola patient care. Most importantly, the regional treatment network practiced its ability to activate improved response capabilities in each region; 100 percent of regional Ebola and other special pathogen treatment centers conducted quarterly exercises that incorporated unannounced first-person drills, patient transport, and patient care simulation. It is important to note that while the initial focus was on preparedness for Ebola, it is likely that preparedness for other novel, highly pathogenic diseases has also been enhanced through these Ebola preparedness grants.

As of June 30, 2017 (the most recent data available), over 31,000 health care facilities and community organizations were participating in 476 HCCs nationwide. This is an increase in HCC membership of 92 percent since June 2012. The diverse membership of HCCs also contributes to their success in preparing a community to respond to a wide variety of incidents that impact public health. Medical evaluation and treatment of incident victims require coordinated activities that extend beyond hands-on medical care. By building and sustaining HCCs, information can be collected, analyzed, and managed to support rapid patient distribution to appropriate facilities, patient tracking, family support, information coordination, and resource and transportation management. HCCs also disseminate knowledge of the range of injury and illness to inform response and timely requests for additional resources. The coordination processes and health care capabilities promoted by HPP's coalitions are designed to limit community morbidity and mortality after exposure to a hazard.

Rep. Pallone:

The Strategic National Stockpile (SNS) is a key line of defense against natural and manmade threats. The SNS is not just a stockpile of medications, antidotes, and medical supplies, but also consists of logistical infrastructure capable of deploying products in the event of a public health emergency. The proposed bill, H.R. ____, the Pandemic All-Hazards Preparedness Reauthorization Act of 2018 would transfer the SNS to ASPR from the Centers for Disease Control (CDC), expand the role of ASPR in responding to public health emergencies and our national response. The

transfer of the Strategic National Stockpile (SNS) from the Centers for Disease Control (CDC) and Prevention to the Assistant Secretary for Preparedness and Response (ASPR) raises a number of concerns about the stability and coordination of the SNS and ultimately, how the departmental changes could affect our national readiness and ability to respond to a public health emergency.

1. Please describe the CDC's past role in leading the SNS, the range and type of deployments and the types of products the CDC has delivered through the SNS program?

Response: The SNS (formerly the National Pharmaceutical Stockpile) has an established record of responsible, scientifically informed product stewardship and a history of successful deployments of products since 1999. The first deployment from the SNS was completed in 2001, deploying portable mechanical ventilators to Houston in support of patients displaced by flooding related to Tropical Storm Allison. In response to the 9/11 attacks CDC deployed large quantities of personal protective equipment and 12 hour push packages of broad spectrum supplies for mass casualty treatment. Following the Anthrax attacks CDC deployed large quantities of treatment and prophylaxis countermeasures for individuals exposed to Anthrax. Since these initial deployments in 2001, CDC has directed more than 100 deployments of SNS supplies, including the largest deployment of medical countermeasures ever in response to the 2009 H1N1 pandemic. In addition, CDC has close, ongoing relationships with state and local health departments, broad clinical expertise, and deep laboratory capacity has been able to direct many SNS small scale deployments of life-saving products for treatment of botulism, anthrax exposures, and for complications of vaccinia (smallpox) vaccination, for which the SNS holds the nation's primary or only supply of approved treatments. These day-to-day emergency deployments ensure that systems and relationships are in place and ready to go when larger scale responses are required. Federal Medical Station sets or FMS sets are another asset CDC frequently deploys in hurricane responses. These FMS sets support the Office of the Assistant Secretary for Preparedness and Response's (ASPR) National Disaster Medical System (NDMS) teams and other trained medical staff involved in augmenting public health and medical needs in communities impacted by disaster. Each FMS set is comprised of medical supplies and pharmaceuticals sufficient to stand up a low acuity healthcare facility in open structures such as arenas, aircraft hangers or empty retail space. Each FMS set can provide a platform for NDMS and other trained medical staff to care for up to 250 patients with non-surgical healthcare needs for up to 3 days without resupply. These FMS sets were first deployed in response to Hurricane Katrina. Since their initial deployment, FMS sets have been used extensively to support the response to hurricanes, flooding and other natural disasters. FMS sets were most recently deployed in response to the 2017 Hurricanes Harvey, Irma, and Maria.

2. How does CDC assist state and local health departments with the "last mile" deployment of SNS items in the event of a public health emergency?

Response: CDC works with state and local health departments to improve readiness to deploy SNS items by providing them with guidance, trainings, evaluation tools, performance metrics, and targeted technical assistance and subject matter expertise. Since 2004, CDC has provided dedicated medical countermeasure (MCM) funding via the Public Health Emergency Preparedness (PHEP) cooperative agreement to 72 of the largest metropolitan statistical area across the country— comprising approximately 60 percent of the U.S. population. This funding supports the Cities Readiness Initiative, an initiative for these metropolitan areas to develop and

exercise plans to rapidly dispense MCMs to their entire populations in response to large public health emergencies. The PHEP cooperative agreement sets requirements and standards for state and local public health preparedness and response programs. PHEP recipients must develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response. MCM distribution and dispensing are two of the public health preparedness capabilities that must be integrated with the other 13 planning areas (including surveillance, responder safety and health, risk communication, public health emergency operations) to ensure a successful response. This work will continue after the SNS transfer.

CDC also assesses state and local public health MCM programs through an Operational Readiness Review. CDC analyzes the Operational Readiness Review data to determine state and local MCM gaps and strengths, develops strategies for improvement, and works closely with state and local health departments to implement jurisdictional improvement plans.

CDC provides a variety of MCM trainings to improve state and local dispensing capabilities. Trainings range from monthly webinars to in-person point-of-dispensing training courses. CDC also has dedicated regional MCM field staff who work directly with 16 high-risk Urban Areas Security Initiative (UASI) cities to improve readiness for release of a Category A agent (Anthrax, Botulism, Plague, Smallpox, Tularemia, Viral hemorrhagic fever, pandemic influenza) and to provide assistance to other jurisdictions upon request. CDC works with PHEP awardees to identify potential state and local surge personnel solutions for MCM dispensing operations.

CDC will continue its direct day-to-day support of state, tribal, local and territorial jurisdictions in the planning and execution of MCM dispensing "last mile" activities. In addition to the funding, technical assistance, operational assessments and training described above, CDC provides expertise to ensure SNS assets are used in the best way possible. These activities, which are specific to and supported by the SNS, augment the "last mile" of a MCM response. Specifically:

- Scientific Research – CDC research seeks to optimize the effectiveness and use of SNS MCMs for smallpox, anthrax and other threat agents in a public health emergency. As one of only two laboratories in the world authorized to work with Variola, the virus that causes smallpox, CDC's high containment laboratory is the only place where smallpox research activities can be conducted.
- Operational Research and Tools- CDC conducts operational research to inform jurisdictions on how to best leverage private sector partnerships (for example with retail pharmacy partners) to augment their MCM dispensing activities, and has developed novel tools to support and augment state and local MCM access, dispensing, and medication compliance tracking.
- Surveillance - CDC's surveillance and epidemiological activities help identify when a threat happens and assess the impact. This helps to define the population that needs to receive SNS MCMs during a response.
- Lab –CDC's laboratory expertise provides surge capacity to better detect and identify a threat and to ensure that the MCMs released from the SNS are effective against the pathogen.

- Clinical Guidance - CDC develops and publishes clinical guidance and clinical tools to inform the use of SNS MCMs in all segments of the population, including the pediatric and other vulnerable populations.
- Regulatory Mechanisms - CDC works with FDA to develop and maintain the necessary regulatory mechanisms to allow for the safe and effective use of SNS MCMs. In addition, CDC assists in the development of post-marketing data collection required by FDA for certain MCMs.
- Communication – CDC is the trusted source for public health information every day and during responses. CDC is also the trusted source for the clinical community – this ensures that clinicians and the public trust and are willing to use the recommended SNS MCMs at the time of an event and in planning for an event.

In addition, CDC and ASPR are working closely with other senior leaders across government to develop federal solutions for specific strategies for improving MCM dispensing and distribution. Efforts are focused specifically on how the federal government can help states, localities, and territories with their MCM mission.

3. What training programs does the CDC sponsor are funded through the SNS program? Will the funding from SNS continue to be used to pay for training activities?

Response: CDC, through the Public Health Emergency Preparedness Cooperative Agreement, provides substantial training to prepare Federal, state, and local partners for effective response to public health emergencies. CDC provides MCM training to improve state and local dispensing capabilities. Trainings range from monthly webinars to in-person point-of-dispensing training courses. CDC also has dedicated regional MCM field staff who work directly with 16 high-risk Urban Areas Security Initiative (UASI) cities to improve readiness for release of a Category A agent (Anthrax, Botulism, Plague, Smallpox, Tularemia, Viral hemorrhagic fever, pandemic influenza) and to provide assistance to other jurisdictions upon request. CDC works with state and local health departments to identify surge personnel solutions for MCM dispensing operations. Training by CDC will continue after the SNS transitions to ASPR, with details currently under discussion between CDC and ASPR.

4. The President's FY 2019 budget requested the transfer of the SNS from the CDC to ASPR. What is the main motivation behind the transfer of the SNS?

At a time when the U.S. threat environment is becoming more complex and dangerous, the transition of the SNS to ASPR will strengthen and streamline the medical countermeasures enterprise and leverage synergies in supply chain logistics.

ASPR was established in 2006; the CDC first received appropriations to support the SNS in 1998, before ASPR was authorized. Operational authority for the SNS was subsequently split between HHS and DHS, but it was unified at HHS in 2004 and maintained in CDC. While placing the SNS at CDC made historical sense, the creation and maturation of ASPR provides an opportunity to align the direct oversight and management of SNS under ASPR.

When disasters occur, ASPR leads the National Response Framework, Emergency Support Function #8 as delegated by the Secretary, thereby coordinating Federal public health and medical responses, including assets from CDC as well as contents of the SNS.

ASPR has a robust medical logistics capability that supports the National Disaster Medical System (NDMS), moving medical personnel, equipment, and supplies across the nation within hours. ASPR works closely with state and local emergency management professionals, clinicians, healthcare facilities, and NDMS response teams who may be called upon to dispense SNS medical products. Shifting operational control of the SNS to ASPR, while continuing to leverage CDC's leadership role with public health agencies, will consolidate emergency response materiel under a single entity and improve the distribution during emergencies.

In addition, making this change will strengthen and streamline the entire medical countermeasures (MCM) enterprise. ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which includes senior representatives from all agencies involved in the medical countermeasures enterprise. The PHEMCE oversees setting MCM requirements, developing and procuring new products through the Biomedical Advanced Research and Development Agency (BARDA) and Project BioShield. Congress established BARDA and Project BioShield to encourage companies to develop medical countermeasures the government needs to keep Americans safe from national security threats, by creating a government market where there is usually not a commercial incentive and to enable public-private partnerships for such advanced research and development.

When MCMs for DHS-identified national security threats are in late stage development, BARDA can procure them using the Project BioShield Special Reserve Fund. After these MCMs are approved or licensed by FDA, procurement responsibility may then shift to SNS.

Having the right MCM is one part of the PHEMCE mission. To ensure that the use of MCMs continues to be coordinated with public health and disease threat experts, CDC will continue to play an important role in PHEMCE activities. In addition to participating in setting requirements as part of the PHEMCE interagency, CDC leads public health surveillance, epidemiologic, and laboratory investigation needed to know when a threat happens, who is impacted, and what MCMs to use. CDC also provides clinical guidance to ensure that clinicians and the public know how to use SNS MCMs, and leads and coordinates with state and local public health partners. These activities, along with CDC risk and health communications, will continue to support PHEMCE efforts to ensure the optimal use of SNS assets.

5. What issues may be solved by this move and what challenges may be created by transferring the SNS from the CDC to ASPR?

Response: Transferring SNS from CDC to ASPR will increase operational effectiveness and efficiencies around the development and procurement of medical countermeasures, and enable nimble responses to public health emergencies.

To ensure a smooth SNS transition with no degradation of operational capability, CDC and ASPR have set up several joint transition workgroups to evaluate all aspects of the program transition. The transition workgroups are devoting substantial effort to issues such as: 1) ensuring that CDC subject matter expertise continues to be involved in SNS work, especially developing guidance on when and how to use medical countermeasures in the SNS, including regulatory support; 2) ensuring that the interests of state and local health departments continue to be represented in SNS planning and operations; and 3) coordination in the distribution and dispensing of MCM.

6. How will moving the SNS from CDC to ASPR affect programs that support the SNS and are run by CDC, such as the Public Health Emergency Preparedness (PHEP) awards, which support state and local capacity to receive, distribute and dispense medical countermeasures (MCMs)?

Response: Ensuring ongoing successful utilization of SNS assets will require CDC's continued ability to provide, in a collaborative and transparent fashion, its expertise in the scientific, clinical, regulatory, laboratory, and state, tribal, local and territorial response coordination (including MCM distribution and dispensing) matters that are a critical part of this mission. SNS transition details are currently under discussion between CDC and ASPR.

CDC will continue to provide subject matter expertise in SNS MCM issues and in the decision-making process. SNS funding supports a portion of the PHEP program's MCM planning work. PHEP recipients must develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response. Two of these capabilities are contained within the Countermeasures and Mitigation domain, and relate to distribution and dispensing of MCMs. PHEP project officers are assigned to specific state and local jurisdictions to support their work in advancing the public health preparedness capabilities the jurisdiction considers priorities. In addition, regional project officers based in the field work directly with 16 high-risk Urban Areas Security Initiative (UASI) jurisdictions to improve readiness for release of anthrax or other Category A agents and provide assistance to other jurisdictions upon request. CDC will continue MCM work after the SNS is transferred to ASPR, with additional details currently under discussion between CDC and ASPR.

Beyond the PHEP grants, CDC provides expertise in multiple areas to ensure SNS assets are used in the best way possible. These activities are specific to, and supported by, the SNS program. Specifically:

- State, Local, Tribal, Territorial (SLTT) Coordination – CDC has over 70 years of experience working with SLTT partners. CDC will continue its direct day-to-day support of SLTT jurisdictions in the planning and execution of MCM dispensing, as an integrated part of overall response capabilities that include epidemiologic and laboratory surveillance, communication strategies, and non-pharmaceutical interventions at the federal, state and local levels. CDC also routinely assesses state, local and territorial plans, with an emphasis on state and local operational response readiness; conducts operational research to inform jurisdictions on how to best leverage private sector partnerships (for example with retail pharmacy partners) to augment their MCM dispensing activities; and has developed novel tools to support and augment state and local medical countermeasure access, dispensing, and medication compliance tracking.
- Research – CDC research seeks to optimize the effectiveness and use of SNS MCMs for smallpox, anthrax and other threat agents in a public health emergency. As one of only two laboratories in the world authorized to work with Variola, the virus that causes smallpox, CDC's high containment laboratory is the only place where smallpox research activities can be conducted.
- Surveillance - CDC's surveillance and epidemiological activities help identify when a threat happens and assess the impact. This helps to define the population that needs to receive SNS MCMs during a response.

- Lab –CDC’s laboratory expertise provides surge capacity to better detect and identify a threat and to ensure that the MCMs released from the SNS are effective against the pathogen.
- Clinical Guidance - CDC develops and publishes clinical guidance and clinical tools to inform the use of SNS MCMs in all segments of the population, including the pediatric and other vulnerable populations.
- Regulatory Mechanisms - CDC works with FDA to develop and to implement the necessary regulatory mechanisms for the safe and effective use of SNS MCMs. These critical activities include supporting emergency use of MCMs that are not yet FDA approved and the use of approved MCMs for unapproved indications through protocols in applications for Investigational New Drug (INDs), Emergency Use Authorizations (EUAs), and Emergency Use Instructions (EUIs), as appropriate. In addition, CDC assists in the development of post-marketing data collection required by FDA for certain MCMs.
- Communication – CDC is the trusted source for public health information every day and during responses. CDC is also the trusted source for the clinical community – this ensures that clinicians and the public trust and are willing to use the recommended SNS MCMs at the time of an event and in planning for an event.

7. How does the CDC and ASPR currently coordinate?

Response: CDC and ASPR have strong working relationships and will continue to collaborate closely to ensure that the expertise and resources of both agencies are most effectively leveraged to protect the health of the American people. CDC is part of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which defines and prioritizes requirements for public health emergency medical countermeasures. Created by HHS in 2006, PHEMCE is an interagency effort led by the ASPR to coordinate the research, development, procurement, and preparation for the effective utilization of medical countermeasures among the civilian population. CDC consults with ASPR on strategic policy decisions during a Public Health Emergency, such as deployment of SNS assets. SNS MCM needs are specific to the incident and the jurisdictional request, with the goal of protecting and saving lives. CDC and ASPR also work together on the Public Health Emergency Preparedness Program (PHEP) and the Hospital Preparedness Program (HPP) to support state and local jurisdictions during emergency responses.

8. What plan does the CDC and ASPR have to ensure PHEP-supported health departments continue coordination after the transfer of the SNS?

Response: CDC will continue to provide subject matter expertise in SNS MCM issues and in the decision-making process. SNS funding supports a portion of the PHEP program’s MCM planning work. PHEP project officers are assigned to specific state and local jurisdictions to support their work in advancing the public health preparedness capabilities the jurisdiction considers priorities. In addition, regional project officers based in the field work directly with 16 high-risk Urban Areas Security Initiative (UASI) jurisdictions to improve readiness for release of anthrax or other Category A agents and provide assistance to other jurisdictions upon request. CDC is committed to continuing, to the maximum extent possible, its support of the overall MCM mission, which includes state and local capacity to receive, distribute, and dispense MCMs. This will ensure support to health departments after the transfer of the SNS.

ASPR and CDC have convened five working groups to oversee the details of the SNS transfer. One of those groups focuses on state and local coordination.

In addition, CDC and ASPR are working closely with other senior leaders across government to develop federal solutions for five specific strategies for improving MCM dispensing and distribution. Strategies include federal support for staffing, distribution support, residential delivery strategies, national partnerships with the private sector, and pre-positioning federal caches within several high-risk jurisdictions. Efforts are focused specifically on how the federal government can help states, localities, and territories with their MCM mission.

9. How does the CDC currently coordinate with state and local health departments? How will this relationship with state and local health departments continue if the SNS is transferred to ASPR?

Response: Since its creation, CDC has established strong relationships with state, tribal, local and territorial health officials and funded them to build and improve capacity, and therefore agency performance, agility and resilience in providing public health services. Whether through programs focused on obesity, environmental health, the opioid crisis, emergency preparedness, influenza, childhood immunization or heart disease, CDC support strengthens public health programs that state, tribal, local and territorial public health officials operate on a daily basis and their ability to effectively prepare for and respond to emergency situations. And, the established foundation of trust and personal relationships, avenues of communication and collaboration, and body of agency knowledge built over time with jurisdictions helps inform CDC's assistance every day and during emergencies. This support will continue after the SNS transfer.

As to the SNS, CDC provides expertise in multiple areas and coordination directly with state and local health departments to ensure SNS assets are used in the best way possible. Specifically:

- State, Tribal, Local and Territorial Coordination – The PHEP cooperative agreement sets requirements and standards for state and local public health preparedness and response programs. PHEP recipients must develop and demonstrate operational capability across CDC's 15 public health preparedness capabilities critical for an effective public health response including distribution and dispensing. CDC will continue its direct day-to-day support of STL jurisdictions in the planning and execution of MCM dispensing, as an integrated part of overall response capabilities that include epidemiologic and laboratory surveillance, communication strategies, and non-pharmaceutical interventions at the federal, state and local levels. CDC also routinely assesses state, local and territorial plans, with an emphasis on state and local operational response readiness. CDC also conducts operational research to inform jurisdictions on how to best leverage private sector partnerships (for example with retail pharmacy partners) to augment their MCM dispensing activities, and has developed novel tools to support and augment state and local medical MCM access, dispensing, and medication compliance tracking.
- Surveillance - CDC's surveillance and epidemiological activities in coordination with state and local partners help identify when a threat happens and assess the impact. This helps to define the population that needs to receive SNS MCMs during a response.
- Lab –CDC's laboratory expertise provides surge capacity for state and local health departments to better detect and identify a threat and to ensure that the MCMs released from the SNS are effective against the pathogen.

- Clinical Guidance - CDC develops and publishes clinical guidance and clinical tools to inform the use of SNS MCMs in all segments of the population, including the pediatric and other vulnerable populations.
- Communication – CDC is the trusted source for public health information every day and during responses. CDC is also the trusted source for the clinical community – this ensures that clinicians and the public trust and are willing to use the recommended SNS MCMs at the time of an event and in planning for an event.

10. Please describe how state and local public health departments were impacted by funding from the PHEP cooperative agreement being redirected for the Zika response?

Response: During the Zika response, \$44.25 million in PHEP funding was redirected in March 2016 to support Zika response activities. This redirection impacted state and local staffing. After the funding was restored through a supplemental appropriation from Congress, some jurisdictions reported that they were not always able to rehire the staff or find new staff with similar expertise and preparedness experience.

11. In the opinion of CDC, could state and local health departments maintain operations and staffing if currently funding was cut or delayed?

Response: CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement funds 62 state, local, and territorial public health departments to create response-ready public health departments. PHEP funds support staff, enable exercises, provide for training, pay for equipment, and provide other services essential to maintaining preparedness for and readiness to respond to a public health emergency. CDC provides ongoing technical assistance to PHEP awardees and, at times, provides on-the-ground personnel to assist with a state's response effort.

Funding cuts to PHEP would likely result in decreased awards to states, localities, and territories. Such reductions could lead to staff layoffs at the state and local levels, which could include public health emergency managers, laboratorians, epidemiologists, public health nurses, and risk/health communicators. Such reductions could also affect activities and functional areas, including:

- Training
- Developing plans and conducting exercises
- Purchasing and maintaining equipment and supplies
- Coordinating with partners
- Conducting community outreach and public engagement sessions

12. When funding cuts or delays occur, how does that impact the ability of state and local health departments to respond to public health emergencies?

Response: State and local health departments rely on the PHEP cooperative agreements to plan, train, and prepare for emergencies so that when disasters strike communities are prepared. Inconsistency in funding could lead to delays in hiring and procurement, and staff layoffs. Funding reductions could also erode an established state and local network of expertise, relationships, and trust built over time through shared responses, training, and exercises.

Funding cuts also could reduce CDC's activities that support state and local preparedness, such as:

- consultation to awardees
- placement of field staff in jurisdictions to address unmet state and local needs
- CDC monitoring and evaluation of awardees
- CDC support for medical countermeasure planning to ensure state and local health departments can distribute and dispense essential supplies during a public health emergency

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
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June 26, 2018

Ms. Anna Abram
Deputy Commissioner for Policy, Planning, Legislation, and Analysis
U.S. Food and Drug Administration
White Oak Campus
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Building 1, Room 2335
Silver Spring, MD 20993

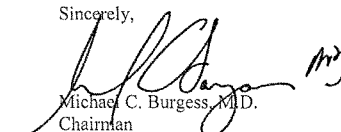
Dear Ms. Abram:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 11, 2018. Your responses should be mailed to Daniel Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to daniel.butler@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment



FDA U.S. FOOD & DRUG
ADMINISTRATION

DEC 10 2018

The Honorable Michael C. Burgess, M.D.
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Burgess:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the June 6, 2018, hearing before the Subcommittee on Health, Committee on Energy and Commerce, entitled "Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "John Martin", written over a horizontal line.

John Martin
Principal Associate Commissioner
for Legislative Affairs

Your questions have been restated in bold below, followed by FDA’s responses.

The Honorable Gus M. Bilirakis

- 1. Resiliency is vital to preparedness and ultimately response and recovery. The stockpile of drugs, vaccines, and other medical products and supplies, known as the Strategic National Stockpile is critical to our ability to respond and recover from catastrophic events. Reliable storage and delivery of these lifesaving medicines is also important in terms of patient safety and cost.**
- a. In what way is your agency working with industry to extend shelf life and improve resiliency of the Strategic National Stockpile?**

FDA recognizes the challenges that public health authorities such as CDC face when managing stockpiles of MCMs and is engaged, when appropriate, in various expiration dating activities.

One of the most significant ways FDA helps the SNS manage its assets is through the Shelf Life Extension Program (SLEP). Through SLEP, the federal, fee-for-service program managed by the Department of Defense, select products undergo periodic stability testing conducted by FDA, and if appropriate, the products’ shelf life can be extended. Through expiration dating extensions, SLEP helps to defer the replacement costs of certain products in the SNS.

FDA has continued to develop novel approaches in this space. For example, in 2013, FDA obtained explicit authority in section 564A(b) of the Federal Food, Drug, and Cosmetic Act to extend the expiration dating of eligible FDA-approved MCMs stockpiled for use in CBRN emergencies. In April 2017, FDA announced the availability of a draft guidance for government public health and emergency response stakeholders entitled “Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles.” This document provides guidance to government stakeholders on testing to extend the shelf life of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response purposes for an anthrax emergency under Section 564A(b) of the Federal Food Drug and Cosmetic Act (FD&C Act). Based on this guidance, in August 2018, FDA extended the expiration date of certain lots of doxycycline tablets. And, most recently in October 2018 for the first time under the 564A(b) authority, FDA extended the expiration date of certain lots of ciprofloxacin held in the SNS. The Center for Devices and Radiological Health (CDRH) works with industry and Agency partners to extend the shelf life of stockpiled medical devices. FDA also has worked with manufacturers of vaccines seeking an extension of the dating period. Reviewers in the Center for Biologics Evaluation and Research (CBER) evaluate information regarding the potency, purity and identity of the product using real time stability data to determine if an extension of the expiration date can be granted.

The manufacturer of approved medical products may extend the products’ expiration dates based on acceptable data in accordance with protocols approved in their marketing applications. FDA

Page 3 – The Honorable Michael C. Burgess, M.D.

encourages medical product manufacturers to submit data in support of longer shelf lives for medical countermeasures (MCMs) stored in the Strategic National Stockpile (SNS); however, the Agency does not have the authority to require drug, biologics, or device manufacturers or sponsors to pursue longer shelf lives for these products.

Through contracts utilized by agencies with procurement authorities, manufacturers can be incentivized to pursue longer shelf lives for their MCMs.

For more information about FDA's expiration dating extension activities, please see FDA's website at:

<https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411446.htm>.

The Honorable Markwayne Mullin

1. **Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?**
 - a. **Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?**
 - b. **Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?**

Defer to ASPR/BARDA

The Honorable Frank Pallone, Jr.

1. **The FDA previously expressed concerns about the medical countermeasure (MCM) priority review voucher (PRV) that was created as part of the 21st Century Cures Act in 2016. Now that the PRV has been in effect for two years, can the FDA comment on the challenges of this program?**

In an effort to provide uniform guidance on the MCM priority review voucher (PRV) program, on January 19, 2018, FDA announced the availability of a new draft guidance, titled "Material Threat Medical Countermeasure Priority Review Vouchers." In the question and answer format in this guidance, FDA provides details about the Agency's interpretation and implementation of the MCM PRV program. As of July 1, 2018, FDA received two comments from industry on the draft guidance and is considering those comments prior to issuing a final guidance document.

Additionally, on July 13, 2018, FDA approved the first product to be awarded a Material Threat Medical Countermeasure priority review voucher. It is the first drug approved with an indication for treatment of smallpox.

The first material threat MCM PRV was awarded on July 13, 2018. This was the 20th voucher to have been awarded, and to date, 7 have been redeemed for priority reviews.

With only one voucher issued for a product that was far along in its development before the program was established, it remains too soon to say that it has impacted FDA resources or to assess whether the program is incentivizing MCM development.

There is some evidence that the value of priority review vouchers has been impacted by the increasing number of vouchers that have been awarded. For example, see BIOPHARM DIVE article at <http://journals.sagepub.com/doi/10.1177/0098858818789430>.

2. Should the PRV program be made permanent during the reauthorization of PAHPA? Please explain why or why not.

Congress established the material threat MCM PRV program in December 2016 with the intent of incentivizing the development of MCMs. We appreciate and share Congress' interest in finding innovative incentives to spur the development of MCMs. However, it is premature to conclude how expanding the PRV incentive programs to include material threat MCMs has impacted MCM development. When expanding the PRV programs to include material threat PRVs, Congress recognized that there are resource implications for the FDA in implementing PRV programs, including impacting FDA's ability to meet its commitments to process applications for priority products (including MCMs). Congress also recognized the importance of assessing these programs, imposing a sunset on the material threat MCM PRV program, and requiring a study of the effectiveness to and overall impact of the three FDA PRV programs: the neglected tropical disease PRV program, the rare pediatric disease PRV program and the material threat MCM PRV program. More specifically, the Cures Act required that the GAO study and report back to Congress by 2020 on the effectiveness of the voucher program for MCMs and other priority areas, including the question "whether, and to what extent, the voucher impacted the sponsor's decision to develop the drug." Pub. L. 114-255, Section 3014(c)(1)(B) of the FD&C Act. FDA believes it would be prudent to wait until the GAO study is completed in January 2020 to inform the future of this program.

3. How can drug development tools and the qualification process impact national security?

Developers can submit very sensitive information to FDA, particularly in the process of qualifying an animal model through the Animal Model Qualification Program (AMQP). The AMQP will qualify animal models that are to be used for efficacy testing of medical countermeasures that are being developed under the Animal Rule. Some examples of the potential impact on national security are as follows:

- If a developer submitted the genetic code of a deadly virus in its qualification materials, we would not want to release that information. Some of these viruses, like the one that causes smallpox, could potentially be created from scratch in the lab, so long as the genetic code is known.

- Similarly, we may need to see the details of how anthrax spores were manufactured for an anthrax animal model. This same information could be a roadmap to weaponize the bacteria that causes anthrax.

4. If the agency is given authority to limit disclosures that may have national security implications, how will the FDA work with sponsors and other stakeholders to ensure consistent implementation of this authority?

FDA would work closely with the submitter (including other government agencies, such as NIH, BARDA, and DoD) to determine if there is any information in the submission that, for the purposes of protecting national security, should not be released. FDA would communicate transparency expectations to sponsors up front as they make their submissions, FDA could highlight sensitive subject matter areas as sponsors proceeded from step to step, and would utilize Agency disclosure personnel as needed.

5. HHS has proposed language that would allow for public postings of drug development tool qualification submissions to be modified if there is information that would compromise national security, when and how would the FDA exercise this authority?

In some cases, sponsors would likely identify national security concerns themselves, near the start of the qualification process. In other cases, FDA personnel who work on medical countermeasures might be the ones to identify concerns, particularly if the sponsor was unfamiliar with the public posting process around drug development tools. In either case, FDA would carefully consider relevant facts, including information provided by sponsors, in determining whether any information should be redacted before posting.

6. What actions has FDA taken to address the cybersecurity threats to medical devices?

FDA has been a leader in addressing the need for strengthening medical device cybersecurity. Part of our public health mission is to help ensure that patients have timely access to safe and effective medical devices, and that devices be protected from cybersecurity vulnerabilities that, if exploited, could potentially harm patients.

At the premarket stage, FDA's approach recognizes that, to avert potential risk, cybersecurity needs to be included in product design and development, including capabilities that enable device patching and updating in a timely way. Appropriate threat modeling and premarket testing needs to be conducted to assess the adequacy of security for the device's use environment. In 2014, FDA issued a guidance document, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," to describe the factors in the design and development of medical devices that manufacturers should consider to help to ensure device cybersecurity, maintain device functionality, and reduce potential risk to patients. Once a device is on the market, risk-management planning is essential to manage any risks that might emerge and to reduce the likelihood of future risks. In 2016, FDA issued a guidance document, "Postmarket Management of Cybersecurity in Medical Devices," to emphasize that manufacturers should take a proactive, risk-based approach to cybersecurity throughout a device's life cycle, including a combination of monitoring, maintenance, identification of potential issues, and action to address

cybersecurity vulnerabilities and exploits.

FDA recognizes that a key to the adoption of proactive postmarket cybersecurity is the sharing of cyber risk information and intelligence within the medical device community. FDA routinely collaborates with the Department of Homeland Security (DHS), the central point for cyber threat information sharing into the government, on potential cybersecurity vulnerabilities and exploits that could impact medical devices or the healthcare sector. In addition, FDA has been taking steps towards creation of a collaborative, multi-stakeholder environment that fosters communication about cybersecurity vulnerabilities that may affect the safety, effectiveness, and security of medical devices, or the integrity and security of the surrounding healthcare IT infrastructure. FDA also continues to work with external partners to advance the state of cybersecurity in the medical device ecosystem through several initiatives, including supporting the establishment of additional medical device vulnerability Information Sharing Analysis Organizations (ISAOs).

Because cybersecurity is rapidly evolving, we recognize the importance of adapting our thinking to meet the emerging threats and vulnerabilities of medical device concerns that challenge the healthcare ecosystem. We therefore are continually looking for ways to improve our cybersecurity activities.

7. What actions does FDA plan to take in the future to help industry prepare and respond to cybersecurity threats?

We are planning several actions to help industry and the broader device community better prepare and respond to cybersecurity threats. We plan to update our premarket guidance on medical device cybersecurity to better protect against moderate risks (such as ransomware campaigns that could disrupt clinical operations and delay patient care) and major risks (such as exploiting a vulnerability that enables a remote, multi-patient, catastrophic attack). Our Medical Device Safety Action Plan, which we published in April 2018, outlines these and other actions we plan to take to help combat cybersecurity threats.

8. Under the proposed bill, H.R. __, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018, FDA's emergency use authorities (EUA) and the definitions of "eligible product" and "qualified pandemic or epidemic product" would be modified. How would extending FDA's EUA be beneficial? What challenges may result from this expanded authority?

The proposal to incorporate cyberthreats into the PAHPA context, including the EUA authorities, raises many novel questions and considerations. FDA is committed to addressing cyberthreats and is considering the implications of this proposal. As discussed in response to questions 6 and 7, FDA is committed to improving our capabilities to prepare for and respond to cybersecurity threats, including working with Congress on these important issues.

9. Please provide an example of how the FDA may issue an EUA related to a cybersecurity threat or how a medical product could be developed with cybersecurity threats in

mind?

In situations where cyber exploits disable all units of a device (regardless of manufacturer), public health would be at risk if there are no alternative products available. In such cases, FDA could envision authorizing (via EUA) the use of uncleared or unapproved devices. While extending FDA's EUA authority to cover cyber threats could provide FDA with the flexible tools we have successfully used to protect public health in response to other threat types (i.e., CBRN threats), more thought may be needed to consider how the existing authorities could be applied to this type of threat.

Medical products can be developed with cybersecurity threats in mind by building cybersecurity considerations into the design of the device. Building capability into a device for it to be updated and patched is one way to address cybersecurity. Another is ensuring devices are accompanied by a Software Bill of Materials (SBOM) that details the software components of a device so users know if their device may be subject to a cybersecurity threat or exploit. FDA is exploring ways to address these considerations. Our recently-published Medical Device Safety Action Plan contains more information about these efforts.

10. Please comment on FDA's implementation efforts of H.R. 4374, To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes and any resources the Department of Defense has expended in the implementation of this legislation.

FDA takes very seriously our role in ensuring the well-being of the warfighter. We continue to be responsive and work collaboratively to address DoD's priorities. We meet regularly with DoD's MCM enterprise experts—in collaborative informal subject matter expert (SME)-to-SME meetings, as well as in more formal leadership-level meetings. After passage of H.R. 4374, FDA and DoD jointly announced a pilot program to better understand the military's medical needs; give the highest level of attention to and expedite the review of priority DoD medical products, treating those products as if they had breakthrough therapy designation. DOD and FDA signed an MOU on November 2, 2018, setting the foundation for these collaborations.

More specifically, DoD's highest priority has been to provide efficient access to a freeze-dried plasma product (FDP) to control hemorrhage from battlefield trauma. In July 2018, FDA issued an Emergency Use Authorization (EUA) for an FDP manufactured in France for the treatment of U.S. military personnel for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical. The FDA issued this EUA in response to a request from DoD and after receiving the required determination by DoD and a declaration by the Secretary of the Department of Health and Human Services. This action was the result of the close collaboration between the FDA and the DoD to prioritize the efficient development of safe and effective medical products intended to help save the lives of American military personnel.

Page 8 – The Honorable Michael C. Burgess, M.D.

In addition, In August 2018, FDA approved the antimalarial drug, tafenoquine, which was a high priority for DoD.

FDA is providing its highest level of attention to help expedite the development and review of DoD priority products. FDA is also providing ongoing technical advice to DoD to aid in the rapid development and manufacture of medical products for the military. We have also successfully collaborated on:

- the conduct of minimal risk research;
- development of products in the chemical defense portfolio, including approval of a new auto-injector for MCMs for nerve agent exposure for warfighter and civilian uses and continued efforts to make available auto-injector products through shelf life extensions; and
- development of diagnostic devices, including marketing authorization of the BioFire Defense FilmArray NGDS Warrior Panel that includes detection of several biothreat agents and in vitro diagnostic (IVD) approvals.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
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Majority (202) 225-2927
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June 26, 2018

Dr. Umair Shah
Executive Director
Harris County Public Health
2223 West Loop South
Houston, TX 77027

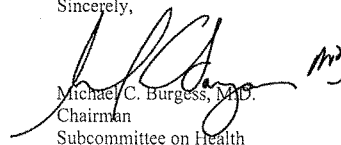
Dear Dr. Shah:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 11, 2018. Your responses should be mailed to Daniel Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to daniel.butler@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Umar A. Shah, M.D., M.P.H.
Executive Director



Harris County
Public Health
Building a Healthy Community

2223 West Loop South
Houston, Texas 77027
Tel: (713) 439-6000
Fax: (713) 439-6080

July 11, 2018

The Honorable Michael C. Burgess, MD
Chairman
Subcommittee on Health
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Burgess:

Thank you again for the opportunity to testify at the hearing "Reauthorizing the Pandemic and All-Hazards Preparedness Act on June 6, 2018 on behalf of NACCHO and Harris County Public Health. Please find below answers to questions submitted for the record.

The Honorable Markwayne Mullin:

1. Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?

The current law has enabled BARDA to make important progress on curtailing the spread of emerging infectious diseases that threaten global health security when left unchecked. BARDA's implementation of the Broad Spectrum Antimicrobials (BSA) Program has helped to address the antimicrobial development gap by expanding engagement with industry partners to develop novel antimicrobials. While the scope of BARDA's efforts has encompassed the dual utility of antimicrobials, its focus on indications for biological threat agents likely limits the extent to which BARDA has been able to partner with certain new companies and technologies working to counter the spread pathogens that demonstrate drug resistance of primarily clinical and public health significance but have the potential to severely impact global and national security.

- a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?

While BARDA's mission to develop and procure medical countermeasures includes diagnostics and non-pharmaceutical countermeasures against natural or deliberate threats, including those caused by emerging infectious diseases, the emphasis on qualified countermeasures and qualified pandemic or epidemic products for biodefense is rooted in the agency's purpose, as described in the legislation. Consequently, while a program such as the BSA allows for and facilitates the development of candidate

HCPH is the local public health agency for the Harris County, Texas jurisdiction. It provides a wide variety of public health activities and services aimed at improving the health and well-being of the Harris County community.

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antimicrobials for their commercial and clinical applications, the program stipulates that partners concomitantly support the development of these products for biodefense threat agent indications. Companies developing non-therapeutic technologies to address antimicrobial resistance, particularly those with a primary or sole emphasis on commercial or clinical application, even if their product potentially benefits biodefense may, in some cases, be at a disadvantage or ineligible for participating in the BSA program.

- b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter antibiotic and antimicrobial resistance?

Giving BARDA the flexibility to work with companies more broadly may be beneficial in achieving the agency's mission to counter antimicrobial resistance. While it will require substantial time and effort to measure the impact of BARDA's efforts on curbing the spread of antimicrobial resistance, BARDA's successful increased engagement of industry partners in moving more candidate antimicrobials through the drug development pipeline was a critical step in the FDA's approval in 2017 of a new antibiotic against highly resistant pathogens. Expanding BARDA's mission and flexibility could help to further identify promising therapies and other non-pharmaceutical products for tackling the spread of drug-resistant pathogens and better protect the health – and thereby national security – of our country.

The Honorable Earl L. Buddy Carter:

In 2014, two American medical missionaries infected with the Ebola virus disease in Liberia were evacuated by air ambulance to Emory University Hospital in my home state of Georgia. At the time, Emory had 12 years of training to address highly communicable diseases, and was chosen by the U.S. State Department and the CDC as a result of the agencies confidence in their ability to treat the patients.

Following the successful discharge of the four patients, Emory has continued to disseminate best practice information and new knowledge about treatment, complications, and the clinical course of Ebola; serve as a national leader in education and training; create new university forums; develop education materials for residents, fellows and the general public; present clinical and research findings at scientific meetings and in journal articles; and engage in the broader policy issues of preventing and treating highly contagious diseases.

1. I had the opportunity to tour the unit where these patients were treated at Emory and was impressed with the contamination prevention efforts the staff employed to protect themselves and others from the spread of this disease. Can you discuss the lessons we have learned from Emory's use of personal protective equipment for healthcare workers?

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In August 2015, NACCHO and the Association of State and Territorial Health Officials (ASTHO) conducted an in-progress review of the public health systems' response to Ebola in the United States. The review included over 90 stakeholders representing federal, state, and local government, healthcare, environmental health, and the private sector. While the review was primarily focused on the public health system, consideration was given to the intersection between healthcare and public health. Lessons learned from the review meeting included the following:

- Additional capacity and subject matter expertise in infection control and prevention are needed across the public health and healthcare system, particularly at the state and local level.
- Specific guidance from the federal government, in multi-media formats, such as training videos and graphic one-pagers that were tailored to the audience (e.g., healthcare, emergency management, law enforcement) were most effective for communicating PPE guidance.
- The federal government should take a lead role in coordinating with PPE manufacturers for the acquisition and distribution of PPE for Ebola and future highly pathogenic infectious diseases.

It should be remembered that what occurred with Ebola in 2015 will most likely be a guide to what would occur in a new Ebola outbreak today or in the future. However, given that emergencies are never the same, this guide should only serve as a roadmap for the future of Ebola type infectious disease response. It is clear that flexible, proactive capacity-building at the local (public health) level – in coordination with strong state and federal funding levels – must be a part of any consideration to ensure appropriate emergency response capabilities for the future. Finally, this is also an appropriate moment to emphasize the link between global health and domestic health – ensuring appropriate attention to both is necessary to assure the health, security, and well-being of all Americans.

2. I have toured the CDC a number of times and am consistently impressed by the work that occurs there on a daily basis. When the SNS is transferred from the CDC to ASPR - we need to make sure that public health response capabilities are not lost. What steps need to be taken during the transfer to ensure that state and local public health departments remain engaged?

To ensure that state and local health departments remain engaged in the SNS:

- Have representatives from State and Local health departments be a part of the transition decision making team as well as any follow up advisory group moving forward.
- Utilize national organizations such as ASTHO and NACCHO to facilitate acquiring additional recommendations from their members.

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- Ensure frequent and constant communication and coordination between CDC and ASPR regarding SNS so that guidance to state and locals are consistent and clear.
 - Have listening sessions and/or requests for feedback from state and local health department representatives. Coordination and communication should occur throughout the transition to ensure that the state and local health department perspective is included in major decisions that could impact state and local capacity and/or response strategies.
 - Make available new processes and frameworks for state and local health department representative comment whenever possible.
 - ASPR and CDC should remain transparent about the changes that will occur as a result of this transition and provide information and guidance to state and local health departments – as well as involve them in the transition planning itself – leading up to the transition and as the transition occurs. Mechanisms to achieve transparency may include press releases, web conferences, guidance documents, and frequently asked questions documents.
3. As you mentioned in your written testimony, you discussed the importance of reauthorizing the Hospital Preparedness Program. The HPP gives health systems the tools they need to save lives during emergencies that exceed the day-to-day capacity of hospitals and emergency response systems. Can you discuss ways that health systems have used these funds in order to establish preparedness infrastructure?

HPP has helped to improve emergency communication and coordination among hospitals, ancillary medical facilities and health officials; facilitate patient tracking in mass casualty events, such as the mass-shooting event that occurred in Las Vegas in 2017, or during the myriad of emergencies our nation has faced this past year such as hurricanes, wildfires, and infectious disease responses; sustain operations in the midst of an event; track medical resources and assets including available hospital beds; and establish systems to reunite family members following an event.

HPP Funds are used in the Harris County, Texas, region, for example, by the Southeast Texas Regional Advisory Council (SETRAC) to plan, train, exercise, and equip hospital systems for the catastrophic disasters they may have to respond to outside of their normal business operations. With the transition of employees every year, these trainings and exercises must continue annually to keep newer employees prepared.

To close, appropriate and sustained funding for both HPP and Public Health Emergency Preparedness (PHEP) programs is critical to the success of any public health emergency planning and response. These inter-connected programs are both necessary to ensure the health, security, and well-being of all Americans.

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The Honorable Frank Pallone Jr.:

1. How do public health departments currently coordinate with the CDC, Division of Strategic National Stockpile, and ASPR to develop medical countermeasures in response to public health emergencies?

Public health departments have not historically been engaged in the development of medical countermeasures for response. State and local health departments should be involved in all phases of the medical countermeasures (MCM) enterprise including in initial investment; research and development of vaccines, medicines, diagnostics and equipment for responding to emerging public health threats; and distribution and dispensing of countermeasures.

Recently CDC announced that state and local health department representatives would be included in the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) to help inform decisions related to the SNS formulary. This has not yet been implemented and details regarding the nomination/application have not yet been released.

2. What issues or challenges do health departments currently face with response to public health emergencies in terms of interfacing with CDC, ASPR, and use of the SNS?

The federal system is the safety net for local public health when dealing with large-scale catastrophic events; however, in some cases the federal system does not always have a good understanding of what is actually happening at the local level. Emergency managers must be able to communicate effectively with state and federal partners, generally communication goes through a state conduit, which can cause a delay in rapid response communications. Local planning and response efforts do not always coincide with federal guidance during operational efforts. It is critical that federal agencies coordinate their activities across the federal government to ensure consistency of messaging and activities when interacting with local health departments engaged in a public health response.

While much progress has been made, the issues and challenges related to public health emergency response coordination very much centers around the fact that emergencies are unpredictable and chaotic. This was seen of course this past year during the myriad of emergencies this nation has faced and will continue to face in the years to come. Given such unpredictability, our nation must be prepared by ensuring that federal and state public health systems are strong and supportive of the work that happens in local communities where local public health departments are best-suited to respond to their community needs in emergencies.

3. Do you feel any issues will be resolved by transferring the SNS from the CDC to ASPR?

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There are currently two sets of stockpiled assets housed separately - with the federal medical station assets managed and stockpiled by ASPR - and the SNS managed and stockpiled by CDC. This transfer under one entity could help streamline processes for requesting medical material and products from the Federal government. However, this transfer must be well-coordinated and details – that are still not known – must be made known so more specificity of what the implications of such transfer can be more clearly considered and articulated.

4. What problems may arise from the transfer of SNS from the CDC to ASPR?

Current funding, support, and expertise provided to state and local health departments for the SNS must be maintained regardless of the infrastructure or location of the SNS – it is too vital to this country’s ability to respond in the midst of a variety of large-scale emergencies. However, there are potential vulnerabilities to this with the proposed transfer of authority for the SNS from CDC to ASPR at the beginning of FY2019. The Committee should include a provision that assures the maintenance of appropriate coordination and support for state and local public health departments. **Under no circumstance can public health response capabilities be lost in the sea of other health care system response capability needs.** This cannot and must not happen.

As proposed, operational and logistical functions that would be transferred to ASPR would essentially be separated from programmatic and support functions already in place at the CDC. If not handled well, such a transfer may introduce added complexity, poor coordination and less expediency as it pertains to the national, state and local operational readiness to distribute and dispense medical countermeasures from the stockpile where the healthcare-public health interface is critical. There needs to be clear communication and engagement between the federal level and state and local levels throughout the entire process to ensure state and local input is incorporated and state and local planners have the information that they need to update their plans in a timely fashion.

5. How can the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and medical countermeasure developers improve their response to health departments and distribution of medical countermeasures?

NACCHO supports the codification of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE Strategy and Implementation should require that state and local health departments be involved in all phases of the medical countermeasures (MCM) enterprise including in initial investment; research and development of vaccines, medicines, diagnostics and equipment for responding to emerging public health threats; and distribution and dispensing of countermeasures.

NACCHO recommends that state and local public health departments have a permanent place in the PHEMCE membership to ensure that all decisions that will affect state and local health

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functions are vetted by public health authorities. Membership should include a state public health authority and a local public health authority.

6. What are the most urgent state and local public health emergency preparedness priorities?

Flooding, winter storms, and infectious disease remain among the top threats, but local health agencies feel more prepared to address these since we've been responding to these kinds of events over and over again. Though there is always the concern that even previous emergencies that have been seen over and over again will throw a "curve ball" in the future, even more attention must be paid to those types of emergencies that are large-scale and with potential for incredible loss of life and property. As such, there are large gaps in addressing critical infrastructure protection, medical supply chain disruption, and cybersecurity, NACCHO's 2018 Preparedness profile results show that opioids and mass casualty events such as large-scale loss of life from mass shootings are among the most concerning issues that health departments feel the least prepared to address. There is also concern that there remains a significant gap in the link between global health and domestic health – a gap that must continue to be paid attention to and be shored up.

7. The proposed bill, H.R. __, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2018, would expand the eligibility for the Hospital Preparedness Program beyond the current state and local grantees, how would this affect state and local public health emergency preparedness?

Expanding the eligibility for HPP is problematic. This is a program that has been cut by 50% over the last decade and is insufficiently funded to support the activities of current grantees and health care coalitions. Improving surge capacity, enhancing community and healthcare system preparedness, and implementing response actions is complex and requires state and local public health coordination. It is critical that public health continues to play this coordination role among the varied first responder and healthcare partners to ensure that the needs of the entire jurisdiction are met. SETRAC is a great asset to our community and surrounding counties.

8. How would the cybersecurity provisions in the proposed bill affect state and local health departments?

The bill highlights the importance of cybersecurity as part of national health security. As people use electronic health data more widely and increasingly rely on networked computer technology to deliver efficient healthcare and public health services, the need to protect public health information and public health infrastructure increases. A successful cyber-attack on public health information infrastructure could severely reduce both public health emergency responses and non-emergency public health functions. However, the Committee should be cautious in expanding the scope of PAHPA without the authorization of commensurate resources to carry out new activities and initiatives.

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The manager's amendment adopted by the Health Subcommittee appropriately clarifies that the ASPR is the lead for continuity of health care in the event of a cybersecurity event and incorporates cybersecurity into the National Health Security Strategy.

9. What lessons did health departments learn from public health emergencies such as Zika and Hurricane Harvey? How can Congress improve state and local public health department efforts to respond to emergencies such as these?

Local health departments – including Harris County – have learned several lessons based on recent public health emergencies such as Zika and Hurricane Harvey. Public health requires a sustainable and long-term emergency public health funding source, and a sustainable capacity to plan for, train, exercise, and respond during emergency situations. Public Health is a first-responder during emergency situations and must be recognized as such. Public health has a large role in both public health and non-public health emergencies as either the lead or support role.

It should be noted that funding must reach the entirety of a community regardless of the jurisdictional line. For example, Harris County oversees mosquito control in the entirety of Harris County, including the city of Houston. However, the funding mechanism that was used to fund Zika-related response previously utilized a mechanism that essentially moved resources away from the very entity that was providing the mosquito control for Zika in our community. This has been a recurring issue and also one in play during Hurricane Harvey funding considerations. Ensuring that there is a focus on an “all-community” approach to funding is necessary and will most appropriately assure that such funding reaches both where the populations are located and the risks are in place.

Additionally, preparedness, response, and recovery requires the whole of a health department as well as the whole of the community (as above). Preparedness funding such as PHEP and HPP supports local health departments by helping build, train, and exercise with partners both internal to the health department (e.g., maternal and child health, environmental health), and external (e.g., public works, behavioral health, volunteers) so that all partners can respond effectively together. Congressional support for a public health emergency response fund and sustained investment in preparedness infrastructure are long-term keys to the promotion of public health for the nation.

10. Based on your experience with the Zika Response, could you describe how state and local public health departments were impacted by funding from the Public Health Emergency Preparedness (PHEP) cooperative agreement being redirected for the Zika response?

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In 2016 during the Zika response, in the absence of supplemental funding CDC redirected \$44 million in Public Health Emergency Preparedness funds from state and local health departments. NACCHO surveyed local health departments on the impact of the cuts to their preparedness programs and found that the cuts were disruptive impacting planning, staffing, exercising, and coordination with partners. It is also important for federal agencies to take an “all-community” approach so those dollars reach the entirety of a community based on population, bonafide risk, and/or actual response needs for all emergencies including those that have already occurred in a community (see above response to Zika funding in #9).

A standing rapid response fund to provide bridge funding between base preparedness funding and supplemental appropriations for acute emergencies and emerging threats is absolutely necessary. NACCHO appreciates that the bill strengthens existing authorities for the Public Health Emergency Fund (PHEF). However, there is concern about the 1% transfer authority to infuse the fund when a public health emergency is declared.

11. What types of coordination services did the South East Texas Regional Advisory Council (SETRAC) provide during hurricane Harvey?

SETRAC coordinated a wide arrange of medical activities including 1,544 patient movements, 24 hospital evacuations, and 20 nursing home evacuations. They established and coordinated ambulance staging areas (three ground assets and 2 air assets) and coordinated with the US Coast Guard Houston/Galveston Sector to run high acuity medical transfer. SETRAC provided mobile medical units into the area where healthcare services were unable to function, established an appointment/transportation process with dialysis centers, held daily conference calls with all hospitals and nursing homes in the region to provide situational awareness and mission priorities, managed surge capabilities in regional healthcare facilities, and coordinated across state lines (Louisiana/Texas) and through regulatory bodies to evacuate hospital and nursing home patients into Louisiana utilizing Louisiana EMS entering and practicing in Texas.

12. What is the impact of having an entity like SETRAC available during a disaster response?

SETRAC is a great asset to Harris County and the southeast Texas region. As the recipient of the HPP grant, they maintain constant communication and interaction with medical facilities and agencies and ensure they are prepared for any disaster response. They serve as the conduit between public health and hospitals, and respond directly to any medical needs during the response. They provide the professional and technical assistance and resources needed to address the complexities of the medical infrastructure and associated ancillary requirements and regulations.

13. How have funding cuts to the Hospital Preparedness Program (HPP) impacted local preparedness and response efforts?

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Funding cuts have resulted in staffing reductions, forced staff to fill multiple roles and hindered the ability to maintain existing or build new partnerships between public health and the healthcare sector. It has also resulted in increased responsibilities for 16 other healthcare provider types that now fall under the new CMS EM rule. If funding were to commensurate with population, needs, and risk, SETRAC would be able to better maintain a basic level of preparedness through education, training, and exercising to address common issues such as surge capacity and disaster transfers.

As always, we remain ready alongside you to prepare and respond to ensure the health, security and well-being of our communities. Most importantly, thank you for your leadership in keeping our communities healthy and safe.

Sincerely,



Umair A. Shah, MD, MPH
Executive Director
Harris County Public Health NACCHO Past-President

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

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ONE HUNDRED FIFTEENTH CONGRESS
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Minority (202) 225-3641
June 26, 2018

Dr. M. Michelle Berrey
President and CEO
Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713

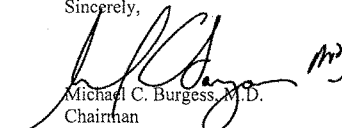
Dear Dr. Berrey:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 11, 2018. Your responses should be mailed to Daniel Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to daniel.butler@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment



CHIMERIX.COM

2505 Meridian Parkway
Suite 100
Durham, NC 27713

July 11, 2018

Congress of the United States
House of Representatives
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Reauthorizing the Pandemic and All-Hazards Preparedness Act

Dear Mr. Butler:

In response to the questions submitted by the Energy and Commerce Subcommittee on Health on June 26, 2018, please find the attached responses.

Very truly yours,

M. Michelle Berrey, M.D., M.P.H.
Chimerix, Inc.
President and Chief Executive Officer

Q: Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?

- a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?
- b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?

A: Given the growing public health and economic burdens posed by antimicrobial resistance (AMR), there is an urgent need to reinvigorate the antimicrobial pipeline. This is particularly critical given the long development times (10-15 years) for new medicines and vaccines. There is a consensus among stakeholders worldwide that multifaceted solutions are needed to reinvigorate antibiotic development and other approaches to addressing AMR. As such, the Alliance for Biosecurity supports measures for novel market based incentives that are sustainable and will adequately strengthen the research and development pipeline. Such incentives through BARDA will advance innovation in, and accelerate and support the advanced research, development, and procurement of, countermeasures and products to address, among other threats, AMR.

Q: In your written testimony you discussed how the passage of the Project BioShield Act, then PAHPA, created a market for medical countermeasures for the first time that created incentives for companies to develop countermeasures. In your view, do you believe this legislation will help industry research and develop the therapies necessary to combat the biomedical threats facing this nation? In your past experiences, what have been some of the challenges your company has faced to develop countermeasures?

We absolutely believe that this legislation will help industry to develop new therapies. There is no commercial market for smallpox countermeasures. If the Project BioShield Act and PAHPA had not created incentives and a government market for medical countermeasures, companies like ours (small cap, pre-revenue) would not be able to invest the time and resources in developing these products. The business of identifying and developing new drugs is a risky and capital-intensive proposition. With no commercial revenue streams, we rely on outside investment to fund the advancement of our product pipeline. It is the promise of a government market that attracts this investment. Putting these pieces together, it is the promise of a governmental market that makes our development of a medical countermeasure possible.

Perhaps even more importantly, BARDA's direct investment has helped bridge the drug development "valley of death" and attract private investment at a stage when committing resources is particularly risky. The draft legislation's support for increased, multi-year funding for the Project BioShield Special Reserve Fund and increased funding for BARDA's research and development efforts will help ensure that this record of success continues into the future.

With respect to our past experiences, we have faced two primary challenges. The first is one that is common to all small companies developing medical countermeasures--the availability of capital. As noted above, our business has extremely long timelines and is highly capital-

intensive. We confront this issue on a daily basis and it affects everything that we do. While this legislation will not resolve all of our capital issues, restoring multi-year funding for Project BioShield will send an important signal to investors, and we commend Congress for taking this step. The second issue that is more specific to our company and our lead compound is the challenge of developing a drug for dual use: Brincidofovir is currently being developed not only for a biodefense indication (treatment of smallpox infection) but also for a commercial medical indication (treatment of a life-threatening viral infection in transplant recipients). Pursuing a dual-use helps leverage scarce federal dollars by procuring private sector investment as well as helping to ensure our continued viability as a company. However, this approach also brings certain regulatory and administrative challenges that we are working to address.

Q: What assistance has Chimerix received from the federal government in the development of your product, brincidofovir?

A: (see below)

Q: How much of the research and development costs related to brincidofovir have been secured from private sources?

A: To date, \$655 million has been secured from private sources for the research and development of brincidofovir for the treatment of adenovirus, cytomegalovirus, BK virus and other viral infections. For our smallpox program, we have been fortunate to receive \$92 million in funding from the U.S. National Institute of Asthma and Infectious Diseases (NIAID) and the U.S. Biomedical Advanced Research and Development Authority (BARDA), which represents about 12 percent of the total investment made to date in the brincidofovir development program.

Q: Do you believe that providing stable, advance appropriations for medical countermeasure development and procurement would be a sufficient incentive to encourage other manufacturers to enter the biodefense space?

A: Yes. Stable government funding is absolutely critical to the development and procurement of medical countermeasures, and the original ten-year advance appropriations for Project BioShield was very helpful in this regard. The transition of the program to annual appropriations introduced substantial uncertainty for private sector partners and decreased the average scope and size of awards. We believe that the return to advance appropriations will help enable and sustain long-term investment in the research and development of medical countermeasures, and we thank the Committee for including this provision. Having the ability to report on future cash flows would encourage small, pre-revenue companies like ours to enter this space and attract additional investment from the private sector.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
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Minority (202) 225-3641
June 26, 2018

Mr. Erik Decker
Chief Security and Privacy Officer
University of Chicago Medicine
5841 South Maryland Avenue
Chicago, IL 60637

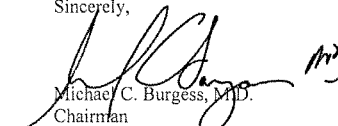
Dear Mr. Decker:

Thank you for appearing before the Subcommittee on Health on June 6, 2018, to testify at the hearing entitled "Reauthorizing the Pandemic and All-Hazards Preparedness Act."

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Testimony before the United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Hearing on “Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act”

Additional Questions for the Record

2123 Rayburn Office Building

July 18, 2018

Statement of Erik Decker

Chief Security and Privacy Officer, University of Chicago Medicine

Advisory Board Chairman, Association for Executives in Healthcare Information Security

Industry Co-Chair, Cybersecurity Act of 2015 Section 405(d) Task Group on Aligning

Cybersecurity Best Practices to the Health and Public Health Sector

A handwritten signature in black ink, appearing to read 'Erik Decker', written over a horizontal line.

Erik Decker

The Honorable Michael C. Burgess, M.D.

1. Cybersecurity is a serious threat to the healthcare sector, and we hear continuous reports of stolen electronic health records. Your testimony discusses possible incentives that could improve cyber security preparedness. I'm interested to hear more about the safe-harbor concept. I would like to understand how Congress could implement something like that to provide meaningful incentives for providers without adding burdensome requirements. Could this approach be applied to HIPAA penalties so that physicians and others who are demonstrating cybersecurity good-hygiene are not further punished with penalties from the Office of Civil Rights?

I am happy to provide further details into types of incentives that could assist our industry. It is important to first reflect that the healthcare industry covers a broad spectrum of organizations; from 1-2 rural provider practices, critical access hospitals, nursing and hospice facilities, rehabilitation centers, and research facilities to the larger health systems that provide broad ambulatory, inpatient and specialized care. Additionally, these organizations are now connected into part of a larger ecosystem, whereby the smaller healthcare facilities interoperate with the larger systems.

Many of these organizations operate with extremely thin revenue margins, whereby every dollar spent not on improving care must be critically weighed and considered. When you compare this resource shortage with the increasing sophistication of cyber criminals, and the further adoption of interoperability, it is easy to see how the threats are outpacing our ability to secure our industry's environments. This is not to say that all healthcare organizations are incapable of dealing with the threats. Those with the resources to establish cybersecurity programs have significantly ramped up their maturity over the last 5-8 years. However, some of those lacking resources are taking a 'wait and see' approach, hoping they are small enough to stay under the radar of the criminal. That is not an effective strategy.

Criminals are attacking organizations because there is a financial reward. We cannot expect the attacks to stop. One analogy I like to use is to compare cyber crime with physical crime. Nobody expects the police departments across the country to prevent all crime before it occurs. Likewise, we cannot expect organizations to be able to prevent all cyber attacks against their institutions. This very fact is the reason for developing comprehensive programs that include prevention, detection and rapid response to attacks that are successful. I believe it is time to update the regulatory enforcement models to reflect this reality.

Incentives could be deployed to assist the resource strapped organizations. I offer three suggestions here:

- 1) *Update the Stark Law and permit the larger organizations to provide cybersecurity measures to its affiliates. Under the current Stark rules, a large health system could not provide security measures to a physician practice as an incentive to adopt affiliation. Many small practices do not have the bandwidth to implement cybersecurity programs, however for the larger systems it would only be an incremental effort to extend their coverage to the smaller practices. This would alleviate the burden on these smaller organizations from becoming cyber experts, and free them up to focus on providing care to their patients.*

- 2) Add cybersecurity measures to the CMS Promoting Interoperability Program¹ and provide higher reimbursements for organizations that demonstrate adoption of cybersecurity programs. This would directly reward those organizations who take cyber seriously. Additionally, it provides extra resources for those with thin margins to invest in cybersecurity.
- 3) Provide enforcement relief to organizations that demonstrate adoption, defined by the Secretary, of the NIST Cybersecurity Framework. The adoption criteria could come from multiple sources, such as the adoption of the Cybersecurity Act Section 405(d) Best Practices, the cybersecurity practices document developed by a Task Group of over 130 leading thought leaders across the industry and government. This Task Group is an industry led effort in partnership with the Department of Health and Human Services (HHS), under the Joint Cybersecurity Working Group of the Healthcare and Public Health Sector Coordinating Council (HSCC), to provide specific guidance on highly impactful cyber practices to help organizations mature their cyber practices. These practices are designed specifically to help organizations mitigate to common threats identified by the Task group, and will help provide consistency across the industry in defense against those notable threats. These best practices will be delivered to Congress and the public in December 2018.

Additionally, the Joint Cybersecurity Working Group is working on many other imperatives identified within the Health Care Industry Cybersecurity (HCIC) Task Force Report. The full CWG membership exceeds more than 300 individuals from 190 organizations across industry and government. Examples include medical device security protections, supply chain management, risk assessment and workforce development. All of the efforts delivered by the CWG are aligned to the National Institute of Standards and Technology (NIST) Cybersecurity Framework, and can represent adoption standards for the purposes of enforcement relief.

My closing comment on this question is the following: It is time to merge the compliance obligations under Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) Act with the modern security measures needed to combat the cyber criminal. It has been 13 years since the establishment of the HIPAA Security Rule. The adoption of technology has dramatically changed since this time. We all agree there must be regulation, and enforcement of regulation. My recommendation is to refocus compliance actions and reward those making significant and meaningful adoption of risk based cybersecurity programs which are resilient and agile to keep up with modern threats. This will go a long way towards increasing our industry's resiliency, and incentivizing our industry to take these threats seriously.

The Honorable Markwayne Mullin

1. Do you all believe that current law puts some constraints on how BARDA is able to partner new companies and new technologies?
 - a. Follow up: Can you explain to me the limits of BARDA's authority to work with companies developing non-therapeutic technologies to counter antibiotic and antimicrobial resistance?

¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html>

- b. Follow up: Do you believe giving BARDA the flexibility to work with companies more broadly would be beneficial to BARDA as they work to achieve their mission to counter anti-biotic and antimicrobial resistance?

I believe this question was intended for the other members of the witness panel. It is my understanding that BARDA does not have direct impact on cybersecurity.

The Honorable Frank Pallone, Jr.

1. Why are healthcare systems and health infrastructure targets for cyber attacks and why is healthcare data valuable to cyber criminals?

In 2016, healthcare expenditures accounted for 17.9% of our Gross Domestic Product (GDP)², which amounts to trillions of dollars. The latest Internet Crime Report estimated that fraud losses exceeded \$1.4 billion in 2017³. Those numbers are likely conservative to the real impact of fraud that occurs.

15 years ago this level of fraud was not occurring⁴ (\$125 million, from the same agency), but with the explosion of the Internet and our digital economy, the criminals realize the immense financial gain that can be achieved. Data theft is one method of fraud. A new method that has gained traction over the last 3 years are digital extortion attacks (ie: ransomware). With trillions of dollars on the table, criminals see a lucrative enterprise that is cash rich and likely willing to pay a small fee for the restoration of their services. For example, a medium sized healthcare organization might have a revenue of \$100 million per year, which corresponds to \$274,000 per day. If an attack locks up the ability for a healthcare organization to deliver care, that is upwards of \$274,000 in revenue per day at stake. Most of these ransomware attacks have demanded fees between \$10,000-\$60,000 to restore services; this is an economics based attack.

For data theft and fraud purposes, healthcare institutions collect nearly every type of information necessary to take out lines of credit, commit tax refund fraud, or other credit scams. To treat patients many types of highly sensitive information are collected, including: social security numbers, date of birth, address information, next of kin/emergency contacts, credit card data and insurance information. It's "one stop shopping" for fraud.

2. What aspects of the HHS response to the WannaCry ransomware attack went well? How could HHS have improved their response?

² <https://www.statista.com/statistics/184968/us-health-expenditure-as-percent-of-gdp-since-1960/>

³ <https://www.fbi.gov/news/stories/2017-internet-crime-report-released-050718>

⁴ https://pdf.ic3.gov/2003_IC3Report.pdf

The very fact that there was a national call to action got the industry's attention. HHS expressed the absolute seriousness of the attack. It was the first of its kind in our industry, where at one point in time there was the threat of national or regional outages. The call to action from HHS propagated through the industry quickly and sparked the deployment of contingency responses across the country. I believe many institutions inoculated themselves directly due HHS leading credence and gravity to the threat, whereas in the past they might not have taken the precautions in a timely manner.

Given it was the first of its kind, there were a few bumps in the road, and I believe HHS has done well at learning from those lessons. Initially there was confusion regarding the dissemination of threat intelligence information through these calls, and that information was not consistent with what the information sharing and analysis centers (ISACs) were reporting. Additionally, the calls were open to the public and some sensitive information was being shared in a manner that organizations might not have been comfortable with. Finally, these responses are not the place to remind the industry of their regulatory requirements. At one point during the calls Office for Civil Rights (OCR) reminded the industry that a ransomware infection was considered a breach, and if infected the organizations have breach response obligations⁵. This type of enforcement reminder in the middle of a national emergency only makes the industry more nervous about sharing critical threat intelligence information; it is also counter to the intent of the Cybersecurity Information Sharing Act and the protections they provide for sharing cyber threat indicators under Section 106(b)(1).

In the future I think these national responses are vital and important as a means of rallying the industry to take these types of national threats seriously. They can be used to effectively communicate down to industry how to respond, how to get more information and what to do in the case of being a victim. I believe they can also be used to facilitate with Department of Homeland Security (DHS) and the Federal Bureau of Investigation (FBI), if necessary, and get resources deployed to assist those that have been attacked.

3. Generally, what kind of support should HHS provide a health system during emergency response to a cybersecurity incident?

I believe HHS is well situated to be a coordinator of response for the industry during these types of emergency incidents, in partnership with DHS. As mentioned before, they can get organizations in touch with the relevant ISACs to distill technical information, they can provide summaries of the attacks from the ISACs to the industry, and they can provide access to DHS, the US-CERT, and the FBI if needed. Most importantly, HHS can impart the seriousness of these attacks that will help organizations mobilize their response and take these threats just as seriously.

In consideration with maturing the cybersecurity provisions, it is important not to duplicate services that already exist. For example, the DHS National Cybersecurity and Communications Integration Center (NCCIC) has a robust program for responding to threat intelligence indicators from other critical infrastructure sectors. The various ISACs have strong sharing and practice programs in place to get the most technically relevant details down to the security practitioners in an actionable manner. HHS should

⁵ <https://healthitsecurity.com/news/hhs-reiterates-ocr-ransomware-guidance-after-recent-attack>

not replicate these functions, but rather augment them and provide the context specifically needed for our industry due to our unique challenges (such as patient safety).

Finally, related to my comment in answer #2 above about HHS messaging to the sector during an incident: it is critical during both a major incident and in steady-state that HHS follow a disciplined internal coordination process across the operating divisions for how they engage and communicate with industry. Mixed messages and inconsistent implementation can undermine the pursuit of solutions to shared challenges. We understand that Deputy Secretary Hargan is designated as the senior-most cybersecurity coordination official in HHS, and it is heartening that cybersecurity is taken that seriously in the agency. To the extent Deputy Secretary Hargan can guide the various HHS equities toward a coherent "one-HHS" policy and operational approach, the more confidence our industry will have in this partnership and the sense that "we are all in this together."

4. What staffing and resources are necessary to be successful in addressing cybersecurity risks in the health systems? Do you feel ASPR or HHS have adequate resources?

Cybersecurity experts and resources, and the funding to support them, are critical. HHS will need dedicated cybersecurity experts – both in operations and strategic policy - across a myriad of disciplines. Examples include risk management, incident response, strategy and planning, governance and frameworks, as well as engineering and architecture. In our industry we break up our programs into two core functions: resiliency (within the NIST Cybersecurity Framework this would be Identify, Prevent and Detect) and response (within the Framework this is Respond and Recover).

HHS might have the resources in place today to accomplish this, however they are likely placed throughout the various Operating Divisions. These resources also communicate independently back to industry based on the particular Operating Division's responsibility. For example, the Food and Drug Administration (FDA) will provide guidance related to cybersecurity concerns for patient safety due to vulnerabilities within medical devices, but is silent when it comes to the HIPAA privacy concerns as it relates to the same medical devices. OCR will offer guidance related to the privacy concerns of medical devices, but when it comes to resolving vulnerability issues that lead to these privacy vulnerabilities, they cannot provide further comment since they do not regulate the manufacturer. The result is industry must determine the best path forward, which can cause inconsistent interpretations and confusion.

5. What current guidance exists on cybersecurity threats from HHS and how could this guidance be improved? Could you provide examples of where you believe guidance is lacking?

Many guidance documents exist, more than can be enumerated in a response. Some of the most prevalent guidance documents are the following:

- *OCR: FACT SHEET: Ransomware and HIPAA*
- *OCR: A Quick-Response Checklist*
- *OCR: HIPAA Security Rule Crosswalk to the NIST Cybersecurity Framework*

- OCR: Remote Use
- FDA: Postmarket Management of Cybersecurity In Medical Devices
- ONC: Your Mobile Device and Health Information Privacy and Security
- NIST: Numerous Special Publications

Each of these guidance documents focuses on a specific topic, which can be useful and actionable. However, there currently does not exist comprehensive guidance to help an organization consider the most relevant threats. The good news is this guidance is forthcoming in December 2018 with the release of the CSA 405(d) Top 10 Best Practices.

6. What could federal agencies do to assist the industry, especially those with limited resources, like critical access hospitals or small physician practices?

I refer back to my answer to Chairman Burgess. Incentivizing the adoption of cybersecurity programs, or allowing the larger systems to extend their existing cybersecurity programs to organizations with limited resources, would have a significant impact on the industry's preparedness.

7. How do ISACs interact with HHS and specifically the HCCIC? Is further coordination with HHS or clarification on the role of ISACs necessary?

My comment here is based on conjecture, as I am not involved in the operations of the ISACs or HCCIC. However, I do know that all of the national ISACs have a cyber threat indicator sharing methodology in place so that a relevant threat to any particular industry can be disseminated to other ISACs and their members. I also know that the NCCIC and the ISACs coordinate and share information, and that this information can be delivered back to organizations through the use of the NCCIC Automated Indicator Sharing (AIS) program. I know there are some established pathways between the NCCIC and the HCCIC.

I also know that the general requirement for robust information sharing between ISACs and government entities is constantly in a state of refinement and recalibration based on changing threats and organizational structures, and business operations. Government often has cyber threat intelligence that industry does not have, and vice versa. The task is to be able to share that information in a way that is timely, relevant, actionable and protected. That is a constant learning and exercising process on both sides, and involves a trust relationship both within industry and between industry and government relationship. Beyond that, I am unfamiliar.

8. From your perspective, what is the best process for sharing threats among industry and with HHS?

Leveraging NH-ISAC, its threat indicator programs and by joining the NCCIC's Automated Indicator Sharing. NH-ISAC provides not only the ability to share and receive threat indicators, but also a

community of practitioners to provide robust analysis of threats to the industry, and the establishment of a security community of practice.

In general, the ISACs and NCCIC can share the most aggregated and salient information with HHS so that they might facilitate accurate analysis of operational impact from a cyber event, and coordinate national responses to emergent critical threats. During a national crisis, the HCCIC could be well suited to coordinating a national response. This can be accomplished by imparting the severity of threats to the industry, receiving threat information from vetted sources (ISACs and NCCIC), distilling this information at a high level for national response actions and providing surge resources if regions or critical health systems are shut down that could cause severe impacts to patient safety. All of this can be accomplished under the protection of the Cybersecurity Act, which would encourage organizations to participate in the national response.

9. Mr. Decker you mentioned in your testimony that you serve as the co-chair and industry lead for the joint Healthcare Sector Coordinating Council (HSCC) and Government Coordinating Council (GCC) Task Group. Could you provide some examples of the best practices you plan to recommend to the Secretary? How do you envision HHS' role in implementing these best practices if they choose to do so?

Certainly. For clarity, I am the co-lead for the CSA 405(d) Task Group, which is a Task Group of over 130 individuals under the Healthcare Sector Coordinating Council Joint Cybersecurity Working Group; the cyber working group which serves as the partnership intersection between the HSCC and GCC. The CSA 405(d) Task Group was charged with delivering an industry-led, consensus based, guidance for managing risks within healthcare. The CSA legislation stated that any guidance produced must be practical, actionable and scalable to providers of all sizes, and be aligned with the NIST Cybersecurity Framework, HIPAA and HITECH.

To achieve this, the group decided to focus on threat scenarios that impact healthcare today, and how to mitigate them. To that end, the group identified 5 critical threats to our industry. Some examples of these threats are digital extortion attacks (ransomware), phishing attacks, and attacks against medical devices that may impact patient safety.

To mitigate these threats, the Task Group identified 10 best practices, and 88 total sub-practices. The goal of the Task Group was not to create a new framework, or a new series of controls, but rather leverage the great guidance that already exists and provide the reader a 'one-stop shopping' index to managing the threats previously identified. Within these volumes are implementation guidance for how to achieve the practice identified. For example, to combat the phishing threats, the adoption of Email Protection Systems, with implementation specification of specific controls, were identified as a best practice. For small organizations, 3 sub-practices were identified to mitigate the delivery of phishing emails. Likewise, for larger organizations with a larger footprint, 7 sub-practices were identified for combating the same threat. Each of these practices provide specific actionable countermeasures for how to implement the safeguards.

I believe HHS can help push the adoption of these best practices through a number of vehicles. First, the process of creating these involved the vigorous debate and input from over 130 members across industry

and government. Leading industry thought leadership put these practices “through the ringer”, so to speak. As such, the result is a thoroughly vetted and robust set of guidance. HHS is perfectly suited to provide validity and credibility to this guidance, which is critical for the industry to take it seriously.

Second, when the best practices are released in December of 2018, we have planned for multiple joint marketing campaigns to raise awareness of the guidance to the public. These campaigns may include webinars, talks at conferences, newsletters, as well as disseminating information out through the ISACs, professional associations, and other channels that both providers and cybersecurity professionals participate, as well as leveraging the HSCC and GCC.

Last, I believe HHS could further stimulate the adoption of these practices by offering enforcement relief to those organizations that can demonstrate adoption, as indicated in my response to Chairman Burgess.

10. In what way can public-private collaboration improve the cybersecurity posture of the healthcare sector?

By providing a credible forum for our national thought leaders to come together. I believe this forum is the Joint Cybersecurity Work Group under the HSCC and GCC. In February of 2018, the JCWG was rebooted, and its Executive Director (former DHS Assistant Secretary Greg Garcia) was established as the administrative leader. Since that time membership has grown over 400%, and 14 Task Groups have been established, each designed to tackle a specific set of topics from the HCIC Task Force Report. I have been a member of the JCWG for over 2 years; this reboot has been a fantastic rally to bring together our industry’s best thinkers. Additionally, the HHS leadership participating in the JCWG has been incredible for making sure any guidance released are impactful and realized. If anything, supply more resources to its operation. This sector coordinating council, like the 15 other officially-designated critical infrastructure sectors organized under homeland security presidential executive orders, is a coalition of the willing, of institutions and associations volunteering their resources and expertise for the public good. I would encourage the Congress to continually seek the HSCC’s counsel on these complex cybersecurity matters. They cannot lobby but as much as possible try to coalesce the broadest and most coherent sector-wide point of view about cross-cutting solutions to cross-cutting challenges.

The Honorable Doris Matsui

Mr. Decker, I appreciate your emphasis on how vital technology is to our country's health. My colleague, Rep. Jenkins, and I just passed legislation out of Committee that would further expand the use of electronic health record technology for behavioral health providers. I also work with my colleague Rep. Billy Long on the HHS Cybersecurity Modernization Act, as a first step in the direction of enhancing agency leadership on cybersecurity.

As we continue to advocate for the need for innovation and connectedness in our health care system, we need to also address new vulnerabilities that have been created.

1. Mr. Decker, could you explain the types of cybersecurity threats you think we need to prepare for?

The landscape of threat has changed over the last decade. Previously, the majority of threats faced by the industry were largely designed to steal sensitive information. The change in recent years are the threats to patient safety, through attacks against vulnerable connected medical devices, and threats against the healthcare industry's digital ecosystem (digital extortion, aka ransomware). The methods cyber attacks deploy are now motivated for these purposes, and will continue to evolve and become more sophisticated.

2. How does this fit in to the conversation about public health preparedness under PAHPA?

I believe that WannaCry provided the perfect example of why we need to expand our thinking of the impact of the cyber threat. The rapid proliferation of these more sophisticated attacks is alarming. In the case of WannaCry, it hit the National Health System in the UK and affected 81 of the 236 trusts across England⁶. As a result, multiple hospitals were forced to divert emergency services, 19,494 appointments were cancelled and at least 139 patients with "an urgent referral for potential cancer cancelled".

These reports exemplify that the threat to the healthcare system is no longer an issue specific to a single hospital or practice, but rather has the ability to cause impact to regional areas. It is no longer a question of if such an attack is possible; WannaCry demonstrated that cyber attacks have the ability to impact the public health of regions impacted. I believe the only reason this did not spread widely through to the US is due to a technical kill switch that was identified early in the proliferation of the WannaCry malware. When that kill switch was activated the proliferation slowed dramatically, and organizations had critical time necessary to implement patches that were missing to inoculate their organizations.

Just like a pandemic outbreak, we must be prepared to handle a cyber attack of the same magnitude.

3. What should the federal government be doing to better coordinate both response to and prevention of cyber attacks? Should HHS take a leadership role in helping the health care industry address these threats?

I refer to my previous answers to Chairman Burgess and Ranking Member Pallone provide sufficient answers. I will summarize by reiterating that the need for further public-private partnership is needed, that the designation of a single point of contact to interface with the healthcare industry on cybersecurity issues is necessary, and that it is vital for HHS to provide leadership which in turn will provide validity and credibility to our industry for adopting more cybersecurity protections.

⁶ <https://www.digitalhealth.net/2017/10/wannacry-impact-on-nhs-considerably-larger-than-previously-suggested/>