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

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

ON

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

JANUARY 23, 2018

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C O N T E N T S

STATEMENTS

TUESDAY, JANUARY 23, 2018

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

Tuesday, January 23, 2018

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

The Committee met, pursuant to notice, at 10:05 a.m. in room SD–430, Dirksen Senate Office Building, Hon. Richard Burr, presiding.

Present: Senators Alexander, Burr [presiding], Isakson, Cassidy, Young, Roberts, Casey, Baldwin, Murphy, Warren, Kaine, Hassan, Smith, and Jones.

OPENING STATEMENT OF SENATOR ALEXANDER

Senator Burr [presiding]. I would like to call the hearing to order.

First off, I would like to recognize the Chairman of the Committee for a statement.

The CHAIRMAN. Thank you, Senator Burr, and Senator Casey, and Members of the Committee.

I want to thank Senator Burr for chairing the hearing today, and Senator Casey for serving as Ranking Member at Senator Murray's request. They have both been real leaders on this subject.

Senator Burr was the original author of the first passage of the Pandemic and All-Hazards Preparedness Act in 2006. The law helps protect us from the full range of public health threats: from natural disasters, to bioterror attacks, to outbreaks of infectious diseases.

Then in 2013, Senators Burr and Casey led the bipartisan authorization of the Pandemic and All-Hazards Act. Many Members of this Committee contributed at that time, some of whom are still on the Committee including Senators Enzi, and Bennet, Isakson, Warren, Hatch, Roberts, and others.

Now, the bill needs to be reauthorized for a second time and today's hearing is the second we have had this year.

Last week, we heard from the Administration on recommendations in advance of the reauthorization of the Act including from the Assistant Secretary for Preparedness and Response, the Food and Drug Administration, and the Centers for Disease Control and Prevention.

In the middle of the flu season, it is critical that we reauthorize the Act before many of its provisions expire in September. I hope we will do this in a bipartisan way and I expect that. That has been the tradition with the law and with this Committee on almost all of our major bills.

People are not as aware of the devastation of, for example, the flu, and I mentioned the flu season. I believe the figures are that between 12,000 and 50,000 Americans die of flu every year. Dr. Collins has talked to us about the expediting of a universal flu vaccine, which he sees soon.

Tennessee has seen heartbreaking stories already this winter as the flu spread across this state and this country. In our state already in this season, a pregnant woman and three children in Tennessee have died of the flu.

The Act provides a public health preparedness framework that enables us to be prepared and able to respond to public health threats by ensuring that we have enough medicines to protect Americans, and to ensure our hospitals and state and local health departments are prepared to respond to public health emergencies.

Thanks to all our witnesses for coming here today, especially Dr. Dreyzehner, who has come from Tennessee.

Thank you, Senator Burr.

STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Chairman Alexander.

This morning, we are holding a hearing entitled, "Facing 21st Century Public Health Threats: Our Nation's Preparedness and Response Capabilities."

We will hear from Dr. Tom Inglesby, Director of the Center for Health Security at Johns Hopkins Bloomberg School of Public Health; Dr. John Dreyzehner, Commissioner of the Tennessee Department of Health; Brent MacGregor, Senior Vice President of Commercial Operations for Seqirus and Co-Chair of the Alliance for Biosecurity, Summit; and Dr. Steven Krug, Head of Pediatric Emergency Medicine at Lurie Children's Hospital in Chicago.

Senator Casey and I will have an opening statement, and then we will hear from the witnesses, and then Members will have up to 5 minutes for questions.

I am pleased to chair this second hearing to inform our work on PAHPA. I would like to thank the Chairman, once again, for giving the opportunity to Senator Casey and I to lead the discussion.

Today, we will hear from some individuals with firsthand knowledge of the challenges we face in combating public health threats, and their ideas on how to move forward.

Since the last PAHPA reauthorization, the emergency preparedness and response framework has been tested by the emergence of pandemic flu, multiple natural disasters, and an Ebola breakout and a Zika virus.

The lessons learned in these events come from individuals, like those sitting before us today, and their efforts to protect and to save lives.

The last hurricane season resulted in three major storms devastating many communities and raising new questions about our ability to manage and withstand multiple periods of response.

The emergence of Zika emphasized the need for improved data collection and surveillance to inform and protect as many mothers and babies as possible. Further, the Ebola breakout in 2014 highlighted the need for an ASPR that brings both the knowledge of the potential damage that can be brought by these threats and a deep understanding of the effort undertaken for research, development, and procurement of medical countermeasures.

I look forward to learning more about the opportunities and barriers each of you see to better leverage innovative technologies to solve these problems.

Whether it is the challenge in the development of a vaccine, the information crucial to a public health department in the midst of a crisis, the infrastructure a doctor needs to rapidly care for patients, or improvements to the ways these policies complement one another, your experiences reminds us that we cannot let up on these efforts or lose sight of the urgency this mission demands.

We must not get distracted by making changes to the laws that are outside of our focus of perfecting PAHPA, improving and strengthening our policies and programs to make them more effective now and in the future.

I look forward to the insight each witness can provide.

Now I would turn to Senator Casey for any remarks he would like to make.

STATEMENT OF SENATOR CASEY

Senator CASEY. Thank you, Senator Burr.

I want to thank Senator Burr for his years of work on these issues.

I want to thank, as well, the leaders of this Committee, Chairman Alexander and Ranking Member Murray, for this opportunity.

Also, of course, I want to thank our witnesses for bringing their experience and work to these issues, and for joining us today.

This is our second hearing on this topic and the focus, of course, is our Nation's preparedness to combat public health threats as we look toward reauthorizing the Pandemic and All-Hazards Preparedness Act later this year.

Now, more than ever, we must continue to build our Nation's resiliency to help security threats. The threats that face our Nation today are increasing in both frequency and intensity. It is critical to foster and advance innovation and drugs, devices, and diagnostics.

Yet, when we are considering an emerging infectious disease, or an engineered bioweapon that has yet to be seen by man, or the response to a natural disaster like a hurricane, we do not and will not have a vaccine or a countermeasure to protect us from these scenarios.

In addition to supporting biomedical innovations, we must also strengthen our hospitals and our public health professionals, our frontline of defense against these health threats.

We must ensure that we give our communities the necessary tools and support they need to be ready when, not if, the next emergency strikes. By all accounts, we have come a long way.

I spoke at the last hearing about the success of the Hospital Preparedness Program, the so called HPP and PHEP, the Public

Health Emergency Preparedness Program in the context of a train derailment in Pennsylvania. One of many examples we could cite.

But these grants for these programs also facilitate preparedness activities that help hospitals and public health systems with more regular occurrences.

For example, when subzero temperatures caused bursting pipes in St. Vincent Hospital in Erie, Pennsylvania—and Erie got hit worse than anyplace with snow this year—the hospital contacted the local emergency management agency and also the regional healthcare coalition, created through HPP funding, who assisted in the response in that circumstance.

Yet, the funding for these preparedness programs has decreased from PAHPA to PAHPRA with appropriations falling behind authorized levels, spiking only in the response to Ebola and Zika.

The impact of funding reductions means a decrease in the amount of time that hospitals and medical staff have to plan and train for an emergency; and the loss of thousands of public health jobs, and the reduction in emergency managers and public health lab technicians.

It is very dangerous to wait for a threat to emerge to try to pass emergency funding bills. We must be proactive, not reactive.

How can we improve our healthcare system preparedness and our public health capacities, and thereby improve our situational awareness in an emergency?

Can we work toward a precision public health using better data to more efficiently guide responses in emergencies to help benefit our communities? I think we can.

For example, it was reported by the publication "Nature," when domestic transmission of the Zika virus was confirmed in the United States, the entire country was not declared at-risk. Instead, precise surveillance defined two at-risk areas of Miami-Dade County neighborhoods measuring less than 2.5 square miles. This allowed for the targeting of resources to these regions.

Building on that experience, we can expand surveillance to illuminate causes of disease and spark opportunities for prevention.

At last week's hearing, we also heard from Assistant Secretary Kadlec about the use of emPOWER, the emPOWER program, to identify and treat at-risk individuals requiring electricity-dependent medical and assistive equipment. Yet, he also identified a weakness. This system only pulls in Medicare data, not Medicaid and not TRICARE data.

How do we ensure that we are acting on the data appropriately to protect these vulnerable individuals?

The tragic death of 12 seniors at a nursing home during Hurricane Irma in September highlights that more needs to be done to protect our most vulnerable citizens. In fact, most of our citizens have additional characteristics that make them more vulnerable during a public health emergency. This includes our children, our parents, our rural communities, individuals who have limited English proficiency, individuals with disabilities and, of course, individuals with chronic illnesses and more.

We must do better to help our communities to prepare for potential health security threats. We must continue to invest in innova-

tive biotechnologies and we must also improve our non-pharmaceutical interventions.

I am looking forward to the hearing, for the witnesses' testimony, and for how we can continue to prepare our hospitals and health systems to ensure equal consideration of all of our constituents.

Senator Burr, thank you very much.

Senator BURR. Thank you, Senator Casey.

I am pleased that we have our four witnesses here today and I thank each of you for taking the time to be here. I would like to introduce all four.

First, I would like to introduce Dr. Tom Inglesby. Dr. Inglesby is the Director of the Center for Health Security at Johns Hopkins Bloomberg School of Public Health.

He is internationally recognized for his work as a writer with numerous publications focusing on public health preparedness, pandemic, and emerging infectious disease, as well as the prevention of, and response to, biologic threats.

Dr. Inglesby, welcome.

I will now turn to Senator Alexander for an introduction.

The CHAIRMAN. Thank you, Senator Burr.

I would like to welcome Dr. John Dreyzehner, who is surely the tallest Commissioner of Health in our history, maybe in the country.

He has served as Commissioner of the Tennessee Department of Health in Nashville since 2011. He has significant experience responding to state and local public health emergencies including infectious diseases like Zika, and natural disasters such as the wildfires that devastated eastern Tennessee in 2016.

Today, he will provide important insights into our Nation's preparedness and response capabilities at the state and local level, what is working, where we can improve, and where we can protect and save more lives.

Dr. Dreyzehner is a physician with more than 25 years of service. As Commissioner of Health, he helps to protect Tennesseans from public health threats.

I appreciate his leadership in Tennessee and we welcome him to the Committee.

Senator BURR. John, I am sure if you were a little younger, there are a couple of Tennessee basketball teams that would probably recruit you tomorrow given their record this year.

The CHAIRMAN. Well, one of them is doing better.

Senator BURR. Next, I would like to introduce Mr. Brent MacGregor. He is the Senior Vice President for Commercial Operations at Seqirus, the second largest flu vaccine company in the world.

Seqirus is an example of the success that can be achieved through public-private partnerships to ensure that we are better prepared for the threats that face us.

Their facility in Holly Springs, North Carolina is one of three advanced manufacturing facilities in the country with the capability to rapidly respond in the event of a pandemic flu outbreak.

Mr. MacGregor is also the Co-Chair of the Alliance for Biosecurity. The Alliance works to promote the critical partnerships be-

tween the Government, industry, and other stakeholders to advance and encourage the development of medical countermeasures.

Brent, welcome.

Finally, Dr. Steven Krug. Dr. Krug is the Head of Pediatric Emergency Medicine at the Lurie Children's Hospital of Chicago. Dr. Krug is also a Professor of Pediatrics at Northwestern University Feinberg School of Medicine, and serves as the Chair of the American Academy of Pediatrics Disaster Preparedness Advisory Council.

Dr. Krug, welcome.

With that, I will turn to you, Dr. Inglesby, and you can lead off for up to 5 minutes of testimony.

STATEMENT OF TOM INGLESBY, M.D., DIRECTOR, CENTER FOR HEALTH SECURITY, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, BALTIMORE, MD

Dr. INGLESBY. Thank you.

Senator Burr, Senator Casey, Members of the Committee.

Thank you for the chance to speak today about these important issues.

My name is Tom Inglesby, and I am the Director of the Center for Health Security at the Johns Hopkins Bloomberg School of Public Health where I am a Professor of Medicine and Public Health. Our Center's mission is to protect peoples' health from epidemics and disasters, and to build resilient communities.

I will provide a brief overview of key areas that Center colleagues and I consider vital to our Nation's preparedness and response capabilities. The opinions expressed here are my own and do not necessarily reflect the views of Johns Hopkins University.

The U.S. faces a range of major public health threats, any of which could occur without much warning. These include natural disasters, technological accidents, mass shootings and bombings, chemical spills and potential use of chemical weapons, radiation and nuclear threats, and biological threats.

Biological threats, whether they are natural like H7N9 in China, or accidental such as an epidemic viral strain released from a lab, or deliberate like small pox or anthrax are of a particular concern, and thus, a big focus of my comments today. Biological threats could range from modest in size up to those capable of posing global, catastrophic risks.

What more can be done to prepare for these threats?

First, we need to strengthen the healthcare system's preparedness. That is, the capacity to care for high numbers of sick or injured in an emergency.

While there has been substantial progress in preparing for small disasters in the country, the Nation is not ready to provide medical care in large catastrophes or big epidemics of contagious disease.

The APSR Hospital Preparedness Program, or HPP, has been helping fund and build these capabilities at the state and local level. But significant resource constraints limit what HPP can do. Its budget has decreased more than 50 percent since it started in 2002. That trend should be reversed.

New initiatives, like establishing regional disaster resource hospitals, could be a strong, new, additional component in improving medical preparedness.

Second, we need to strengthen the ability of our public health system to detect and respond to threats.

Since 2001, there have been serious efforts at the CDC, and state and local levels, to provide early warning of new outbreaks, provide lab diagnostics, investigate and contain outbreaks, communicate to the public, ensure biosafety and biosecurity, and much more.

There has been good, forward movement, but there is too much to do and not enough trained professionals to do the work. Public health relies on funding from the CDC's Public Health Emergency Preparedness grants, or PHEP.

That funding has been reduced by nearly 30 percent since 2002 even though public health crises have not declined. PHEP should be strongly supported.

In addition, I believe that a public health emergency contingency fund should be established, which would allow rapid, public health response funding in emergencies.

Third, we need to move ahead in medical countermeasure development. There has been good progress, but many priorities remain including sustained funding in research, development, and manufacturing and acquisition of countermeasures; transitioning to new flu vaccine technologies; and setting more ambitious targets for rapid development of products in emergencies so that they are ready in the course of a given pandemic or epidemic.

Fourth, the U.S. needs to recognize threats that could inadvertently emerge from biological research.

After the U.S. moratorium on potential pandemic pathogen research was lifted last month, researchers can now again apply for funding to study, for example, ways of making the world's most lethal viruses, like H5N1 bird flu, respiratory transmissible like seasonal flu.

In the worst case, this could lead to the accidental or deliberate release of a novel strain of virus that could cause an epidemic or even a pandemic.

I do not believe the benefits of this work are worth the risks, but if it is going to go ahead, I would advise there be high transparency in the program and serious dialog among concerned governments internationally on how to proceed.

Finally, we should fund the Global Health Security Agenda, or GHSA. In 2014, the U.S. helped launch GHSA with a billion dollar commitment to help countries prevent, detect, and respond to infectious disease threats.

Since then, the CDC and USAID have been working in 39 countries, leading programs to stop antimicrobial resistance, increase lab and surveillance capabilities, strengthen public health workforces, and much more.

But at this point, U.S. funding for GHSA is ending soon. If we pull away from the GHSA, other countries will likely do the same. We should continue to support it. It is the most effective program we have to contain international outbreaks at their sources overseas.

Improving our Nation's preparedness and response capacity is a daunting, complex endeavor, but I am confident it is an achievable goal if we focus our efforts on these initiatives.

I appreciate the Committee's time and I welcome your questions.

[The prepared statement of Dr. Inglesby follows:]

PREPARED STATEMENT OF TOM INGLESBY

Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for the chance to speak with you today about Facing 21st Century Public Health Threats: Our Nation's Preparedness and Response Capabilities.

My name is Tom Inglesby. I'm the Director of the Center for Health Security of the Johns Hopkins Bloomberg School of Public Health and a Professor of Public Health and Medicine at the school. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University. Our Center's mission is to protect people's health from epidemics and disasters and build resilience in communities. We study the organizations, systems, and tools needed to prepare and respond, and work to help translate what we find into stronger programs and policies.

I will provide comments on the kinds of threats that the country faces, health care system preparedness, public health needs, medical countermeasure development, potential pandemic pathogen research and the global health security agenda.

Public Health Threats to the Country

The country faces a range of potential sudden, major public health threats, any of which could occur without much warning: natural disasters including major hurricanes, earthquakes, fires and mudslides; technological accidents; mass shootings and bombings; chemical spills and the use of chemical weapons, such as we saw on horrific scale in Syria; radiation and nuclear threats; and, biological threats, either natural, accidental or deliberate. I will say more about biological threats given the particular kinds of threats they pose.

We have seen signs of what natural epidemics can do in recent years. We saw what damage Ebola could do when it got into cities in West Africa, what MERS did in S Korea when it arrived there, how Zika could transmit congenital deformities by mosquito. And health agencies around the world are tracking H7N9 in China, the most serious of avian influenza potential threats to emerge in years, with case fatality rates on the order of 40 percent. If H7N9 ever evolved into a virus capable of sustained human to human transmission, it is hard to describe how devastating that would be to the world.

We are also now in an era where there is incredible power in biotechnology and science. This power is almost entirely for the good, with the development of new medicines, better agriculture, improvements to the economy, and more. But with every new technology we need to acknowledge the potential downsides of accidental or deliberate misuse. It is now possible to engineer new traits into old viruses. For example, it is becoming possible to take the lethality of one virus and combine it with the contagious qualities of another virus. And, last week scientists published research showing how they synthetically could create horsepox, a close viral relative of smallpox. We don't have the oversight system we need to fully understand or manage these kinds of developments yet, either in the U.S. or internationally. Whatever we do about this, we need to ensure that we don't slow down science that drives so many good things forward. But we also can't ignore that new risks are becoming possible.

Even without the advent of new science, there are the known deliberate biological threats including anthrax and smallpox. The government's own modelling has shown repeatedly how severe the impact could be in the event of larger scale biological weapons use in the U.S., and there is continued urgency in preparing for these possibilities.

There is a broad range of potential consequences from biological threats. Some are common and of a more modest scale. On the other end of the spectrum, some conceivable scenarios could even pose globally catastrophic biological risks, with lasting damage to countries and societies around the world.

Given the range of biological scenarios and possible consequences, the forthcoming White House National Biodefense Strategy will be of great importance in helping to set national priorities, assign agency responsibilities, and identify funding requirements.

Health Care System Preparedness

An essential component of medical preparedness is the capacity to care for high numbers of sick or injured in the event of an emergency. And while there has been substantial progress in preparing for smaller disasters, the Nation is not ready to provide medical care in large catastrophes or big epidemics of contagious disease.

For smaller events, there is evidence that preparedness has gotten better. We saw this with the response to the Boston marathon bombing in which 264 were injured and treated at 27 hospitals— all victims who made it to the hospital survived. The health care and EMS response to the Las Vegas shootings was also considered to be effective in providing trauma care. Hospitals, for the most part, do well in normal flu season, handle smaller outbreaks, and they provide good care for the victims of car and bus accidents. The Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) has been working to help fund and build these capabilities.

In larger scale infectious diseases emergencies, most U.S. health care systems would not do well. It was quite evident how difficult it was to care for even one hospitalized Ebola patient, let alone to consider how a hospital would handle a larger scale infectious disease emergency. The ASPR program to build 10 regional biocontainment units (BCUs) was smart, and we should build on that capacity. But it is important to know that most of these units can handle only a couple of patients at a time. More broadly, there is no surge plan for taking care of larger numbers of patients with contagious, potentially lethal infectious diseases. If hospitals do need to take care of patients with contagious infectious diseases, there could be major disruptions to the regular operations of their systems. They will need to protect against that, or could put at risk their normal work of taking care of heart attacks, delivering babies, performing surgeries, and more.

If you consider what would be required to manage the ill in a flu pandemic or smallpox or after a sizable anthrax event, it is clear that hospitals do not have that capability— they are simply not equipped for those larger events, and they are living too close to the margins with just in time inventories to be able to surge.

In larger events, a responding hospital would need to be part of a larger entity that connects hospitals to each other and to other key parts of the system—a system called Health Care Coalition. HPP has funded the creation of these coalitions around the country, and they largely comprise of hospitals, public health, EMS. In places where they don't already, coalitions should also include minute clinics, surgiclinics, pharmacies, mental health and dialysis centers. We saw in the response to Hurricane Sandy just how much medical care is delivered in the community outside of hospitals themselves, so these kinds of organizations need to be prepared to respond in emergencies too. With the hurricanes of last fall, we also saw how much the affected communities relied on the assistance of ASPR, the emergency personnel it led, and the emergency medical assets it helped to provide.

On a national level, for planning for major epidemics and disasters, we should build on the strengths we see in Level 1 Trauma Centers and the BCUs to create what could be called specialized Disaster Resource Hospitals (DRH). These would be designated facilities with special national and regional responsibilities to prepare for disasters and epidemics. They would have more reserve in the system, better trained people, resources to support a larger mission, and could serve as resources to other hospitals. Many would be academic medical centers, probably already Level 1 Trauma Centers, probably many would be the existing BCUs, because they are already organized to take on high end risks and problems that smaller hospitals in system can't manage.

There are other actions we can take to improve our health care response. Doctors and nurses should be able to take their healthcare credentials acrosslines in order to facilitate response to a regional or national emergency.

We should also be able to rapidly deploy clinicians internationally in new outbreaks. We had substantial difficulty doing that in Ebola. It would be good for ASPR to work with CDC, State Department, USAID, DoD and other partners as needed to develop a plan delineating under what conditions, with what personnel, and how clinicians would be officially deployed internationally from the U.S. in the event of a pandemic or other emergency of international concern. Early deployment of clinical experts could help outbreaks overseas from becoming out of control and spreading.

The U.S. government should put in place a plan for conducting research during public health emergencies to study new medicines, vaccines, and other clinical and public health interventions to gauge whether they are effective and safe. We have seen in past epidemic responses that a number of new products and efforts are tried, but not necessarily in careful ways that create the evidence needed to deter-

mine effectiveness and safety. Clinical trial designs that help us answer those questions should be worked out ahead of any crisis.

Overall, we need a stronger approach to prepare for the most serious catastrophes that could hurt the country. We need planning for the most consequential of the FEMA national planning scenarios. In the dozen years since these scenarios were issued, we have not made a lot of progress in the health care system in being able to respond effectively to many of the threats detailed in those scenarios. A vivid example of this was Hurricane Maria that destroyed the basic infrastructure that we need to provide medical care to victims.

In terms of resources, the HPP budget of $250M is down from $515M at its inception. This is worrisome, given what we have learned about how hard it is to prepare to provide mass care for the range of emergencies experienced by Americans. The HPP program should be supported at a higher level, and other avenues of funding should be explored for funding a new DRH program. Possible additional Federal funding avenues to explore include adding a modest amount of additional reimbursement for each Medicare and Medicaid admission to DRHs. This could help reduce the uncertainties surrounding annual appropriations for preparedness that come through the annual HPP program. In any event, ASPR and its mission to build national preparedness, including the hospital preparedness program and the medical countermeasure enterprise, need to be strongly supported.

Public Health Preparedness

Another national pillar for preparedness is the capacity of our public health system to detect and respond to public health crises. Since 2001, there has been a major effort at CDC and around the country at a state and local level to build programs that would help provide early warning of new outbreaks, provide laboratory diagnostics, investigate and help contain outbreaks, communicate risk to the public, ensure biosafety and biosecurity practices and more.

A great deal of progress has been made, and there is a committed cadre of public health officials working on these issues around the country to protect Americans during times of public health crisis. But there is too much to do and not enough trained professionals to do it. The public health workforce has been reduced by budget pressures by tens of thousands in the last decade. This is the same public health workforce that every day deals with urgencies like the opioid crisis, a nasty seasonal flu season, outbreaks of diseases like measles or norovirus in a school or meningitis on a college campus or legionella in an apartment building, medicine and vaccine shortages, HIV, hepatitis, tuberculosis, the safety of water supplies, and so much more. The National Health Security Preparedness Index, which measures state by state capacities in key areas of public health, shows an average state score of 6.8/10, with substantial variation around the country.

Public health agencies critically rely on funding from the Public Health Emergency Preparedness Program (PHEP) program administered by the CDC to prepare for emergencies. That funding has been reduced to $660M from $940M in 2002, and yet the public health crises faced by Americans have not commensurately declined. Early in 2018, the Administration proposed substantial cuts to PHEP grants. Congress didn't go along with those cuts. I am hopeful that this year, the Administration will recognize the role of the PHEP program and public health grants in preparing the country for disasters and epidemics that befall our communities. There should be more funding for public health preparedness for emergencies, not less. If current funding goes down or away, public health jobs are cut, key labs don't get supported, outbreak investigations will be slowed, disease surveillance programs will suffer, along with the rest of what public health provides every day and in emergencies.

Some have asked whether there should be changes made regarding which states and cities should receive HPP and PHEP funding based on some new determination of risks. We haven't seen evidence that serious changes to the programs' formulas would provide meaningful benefit or that the current formula is flawed (currently there are already risk-based considerations in both formulas). Funding formulas that lean too heavily on risks from prior natural disasters ignore both universal risks, such as an influenza pandemic or other outbreaks, and unpredictable threats such as acts of terrorism and mass shootings. Because disasters can occur anywhere in the U.S., preparedness should occur broadly around the country.

Within CDC too there are essential public health preparedness programs that should be noted, including the programs that provide support and technical preparedness assistance to states and locals public health agencies; the Biosafety and Select Agent and Toxin program; the Strategic National Stockpile of meds and vaccines we will need in crises; a range of critical disease surveillance programs; and,

the Emergency Operations Division which is the nerve center for CDC's deployments around the U.S. and the world. These programs need to continue to be supported.

There is a new proposed element in public health preparedness that should be supported—a Public Health Emergency Contingency Fund. We saw during the initial response to Zika that it took more than 230 days to get emergency appropriations for that epidemic. A way to address this would be to create a new Fund that allows rapid access funds in the aftermath of an emergency. Such a fund should supplement and not supplant existing public health and preparedness grants which are needed in order to have a public health essential workforce, labs, and infrastructure in the first place, and to prepare for the range of disasters and epidemics that could arise. A Public Health Emergency Contingency Fund would allow rapid initiation of responses to acute emergencies so that families and children wouldn't have to wait for a special appropriation before help could start. Resources from that fund could be made available immediately following a public health emergency declaration, with reporting requirements to Congress following the initial emergency period and an automatic process to replenish funds when depleted. A balance of $500 million to $1 billion would be appropriate based on past emergency appropriations for Zika, Ebola, and H1N1. It would be enough to get the emergency response started for public health, the healthcare system, and for initiation of medical countermeasure development, but may not be sufficient for the extended response, which would need to come through emergency congressional appropriations.

Medical Countermeasure Development

Another essential component of the country's medical and public health preparedness is the capacity to make medical countermeasures to respond to threats. As of 15 years ago, there was no national approach to medicine or vaccine acquisition for civilian needs in emergencies. Since then, there has been substantial progress. There are now: a research program at NIH; an advanced development program at BARDA; an FDA program dedicated to medical countermeasure approval and regulatory science; engagement of the biopharma companies which develop and manufacture needed products; and, a substantial stockpile of medicines in the National Pharmaceutical Stockpile.

But we need to keep strengthening and sustaining this medical countermeasure research, development and stockpiling system. It is a very challenging mission primarily because of the complexity of the science and the breadth of the needs. It is also difficult because—outside of the U.S. government and sometimes other governments or international organizations——there are no commercial markets for most of these products. So the country relies on this system to prepare for a range of biological, chemical and radiological threats.

There are a number of things about medical countermeasure development that are worth special mention. We have to press forward on new approaches to flu vaccine. We certainly need to forge ahead as rapidly as is possible in the development of a universal flu vaccine which could provide broad coverage to the range of flu threats that could face the country. But our best flu scientists say that there are major technical challenges in that pursuit, and that it will take time to develop a universal flu vaccine, no matter how we approach it. So in the meantime, we need to do all we can to improve the flu vaccine approaches that are now available.

For instance, we still rely on eggs to produce annual flu vaccine as we have for years. We do this even though we have the technology to produce vaccine using modern recombinant techniques. Using new production approaches would allow us to accelerate our response in the event of a flu pandemic. It would also lessen the chances the vaccine strains could drift to become less effective in the manufacturing process as can happen in the process that relies on eggs.

In the event of the onset of a pandemic flu, the USG working with its biopharma company partners have a plan that will take 5 to 6 months to begin delivering the needed flu vaccine for that pandemic. We should continue to exercise and support that plan and work to accelerate that timeline. But at least in the case of flu, we do have targets and an exercised process to go from new pandemic discovery to vaccine manufacturing in 6 month timeline. We don't have that kind of process for epidemics that might be caused by other pathogens.

For example, during the Ebola outbreak in West Africa, a new Ebola candidate vaccine was developed, but it took so long that it was not available until after the outbreak was over. And in some ways, we were better positioned to respond to Ebola than we would be for many other diseases—there had been substantial science efforts related to early Ebola countermeasure development in DOD and NIH programs

for years. For other infectious diseases, we would be further behind at the start, and it could take much longer than it did for Ebola.

As per the November 2016 PCAST report to the President on How to Protect Against Biological Attack recommended, the country should set a national target of 6 months or less for developing a new medicine or vaccine for major epidemics and pandemics beyond pandemic influenza. To do that would require people, systems and infrastructure dedicated to that goal within government, and a budget to go with that. Right now when new epidemics emerge that require a sudden start of a new MCM program (e.g. Zika), it is almost guaranteed to be a long, uncertain, and complicated process with no clear or well worked-out pathways. In the case of Zika, a major company that was developing the vaccine ultimately dropped out of the process, in part because of the challenges of working with the government.

Potential Pandemic Pathogen Research

It is also important for the medical and public health preparedness community to pay attention to the kinds of new threats that could inadvertently come from biological research. For example, it was announced last month that the USG moratorium for funding potential pandemic pathogen (PPP) research is over. It is possible once again to apply for USG funding to study ways of making the world's most lethal viruses (like H5N1), respiratory transmissible (like seasonal flu). In the worst case, this could lead to the accidental or deliberate release of a novel strain of virus that could cause an epidemic, or even a pandemic. I don't believe the benefits of this kind of research are worth the risks of doing it. But since the end of the moratorium has occurred, I would make a number of recommendations regarding this program.

There should be transparency in how the government approaches this research. Agencies that fund this work should make their processes public. What PPP experiments are being proposed? How were risks and benefits determined, what experiments were approved, and which were denied? What kind of biosafety and biosecurity will be required to do this work? There should be clarity regarding the special review process that has been established to handle this research. How will it work? Who will be involved? How to avoid conflicts? Are there red-lines that should not be crossed by scientists?

What will the international approach be? It is good that U.S. has taken a lead in formulating new PPP framework given that the USG provided the majority of government funding to date for this kind of work. Since the USG has acknowledged there are high risks in PPP, what will USG do internationally to help establish norms for this? What will our reaction be if we learn that other countries are pursuing PPP research? I disagree that the U.S. should be pursuing this work, but if the U.S. is going to do it, then it should be working to engage other countries to try to establish rules of the road regarding under what conditions it will be done.

Global Health Security Agenda

A final element to note in medical and public health preparedness is the importance of international programs in preventing the emergence of major outbreaks that have the chance to spread to the U.S.. In 2014, the U.S. helped to launch the Global Health Security Agenda (GHSA) to improve the capacity of countries around the world to prevent, detect and respond to infectious disease threats. One lesson from Ebola was that we have to do more to help countries control infectious diseases. Because of that experience and because so many other countries were having trouble building basic capacity to detect and respond to infectious diseases, the U.S. made a $1Billion commitment to the GHSA for a period of 5 years. Other countries have also been big supporters of this effort. South Korea has pledged to spend $100 million to build capacities in 13 countries. Japan and Australia have pledged $40 million and $100 million, respectively.

With U.S. GHSA funds, the CDC and USAID have been working to improve these capabilities in 39 countries around the world. These programs work to diminish antimicrobial resistance, increase laboratory and surveillance capacities, improve vaccination rates, strengthen the public health workforce, and much more.

But at this point the future of the GHSA is uncertain. Even though a number of senior officials in the Administration have voiced support for the GHSA, and signed onto a declaration to extend the GHSA for another 5 years, U.S. funding for the initiative is ending soon, and no commitment for future financial support has been made. Without any sign that funding will be continued, CDC has notified countries that it will begin planning to shut down those programs. And if we pull away from the GHSA in this way, other countries that provide funding and technical assistance will also likely do the same.

U.S. leadership in the GHSA not only has the advantage of improving the capabilities of countries to prevent, detect and respond to infectious diseases. It is also, as U.S. Secretary of State Tillerson said last year, vital to U.S. national security interests. If vulnerable countries (many of which are either politically or financially unstable) do not have the capacity to quickly cope with disease outbreaks, those outbreaks are more likely to spread internationally, including to the U.S.. The GHSA is a powerful tool for helping to ensure that global gaps in health security are addressed before disease outbreaks occur. To continue the pace of U.S. efforts for the GHSA set by the original U.S. investment and programs, an estimated $100M to $200M annually would be needed. It is important for the United States to commit to support the GHSA to help protect the Nation and the rest of the world from epidemic disease. Over time, as countries build their own capabilities, the need for the U.S. and other national commitments should diminish. But at this time, GHSA remains a central element in building international capability to prevent, detect and respond to epidemic diseases.

Senator BURR. Thank you, doctor.
John.

STATEMENT OF JOHN J. DREYZEHNER, M.D., MPH, FACOEM, COMMISSIONER, TENNESSEE DEPARTMENT OF HEALTH, NASHVILLE, TN

Dr. DREYZEHNER. Good morning, Chairman Alexander, Senator Burr, Senator Casey, and distinguished Committee Members.

Thank you for this opportunity to appear before the Committee and to discuss an initiative of significant importance to the common defense of this country; a strong, agile, and resilient public health and medical preparedness and response system.

It is an honor to be here.

Senator Alexander said I am a physician. I am the Commissioner of the Health in Tennessee. I was a local health director in central Appalachia for a decade before that and an Air Force flight surgeon for many years before that as well.

The thoughts I will be sharing with you today are my own, but I am confident that they are shared by my public health colleagues across the country who strive every day to prepare and respond to threats of all kinds. These threats may be infectious disease outbreaks like measles, food borne illness, and our annual epidemic of seasonal influenza that can, like this year, unpredictably test our Nation's response readiness and surge capacity.

These threats can be also large scale national or global events like an influenza pandemic, Ebola, Zika, the opioid epidemic, or acts of terrorism.

Public health also mobilizes, as you know, during natural disasters like winter storms, hurricanes, tornadoes, floods, wildfires as Senator Alexander mentioned, and other extreme weather events. Unfortunately, seldom does a public health jurisdiction of any size go more than a few years without experiencing it.

As well, through mechanisms like the Emergency Management Assistance Compact, or EMAC, even unaffected jurisdictions are frequently called upon to assist neighbors.

Public health, and emergency preparedness response and recovery, is a responsibility, discipline, and service that we have to get right. Lives, as well as physical and economic health, depend on it. It is something we, in public health, do every day. It is a matter of local resiliency. All disasters play out locally and it is also a matter of national security.

In the few moments that we have together, I would like to share my perspective with you, having been directly involved in the planning, implementation, and execution roles at all levels both in the military and civilian capacity over 25 years. Let me start with a simple question.

What is health and medical emergency preparedness response and recovery?

At root, it is not stuff, or equipment, or plans. It is people. Shelters do not staff themselves. A fire truck cannot put out a fire without firefighters. And people, like public health nurses or firefighters, cannot be hired and trained after the alarm sounds. They need to be there, ready to go, before the threat ever emerges if they are to be effective in responding to it. Preparedness is about the people involved and their interconnected networks.

To be truly prepared, we need three key things.

One, trained people, some with local knowledge and all connected by relationships built on trust;

Two, expertise and leadership at all levels, local, state, and Federal, and;

Three, communication and shared situational awareness among responding leaders, people on the ground, and experts.

Trying to create these three things after an event begins takes the one commodity that is most precious in an emergency: time. We do not have time to create this network after the event starts.

In a way, the public health, and emergency preparedness, response and recovery network is like afor a performer. It has to be in place before the show starts, anchored, inspected and in good shape to do the job.

Many people think equipment or supplies are the net, but if you remember nothing else from my testimony today, I would like you to remember this. People, not things, are the net. People are the net. The anchors matter, but it is the people that run the response. The relationships, the knowledge, and the trust created over time are what strengthen the cords, hold them together, and keep them adaptable and resilient. The more that cords and nodes on the net degrade or unravel, the less capable the net is for what we need it to do at our most vulnerable times.

Things like durable medical equipment, medical countermeasures, and communications infrastructure are essential anchors for the net. Without them, the network of people cannot be as effective, but the people are the net.

Our accomplishments and successes in preparedness response and recovery over the last 15 years, which I have illustrated in my written remarks, can be directly attributed, I believe, to the Pandemic and All-Hazards Preparedness Act.

This Act, both in its initial and first authorization form, was transformative relative to public health and healthcare preparedness, and has provided the requisite direction authorities, the authorization of resources, and the cadence of accountability that has become part of the culture of public health, and enable us to do our job in the best way possible.

As you consider PAHPA reauthorization, PHEP and HPP priorities and resources must be lined up with the demands of an ever expanding threat environment, given our frontline of defense and

safety net ability. The scale and speed it needs to protect the public's health and safety are critical to this ability.

Congress, and especially this Committee, should be applauded for its continued work on laws like PAHPA that give states, territories, localities, and tribes the resources and tools needed to stay vigilant at this critical post and get the job done. These funds are not duplicative of emergency management and Homeland Security, as you know, but complementary and essential. Sometimes, depending on the hazard, public health is the only responder.

What we ultimately need as a Nation to ensure a strong safety net is consistent, reliable, and sufficient funding to keep the people, the net, their knowledge, their networks, and their trust intact.

Thank you, again, for the opportunity to speak with you today about this fundamental issue and for caring about preserving our ability to respond to any hazard or threat for generations to come.

I appreciate the opportunity to present to you. Thank you.

I am happy to take questions.

[The prepared statement of Dr. Dreyzehner follows:]

PREPARED STATEMENT OF JOHN DREYZEHNER

Chairman Alexander, Ranking Member Murray, Senators Burr and Casey, and distinguished Committee Members. Thank you for this opportunity to appear before this Committee today to discuss an issue of significant importance to the common defense of the country—a strong, agile, and resilient public health and medical preparedness and response system. It is an honor to be here. The thoughts I will be sharing with you today are my own, but I am confident that they are shared by my public health colleagues across the country who strive every day to prepare for and respond to threats of all kinds. These threats may be infectious disease outbreaks like measles, food borne illness, and our annual epidemic of seasonal influenza that can, like this year, unpredictably test our Nation's response readiness and surge capacity. These threats can also be large scale national or global events like an influenza pandemic, Ebola, Zika, the opioid epidemic, or acts of terrorism. Public health also mobilizes during natural disasters such as winter storms, hurricanes, tornados, floods, wildfires, and other extreme weather events that, unfortunately, seldom does a public health jurisdiction of any size go more than a few years without experiencing. Through mechanisms like the Emergency Management Assistance Compact, or EMAC, even unaffected jurisdictions are frequently called upon to assist neighbors.

Public health and medical emergency preparedness, response, and recovery is a responsibility, discipline, and service that we must get right; lives, as well as physical and economic health depend on it. It is something we in public health do every day, it is a matter of local resiliency, as all disasters play out locally, and it is a matter of national security. In the few moments we have together, I would like to share my perspective with you, having been directly involved in planning, implementation, and execution roles at all levels, both in a military and civilian capacity, for over 50 years.

Let me start with a simple question: "What is health and medical emergency preparedness, response, and recovery?" At root, it's not "stuff" or equipment or plans. It's people. Shelters don't staff themselves. A fire truck can't put out a fire without firefighters, and people, like public health nurses or firefighters, can't be hired and trained after the alarm sounds. They need to be there, ready to go before the threat ever emerges if they are to be effective in responding to it.

Preparedness is about the people involved: It is about their interconnected networks. To be truly prepared we need three key things: (1) Trained people, some with local knowledge, and all connected by relationships built on trust, (2) Expertise and leadership, at all levels; local, state, and Federal and (3) Communication and shared situational awareness among the responding leaders and experts. Trying to create these three things after an event begins takes the one commodity that is most precious in an emergency: Time. We don't have time to create this network once the event starts.

In a way, the public health and medical emergency preparedness response and recovery network is like a safety net for a performer—it has to be in place before the show starts, anchored, inspected, and in good shape for it to do its job. Many

people think equipment or supplies are the net, but if you remember nothing else from my testimony today, please remember this: people, not things, are the net. The relationships, knowledge, and trust created over time are what strengthen the cords, hold them together and keep them adaptable and resilient. The more the cords and nodes on the net degrade or unravel, the less capable the net is for what we need it to do at our most vulnerable times. Things, like durable equipment, medical countermeasures, and communications infrastructure, are essential anchors for the net. Without them, the network of people can't be as effective, but it's the people who are the net.

Our accomplishments and successes in preparedness, response, and recovery over the last 15 years (illustrated in my written remarks) can be directly attributed to the Pandemic and All Hazards Preparedness Act. This Act, both in its initial and first reauthorization form, was transformative relative to public health and healthcare preparedness and has provided the requisite direction, authorities, authorization of resources, and cadence of accountability that have become part of the culture of public health and enable us to do our job in the best way possible.

As you consider PAHPA reauthorization, PHEP and HPP1 priorities and resources must line up with the demands of an ever-expanding threat environment and give our frontline of defense and safety net the ability, the scale, and the speed it needs to protect the public's health and safety. Congress, and especially this Committee, should be applauded for its continued work on laws like PAHPA that give states, territories, localities, and tribes the resources and tools needed to stay vigilant at this critical post and get the job done when needed. These funds are not duplicative of emergency management and Homeland Security, but complementary and essential. Sometimes, depending on the hazard, public health is the only responder.

What we ultimately need as a nation to ensure a strong safety net is consistent, reliable, and sufficient funding to keep the people, the net—their knowledge, networks, and trust—intact.

1 Public Health Emergency Preparedness (PHEP) Cooperative Agreement & Hospital Preparedness Program (HPP)

Thank you again for the opportunity to speak with you today about this fundamental issue and for caring about preserving our ability to respond to any hazard or threat for generations to come.

State and territorial public health departments play a critical role in national security and have increased their individual and collective capacity, capabilities, and impact over the last 15 years to manage the consequences of local, regional, and national emergencies more effectively, saving lives and preventing or reducing injury and illness. These accomplishments are due, in large part, to the leadership, strategy and policy provided, and the investments by the Federal Government in state and local partners, to build and sustain a strong public health and medical preparedness system—both a front-line defense and a safety net. Our accomplishments and successes can be directly attributed to the Pandemic and All Hazards Preparedness Act. This Act, both in its initial and first reauthorization form, was transformational as it pertains to public health and healthcare preparedness and has provided the requisite direction, authorities, and authorization of resources to enable us to do our job in the best way possible.

In Tennessee, our front line of defense and safety net is very adaptable. We have deployed it recently for fires, floods, for winter storms, wind and tornado events, and to provide mutual aid to neighboring states and those as far away as the US Virgin Islands. The list continues with other hazards like Ebola, Zika, measles and mumps outbreaks, foodborne illnesses, the fungal meningitis associated with contaminated compounded injectable drugs which I will come back to in a few moments, and "white powder" incidents. These are real and often different threats requiring flexible and adaptable response capabilities. In each instance, the strength of our system is tested, and each time we assess our performance with a commitment to learn from each and every experience and to make improvements so that our actions will be even stronger the next time.

Among other features, the Pandemic and All Hazards Preparedness Act created and authorized two critically important, aligned and coordinated programs: The Public Health Emergency Preparedness Program administered by the CDC and the Hospital Preparedness Program administered by the HHS Assistant Secretary for Preparedness and Response. These two programs are the bedrock for state and local public health preparedness and response providing essential cooperative agreement funding as well as guidance and technical assistance. They not only enable jurisdictions to plan, train and exercise, but also to purchase laboratory and communications equipment, medical countermeasures, and personal protective equipment for first responders. More importantly, it allows public health departments to hire and

retain a skilled workforce and to make a long-term investment in "people" such as epidemiologists, laboratory technicians, nurses, environmental health specialists and other subject matter experts. It is the people, their networks, expertise, and relationships built on trust that are truly the safety net.

Eighty-one percent of Tennessee's Public Health Emergency Preparedness (PHEP) program award goes to personnel costs. I realize this is not an appropriations Committee hearing today but I would be remiss if I did not mention that the aforementioned funding is essential, but not sufficient. The primary source for state and local public health preparedness has been cut by about one-third (from $940 million in 2002 to $667 million in 2017) and hospital emergency preparedness funds have been cut in half ($514 million in 2003 to $254 million in 2017). These reductions have degraded the safety net and our resiliency as a nation in the face of these ongoing and increasing threats. This is a high value investment in the health, safety, and security of our homeland, and returning to these earlier levels of funding is a relatively small investment that could reap billions of dollars in savings given the potentially high cost it could take to respond to an unmitigated disaster or pandemic. Having the resources to get it right rapidly at the local level is far more effective and less costly than a poorly coordinated response that would require Federal intervention. As you consider PAHPA reauthorization, funding authorization levels for both PHEP and HPP must line up with resource demands of today and into the future to sufficiently handle the ever-expanding threat environment and to give our frontline of defense and safety net the ability, the scale and the speed it needs to protect the public's health. It is important to understand that public health emergency preparedness and response infrastructure is people. One can think of it in terms of three tiers of public health responders: (1) Emergency preparedness professionals, (2) those who have deep emergency preparedness training but whose daily duties are more in line with traditional public health work, and (3) all other public health professionals like public health nurses who stand ready to assist when needed. Each of these tiers, while they may have differing levels of direct involvement in responding to threats, are all essential to enabling a fully functional net and all must work together when needs arise to support each other.

Using just two examples in my own State of Tennessee, a strong public health response was crucial in saving lives during the 2016 wild fires in Sevier County that impacted the beautiful town of Gatlinburg. In addition to staffing shelters, providing vaccines and care, tracking down and accounting for missing persons, providing for the decedents, assuring food safety, testing water, staffing of local, regional, and state emergency operations centers around the clock, the Tennessee Department of Health (TDH) trailers served as the communications hub for multiple other agencies including the hospital, EMS, and 911 system. We were all part of the same team, and having the proper resources deployed at the right place and time saved lives and property.

During the fungal meningitis outbreak of 2012 that led to 751 cases across 20 states, with 64 total deaths nationwide, the TDH leveraged a PHEP-funded communication system called the Tennessee Countermeasure Response Network to integrate public health in this unprecedented response that included public health and healthcare sectors. It was Tennessee's leadership that pinpointed the source of the outbreak and helped to identify patients at risk. Relationships and trust built between TDH and Tennessee healthcare providers and other public health agencies and, most critically, the relationships between public health nurses and the victims of this terrible event themselves, enabled a swift and coordinated response. The outbreak response was concluded in 4 months (though the suffering of the victims in some cases continues), and the rapid identification and response eliminated further exposure and cases.

These incidents could have been far worse if it were not for the preparedness efforts of the public health and medical systems. Similarly, I am confident that my colleagues like Dr. John Wiesman in Washington State when responding to the tragic train derailment last December or Danny Staley in North Carolina recently responding to extreme winter weather, do not want to know how their experiences could have evolved without the critical support from the Federal Government for public health preparedness efforts. Each of these examples, and I can certainly provide you with many more, demonstrates a return on the investment. That being said, we must also remember that the system built on passionate, compassionate public health professionals can degrade quickly if not maintained and the investment continually renewed.

In closing, allow me to reemphasize the point that the Pandemic and All Hazards Preparedness Act (PAHPA) is the mechanism that undergirds the Federal, state, and local governments in these efforts. It is an extremely important and proven piece of legislation that is responsible for transforming public health preparedness

over what is approaching two decades and is paramount as it pertains to our ability to protect the public's health from a constant, challenging, and changing threat landscape. Congress, and especially this Committee, should be applauded for its continued work on laws like PAHPA that give states, territories, localities, and tribes the resources and tools needed to get the job done. These funds are not duplicative of emergency management and Homeland Security, but complementary and essential.

As you consider suggestions for the refinement and enhancement of PAHPA, I respectfully submit the following principles to consider:

- Preparedness Programs should be nationwide and extreme care should be given not to change the funding formula or criteria that would result in reduced or eliminated funding to jurisdictions thus compromising their preparedness and response capacity and capability; all states and localities need their neighbors to be as strong as they are,
- I mentioned previously Preparedness Programs should be authorized at sufficient funding levels to strengthen and maintain support for public health infrastructure and workforce; to retain this highly trained and effective workforce, they need to have some reasonable certainty regarding continuity in the Nation's need and wish for their professional activities; these people form the core of the safety net,
- We need a viable Immediate Response Fund allowing for the timely infusion of additional resources to support surge when existing capacity is or will soon be exceeded. This principle is well understood and used routinely by other first responders dealing with natural disasters. A current fund already exists but is not truly funded. The practice community would gladly work with the Committee and others to identify those "triggers and guardrails" to be expressed in statute possibly through this reauthorization cycle that will give Congress the necessary comfort and confidence of stewardship to then appropriate reasonable and necessary funds for future use, and
- Strengthen the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) strategy and implementation plan process to require coordination with state and local entities to ensure the products being developed reach the end users in a timely and well-coordinated manner.

Thank you again for your attention today and for caring deeply about our Nation's emergency preparedness, response, and recovery system for today and tomorrow.

Senator BURR. Thank you, John.

Brent, the floor is yours.

STATEMENT OF BRENT MACGREGOR, SENIOR VICE PRESIDENT, COMMERCIAL OPERATIONS, SEQIRUS; CO-CHAIR, ALLIANCE FOR BIOSECURITY, SUMMIT, NJ

Mr. MACGREGOR. Good morning, Senator Burr, Senator Casey, and Members of the Committee.

My name is Brent MacGregor and I am the Senior Vice President of Commercial Operations for Seqirus.

I appreciate the opportunity to appear before you today as you prepare to consider the second reauthorization of the Pandemic and All-Hazards Preparedness Act.

I would like to focus my remarks on the importance of preparedness against pandemic influenza and the critical role played by the Biomedical Advanced Research and Development Authority, BARDA, and its industry partners.

There are three issues that I would like to highlight from my written testimony.

First, that pandemic influenza is one of the most urgent public health threats we face as a Nation and must be a priority of HHS's biodefense enterprise.

Second, BARDA's pandemic influenza program must finally be authorized in this year's PAHPA legislation.

Third, that Congress must provide sustained, and predictable, MCM funding to strengthen partnerships with the private sector and ensure our Nation's preparedness.

Now, regarding my first point, preparing against pandemic influenza, this is critical to our national and economic security. Seqirus is proud of the partnership we have with BARDA to supply one-third of the Nation's vaccine needs when the next pandemic strikes.

Thanks to the leadership of Senator Burr and Senator Casey, and Members of this Committee, and the dedicated team at BARDA, our state-of-the-art vaccine production facility in Holly Springs, North Carolina is one of the best examples of a successful public-private partnership in biodefense.

Second, regarding BARDA's pandemic influenza program, despite representing the "P" in PAHPA, authorized funding for pandemic influenza has never been included in the legislation. As a result, funding for critical BARDA activities, such as vaccine stockpiling, advanced research and development, has been largely episodic since 2009. Emergency supplemental funds provided during the 2005 and the 2009 pandemics are now fully exhausted.

Having a program authorized by Congress will provide a clear signal to the private sector that the U.S. Government is committed to preparing against pandemic threats in the future.

BARDA's most recent 5-year budget outlined $630 million in pandemic influenza funding needs for Fiscal Year 2019 alone. We believe an annual authorization level of at least $535 million is needed to support HHS's most critical pandemic influenza activities.

Finally, regarding sustained and predictable MCM funding, over the last 12 years, this enterprise has greatly improved our Nation's security. And while BARDA has improved its communication with industry partners, better reporting from the Government could provide more end to end certainty in the MCM development process.

Procurement funding provided by the Project BioShield Special Reserve Fund, the Strategic National Stockpile, and BARDA's pandemic influenza program provides manufacturers in the market certainty after investing for many years in R&D.

Because there is no commercial market for MCM's, companies like Seqirus can only rely on the commitments provided by HHS to make investments in MCM research. Unfortunately, over the last several years, the private sector has become more skeptical of the Government's commitment to biodefense. The lack of multiyear funding for the SRF has created uncertainty in the long term sustainability of MSM programs. Public-private partnerships must be sustained over time through a demonstrated commitment by the Federal Government.

There are dozens of companies, both large and small, that have committed to BARDA's mission and made significant new investments in MCM development. Reauthorization of PAHPA's authorities and a renewed commitment to MCM funding will ensure these investments yield even more FDA approved medical countermeasures.

Seqirus strongly supports the PAHPA reauthorization priorities identified by the Alliance for Biosecurity, to which I am privileged

to be a co-chair, and by the Biotechnology Innovation Organization, or BIO.

I would like to thank Members of this Committee, and in particular, Senator Burr, for their commitment to reauthorizing PAHPA in a timely manner. Seqirus believes tremendous progress has been made to ensure Americans are better protected against the threat of pandemic influenza, and we are excited about the future of our partnership with BARDA.

We strongly encourage the Committee to formally authorize BARDA's pandemic influenza program. This is a critical opportunity for Congress to ensure BARDA has the resources it needs to prepare against one of the most predictable threats we face as a Nation.

I look forward to serving as a resource for this Committee during the PAHPA reauthorization process.

I am happy to answer any questions you may have, and I thank you for inviting me here today.

[The prepared statement of Mr. MacGregor follows:]

PREPARED STATEMENT OF BRENT MACGREGOR

Good morning Mr. Chairman, Ranking Member Murray, and Members of the Committee. My name is Brent MacGregor and I am the Senior Vice President of Commercial Operations for Seqirus. I appreciate the opportunity to appear before you today as you prepare to consider the second reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA). I would like to focus my remarks on the importance of preparedness against pandemic influenza and the critical role played by the Biomedical Advanced Research and Development Authority (BARDA) and its industry partners.

Seqirus is a global leader in the development and manufacturing of influenza vaccines. With extensive research and production expertise and facilities in the U.S., U.K. and Australia, Seqirus is a committed partner in pandemic preparedness and a major contributor to the prevention and control of influenza globally. Seqirus' influenza vaccine business comprises a workforce of over 3,000 employees, significant manufacturing capacity, a commercial presence in 20 countries, and product and geographic diversity. We are the only influenza vaccines manufacturer with the flexibility of two scaled up production technologies, including, cell-based vaccines.

Our long-established parent company, CSL Limited, has a rich heritage in influenza dating back to the Spanish flu pandemic. As you may know, this year marks the 100th anniversary of the 1918 pandemic, which killed more than 50 million people and represents one of the deadliest natural disasters in human history. It is especially timely for this Committee to be considering how the U.S. can be better prepared against pandemic influenza in the future.

I would like to highlight Seqirus' state-of-the-art vaccine production facility in Holly Springs, North Carolina. Thanks to the leadership of Senator Burr, Members of this Committee, and the dedicated team at BARDA, we believe the Holly Springs facility is one of the best examples of a public-private partnership envisioned by the authors of PAHPA when it was originally signed into law in 2006.

I would also like to highlight Seqirus' proprietary adjuvant MF59 which boosts response, and broadens vaccine match as well as enabling dose-sparing of vaccine antigen. MF59 is a cornerstone of broader access to pandemic influenza vaccines and part of BARDA's pandemic preparedness and response stockpiling strategy. We believe it is critical to manage MF59 as a long term asset within the pandemic preparedness enterprise which means that it needs a life cycle management strategy consistent with industry standards.

We are currently working with BARDA to manufacture candidate vaccines against the H7N9 strain circulating in China. Last week, testifying before this committee, the Assistant Secretary for Preparedness and Response, Dr. Kadlec, highlighted his concern with the ominous trends that they are seeing with the evolution of the H7N9 strain.

Seqirus believes it is critical that PAHPA be reauthorized in a timely manner to ensure BARDA has the resources it needs to continue its unique national security mission at the Department of Health and Human Services (HHS). We also strongly believe that the Committee's reauthorization of PAHPA should finally include an

authorization of BARDA's pandemic influenza program. Despite representing the "P" in PAHPA, authorized funding for pandemic influenza preparedness has never been included this legislation.

Similar to medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) threats, there is no commercial market for pandemic influenza vaccines. Seqirus relies on our partnership with the U.S. Government to make continued investments in research, development, infrastructure, and vaccine production. Authorizing BARDA's pandemic influenza program and providing robust, sustained annual funding for the program would send a clear signal to the private sector that the United States is committed to preparedness against pandemic influenza.

Seqirus also supports the PAHPA reauthorization priorities identified by the Alliance for Biosecurity, to which I am privileged to be a Co-Chair, and by the Biotechnology Innovation Organization (BIO). These priorities include multi-year funding for the Project BioShield Special Reserve Fund (SRF) and increased funding for BARDA's advanced research and development programs, including for emerging infectious diseases and antibiotics. Finally, I would like to thank the members of this committee for all the work they have done to support HHS' preparedness enterprise since the last PAHPA reauthorization, including making important changes to BARDA's contracting process in last year's 21st Century Cures Act.

PAHPA has been a success since it was first passed by Congress in 2006. The biodefense enterprise created at HHS over the last 12 years has greatly improved our Nation's security. From the perspective of a manufacturer, this enterprise has made it more attractive to invest in partnerships with the U.S. Government. However, there are areas where the medical countermeasure (MCM) enterprise could be improved.

At the beginning of this process, industry partners with the National Institutes of Health (NIH) to conduct basic research and discovery. These public and private investments often yield promising MCM candidates which can progress to advanced development with BARDA. While BARDA has improved its communication with industry partners to ensure smooth transitions, better coordination and communication within the government could improve the ability to provide end-to-end certainty to government partners. In recent years, BARDA has focused on the promise of platform technologies which can speed up development timelines and provide rapid response capabilities in an outbreak.

Because there is no commercial market for MCMs, the procurement funding provided by the Project BioShield Special Reserve Fund (SRF), the Strategic National Stockpile (SNS) and BARDA's pandemic influenza program provides manufacturers with market certainty after investing for many years in research and development. However, the lack of multi-year funding has created uncertainty in the long term sustainability of some medical countermeasures programs. And importantly, the Food and Drug Administration's (FDA) dedication to addressing the unique challenges of MCM development has given companies confidence that MCM candidates can ultimately gain licensure. FDA approval is an important milestone for companies and a key public health goal for the government.

Of course, this process is not perfect and can certainly be improved. The overall structure created by PAHPA has enabled dynamic public-private partnerships to thrive, but these partnerships must be sustained over time through a demonstrated commitment by the Federal Government.

Seqirus is just one example of how a partnership with BARDA could be successful in the pandemic influenza space. There are dozens of other companies—both large and small—that have committed to BARDA's mission and made significant new investments in MCM development. Reauthorization of PAHPA's authorities and a renewed commitment to MCM development funding will ensure these investments yield even more approved MCMs.

The Threat of Pandemic Influenza

As Members of this Committee know well, one of the most urgent public health threats we face as a nation is pandemic influenza, a constantly changing global viral threat. It is often forgotten that the 2009 H1N1 pandemic, a relatively mild pandemic, killed more than 12,000 Americans and hospitalized 300,000 more. The cost to our citizens, our economy, and our security was incredibly high. It is not a matter of if, but when, the next pandemic strikes.

Pandemic influenza is not just a public health threat; it is indeed a national security threat. Ensuring we are prepared to respond to an influenza pandemic is critical to our national and economic security. The World Bank has estimated that a severe global influenza pandemic could cost nearly 5 percent of global GDP.

To be ready when a pandemic is declared, we have to invest in R&D for new and better influenza vaccines, to invest in, and sustain, the manufacturing surge capacity to rapidly produce more than 600 million doses of matched virus—two for every American, and we have to maintain stockpiles of vaccine against circulating pre-pandemic strains so we can protect first responders and essential personnel during the time it takes to manufacture matched vaccine.

Pandemic influenza is related to seasonal influenza, but is also different in many significant ways. Most importantly, new pandemic influenza strains show up across the globe in real-time, emerging from animal to human transmission of strains new to our immune system. Because there is no commercial market to develop vaccines against these new pandemic strains, the U.S. Government must work with private sector partners to ensure vaccines against these strains are available if an outbreak occurs. This process of developing pandemic influenza vaccines requires a robust partnership between the government and the private sector. We are proud of our decade-long partnership with BARDA to ensure the United States is prepared to respond to a pandemic influenza outbreak.

Unfortunately, funding for preparedness against pandemic influenza threats has been episodic since 2009. The vast majority of funding provided to the Department of Health and Human Services (HHS) for pandemic influenza was in emergency supplemental legislation during the 2004, 2005, and 2009 outbreaks. These emergency funds helped stand up critical response efforts at HHS, but are now fully exhausted. Since that time, annual funding for HHS' pandemic influenza readiness programs have dramatically declined. It is critical that our domestic influenza manufacturing capabilities are strengthened and sustained, and private sector partners see a renewed commitment from Congress and HHS.

Seqirus' Pandemic Influenza Partnership With BARDA

In 2007, BARDA partnered with Seqirus (then Novartis) in the construction of a new influenza vaccine manufacturing facility in Holly Springs, North Carolina. Seqirus currently has several contracts with HHS to (1) complete advance stage development of antigen-sparing capability for pandemic influenza vaccination; (2) facilitate domestic vaccine capability with more rapid response and with greater surge capacity in the event of an influenza pandemic; (3) stockpile pandemic vaccine supplies; and (4) develop a synthetic influenza seed process for rapid pandemic response.

The Holly Springs facility will quickly surge domestic production capacity of pandemic influenza vaccine to combat public health emergencies. The facility has been designed to provide pandemic vaccines to protect one third of the US population, within 6 months of the declaration of a pandemic.

The facility employs approximately 500 high-skilled workers to produce both pandemic and seasonal influenza vaccines using innovative cell culture-based manufacturing technologies. We believe Holly Springs is one of the most successful public-private partnerships between industry and BARDA. The total investment in the facility committed by both Seqirus and BARDA has now surpassed $1 billion. The innovations developed at Holly Springs—like new, cell-based flu vaccines—are critical to improving U.S. preparedness.

Seqirus is a Leader in the Development of Innovative, Cell-Based Vaccines Technologies

How well flu vaccines work can vary from season to season. One of the main factors that impact flu vaccine effectiveness is the "match" between the viruses that the flu vaccine is designed to protect against, and the flu viruses spreading in the community.

How closely the vaccine is "matched" to circulating strains can be impacted by changes in the circulating viruses between the time the influenza vaccine was manufactured and the public is vaccinated, as well as changes that can take place in the influenza vaccine production process.

The majority of currently available influenza vaccines globally are manufactured using egg-based technology, and work reasonably well. However, the viruses used by manufacturers to start the production process can undergo changes when optimized for growth in eggs. When this occurs, the resulting vaccine may not be as closely matched to the circulating virus as would be preferred, which can reduce the level of protection against influenza infection.

The influenza vaccine industry is pursuing several new technologies to improve vaccine effectiveness. One of the new technologies used by Seqirus is a cell-based influenza vaccine manufactured in the United States. Cell-based influenza vaccines are not subject to egg-adaptation issues, and may therefore be more closely matched

to circulating viruses. We believe the use of cell-based influenza vaccines in future flu seasons and flu pandemics has the potential to significantly improve vaccine effectiveness, and as a result, save more lives.

PAHPA Reauthorization Must Include BARDA's Pandemic Influenza Program

Over the last 13 years, Congress has passed three separate emergency supplemental bills providing $13.2 billion in funding to respond to the threat of pandemic influenza. This funding sustained HHS programs to develop and purchase flu vaccines, antivirals, and necessary medical supplies. The funding also supported the construction and renovation of manufacturing facilities for the production of pandemic influenza vaccines to secure sufficient supplies for the U.S. population.

For more than a decade, HHS has relied on and drawn down balances from supplemental appropriations bills to fund pandemic preparedness. These balances are now exhausted. Since the passage of these three emergency supplemental bills, sustained resources for HHS' pandemic flu readiness programs have dramatically declined. This has led to an aging stockpile that doesn't match currently circulating strains, critical adjuvants such as our MF59 that are expired, domestic manufacturing capabilities that must be sustained, and private sector partners who aren't sure if HHS is committed to this partnership that is so critical to the Nation's readiness.

In order to successfully prepare against a future influenza pandemic, Seqirus believes Congress should finally enact a permanent authorization of BARDA's pandemic influenza program in the reauthorization of PAHPA. This authorization is necessary to support research and development of new influenza technologies, regularly test and evaluate rapid response capabilities for known and new pandemic threats, and maintain influenza stockpiles of vaccine and therapies. Having a program authorized by Congress will also provide a clear signal to the private sector that the U.S. Government is committed to preparing against pandemic threats.

BARDA's most recent 5-year budget outlined $630 million in pandemic influenza funding needs for Fiscal Year 2019 alone. We believe an annual authorization level of at least $535 million is needed to support HHS' most critical pandemic influenza activities. These activities include pandemic vaccine stockpile maintenance, diagnostic research, infrastructure improvements, universal flu vaccines research, and flu therapeutic research.

Conclusion

We believe tremendous progress has been made to ensure Americans are better protected against the threat of pandemic influenza, and Seqirus is excited about the future of our partnership with BARDA.

I would like to thank Members of this Committee, and in particular Senator Burr, for their commitment to reauthorizing PAHPA in a timely manner. This is a critical opportunity for Congress to ensure BARDA has the resources it needs to prepare against of the most predictable threats we face as a Nation.

I look forward to serving as a resource for this Committee during the PAHPA reauthorization process, and I am happy to answer any questions you may have today. Thank you.

Senator BURR. Brent, thank you for that testimony.

Steven, the floor is yours.

STATEMENT OF STEVEN KRUG, M.D., FAAP, HEAD, PEDIATRIC EMERGENCY MEDICINE, ANN AND ROBERT H. LURIE CHILDREN'S HOSPITAL OF CHICAGO; PROFESSOR OF PEDIATRICS, NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE; CHAIR, DISASTER PREPAREDNESS ADVISORY COUNCIL, AMERICAN ACADEMY OF PEDIATRICS, CHICAGO, IL

Dr. KRUG. Good morning, Chairman Burr, Ranking Member Casey, distinguished Members and staff of the HELP Committee.

I am Dr. Steve Krug. I am the Head of the Division of Emergency Medicine at the Ann and Robert H. Lurie Children's Hos-

pital, Chicago and Professor of Pediatrics at the Northwestern University Feinberg School of Medicine. I am the Chair of the American Academy of Pediatrics Disaster Preparedness Advisory Council. And on behalf of the 66,000 Members of the AAP, thank you for holding today's hearing and for inviting me.

I have also been privileged to serve on Federal Advisory Committees and presently as the Chair of the HSS National Biodefense Science Board, now known as the NPRSB. My comments today, however, are as a private citizen and as a member and leader within the Academy.

I applaud the work of this Committee for strengthen and improving our Nation's public health and medical preparedness with the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. In particular, I must thank you for the first-ever provisions for children in the last reauthorization. Those changes have helped to make the needs of children a much higher priority in emergency planning and response.

As we heard last week from ASPR, CDC, and FDA leadership, each agency has a vital and distinct role to play in ensuring that our healthcare system is better prepared to meet the needs of all Americans including, of course, children during and after a disaster.

The leaders of these Federal agencies—and the countless hardworking, dedicated Federal employees that they oversee—really are the backbone of our Nation's 24/7 Federal emergency readiness and response capacity.

By most accounts, the frequency, severity, and cost of disasters and emergencies are increasing, meaning that they will remain a significant threat to the health and safety of our communities and our Nation.

As such, maintaining and expanding the Federal Government's strategic focus on all hazard approaches that address both routine and health security related needs is critical. This will require continuing engagement of all stakeholders including public health, medical and mental health services, academia, industry, and day to day emergency and trauma services.

Foundational elements core to preparedness, including the HRSA Medical Emergency Services for Children program and our Nation's children's hospitals, must also be strong and engaged.

It is evident that healthcare, and other systems that are regularly tested, will be the most reliable and effective during a response. Regular exercises and drills, along with continuing education for care providers and first responders, are necessary in order to be ready for all populations when a disaster strikes. This is especially important if we hope to be ready to meet the unique needs of children.

At a population level, we should strive for a healthier and more resilient community pre-disaster as this will reduce the burden on the healthcare system during and after disasters. This means ensuring access to affordable healthcare and preventative services, and reducing healthcare disparities in all populations.

Financial drivers in today's healthcare environment are not aligned with the need for facilities to be prepared for public health emergencies. Cost reduction measures have resulted in a leaner

stockpile of supplies, medications, and equipment and a substantially smaller workforce with daily operations, particularly inpatient operations functioning much closer to full capacity.

This has promoted emergency department overcrowding, that is where I work, and poor surge capacity during seasonal epidemics and pandemics, like the one we are going through right now. The surge capacity gap is particularly precarious within pediatrics.

Current disaster planning does not adequately integrate primary care. These clinicians, who largely operate as small, private sector businesses, provide vital services before, during, and then after disasters. In the absence of mechanisms to provide assistance to impacted providers and disrupted practices, many have been forced to leave.

Given this, it is not hard to see why so many communities have struggled to respond and why so many never fully recover after a disaster. Community resilience relies heavily upon the resilience of the healthcare sector. It is a key pillar.

Children account for 25 percent of the population and their unique vulnerabilities mean that preparedness and response activities at all levels must account for their needs. Children are not little adults.

I concur with the comments of my esteemed colleagues here, but I would offer three additional thoughts in terms of recommendations.

First, reauthorize and strengthen the HHS National Advisory Committee on Children and Disasters with subject matter experts from the public and private sector, the NACCD has provided insightful reports with cogent recommendations to improve healthcare preparedness for children.

Two, authorize the CDC Children's Preparedness Unit, which 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. This unit is a best practice example of an effective public and private sector partnership that has brought tremendous value to preparedness.

Finally, to reiterate comments that have been made already, let us maintain the HPP and PHEP grant programs as distinct, nationwide programs with strong pediatric performance measures, and with increased funding.

As disasters and universal risks, such as influenza, can occur anywhere in the Nation, it is essential that all jurisdictions have a baseline level of preparedness aided by each of these programs.

I want to thank the Committee for the opportunity to testify and I look forward to your questions.

[The prepared statement of Dr. Krug follows:]

PREPARED STATEMENT OF STEVEN E. KRUG

Chairman Alexander and Ranking Member Murray, thank you for the opportunity to speak here today about our Nation's preparedness and response capabilities. My name is Dr. Steven Krug. I am head of the Division of Emergency Medicine at Ann & Robert H. Lurie Children's Hospital of Chicago and Professor of Pediatrics at Northwestern University Feinberg School of Medicine in Chicago, IL. I am board certified in Pediatrics and Pediatric Emergency Medicine. I am here today in an official capacity representing the American Academy of Pediatrics where I serve as chair of its Disaster Preparedness Advisory Council. The American Academy of Pediatrics (AAP) is a non-profit professional membership organization of 66,000 pri-

mary care pediatricians and medical and surgical pediatric subspecialists dedicated to health and well-being of children.

By way of additional background, I also serve as chair of the Assistant Secretary for Preparedness and Response (ASPR) National Biodefense Science Board, now referred to as the National Preparedness and Response Science Board (NPRSB). Additionally, I am a member of the Food and Drug Administration's Pediatric Advisory Committee Ethics Subcommittee. I am not representing either of these entities here today.

I applaud the work of this committee for strengthening and improving our Nation's public health and medical preparedness with the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013. In particular, AAP thanks the leadership of Members of this Committee for including first-ever provisions for children in the last reauthorization. Those changes have helped to make the needs of children in emergency planning and response a higher priority in our Federal agencies.

As we heard last week from Drs. Bob Kadlec, Stephen Redd, and Scott Gottlieb, each of our key Federal health care agencies—ASPR, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA)—has an important and distinct role to play in ensuring our public health and medical sectors are better prepared to meet the needs of all Americans, including, of course, children before, during, and after a disaster. The leaders of these Federal agencies, present and past, and the countless hard-working, dedicated Federal employees they oversee serve as the backbone of our Nation's 24/7 emergency readiness and response capacity and deserve much credit for their work on behalf of all Americans. AAP values its close partnership with these Federal agencies and others and we look forward to continuing to work collaboratively with them.

By most accounts, the frequency, severity, and cost of disasters and emergencies are increasing, meaning they will remain a significant threat to the health and safety of communities and our Nation. As such, maintaining and expanding the Federal Government's strategic focus on multi-and all-hazard approaches that address both routine and health security related needs is critical. This means continuing to engage all stakeholders, including public health, medical, mental and behavioral health services, academia, industry, and day-to-day emergency medical and trauma services in strengthening "foundational" programs core to preparedness.[1] Emergency Medical Services (EMS), trauma and burn centers, and our Nation's children's hospitals must be strong and engaged.

Healthcare systems that are regularly tested may be the most effective and reliable in a response. In a sense, the concepts of preparedness and response are actually interchangeable. The Centers for Medicare and Medicaid Services (CMS) Emergency Preparedness Rule which sets national emergency preparedness requirements for Medicare and Medicaid-participating providers and suppliers is critically important for ensuring adequate planning for both natural and man-made disasters, and coordination with Federal, state, tribal, regional, and local emergency preparedness systems. However, investments in preparedness, maintenance of a stable workforce, and sustainment of core response capabilities can be challenging. Major reductions in Federal spending on public health and medical preparedness as well as intermittent surges around specific disasters or spikes in seasonal influenza like we are currently experiencing combine to adversely impact the preparedness of the Nation.

Physician and health care professional workforce burnout and inability to practice self-care in the face of a disaster, one in which health care providers and their families may have personally experienced injury or loss, must be addressed as part of medical preparedness and response.

At a population level, we should strive for healthier communities pre-disaster which will reduce the burden on the health care system during and after a disaster. This means ensuring access to affordable medical and mental or behavioral health care and preventive services and reducing or eliminating health care disparities in all populations.

Ensuring the Health of Children in Disasters

Children account for twenty-five percent of the population and their unique vulnerabilities mean that preparedness and response activities should account for their distinct needs. Children are not little adults and the factors a state, city, hospital, or community must consider when planning for children may differ when con-

[1] National Preparedness and Response Science Board. ASPR Future Strategies Report. March 30, 2015. *http://www.phe.gov/Preparedness/legal/boards/nprsb/recommendations/Documents/aspr-fswg-report03162015.pdf*

sidering the care needs of infants versus preschool-aged children versus adolescents. Additionally, children spend much of their day separated from their parents at school or in child care, making issues of preparedness planning in these settings, including training exercises and drills, mechanisms for child tracking and timely family reunification, and, consent for treatment, if needed, particularly important.

At the Federal level, AAP remains concerned about the appropriateness of the current statutory definition of and references to "at-risk individuals" throughout PAHPA. According to ASPR, at-risk individuals are children, older adults, pregnant women, and individuals who may need additional response assistance. This includes but is not limited to individuals with disabilities, individuals who live in institutional settings, individuals from diverse cultures, individuals who have limited English proficiency or are non-English speaking, individuals who are transportation disadvantaged, individuals experiencing homelessness, individuals who have chronic medical disorders, and individuals who have pharmacological dependency. By some estimates, this could amount to fifty percent of the total population.

The expertise needed to successfully plan for and respond to a public health emergency involving a person with a pharmacological dependency is very different from that of a child or of a pregnant woman. Given the discretion allowed under current requirements for states and cities in the CDC's Public Health Emergency Preparedness Program (PHEP), a jurisdiction can "check the box" by including one of these categories in disaster drills and exercises. In fact, in a PHEP Impact Assessment conducted in 2014, of the select PHEP capabilities reported on, the two poorest performing measures were those that directly related to children: Did the grantee have a sufficient plan for vulnerable populations (55 percent) and did the grantee have patient tracking capability for family reunification (47 percent). By contrast, all other measures were met 73 to 100 percent of the time.

AAP would urge Federal agencies including ASPR to move away from generic terms like "at risk" or "vulnerable" populations. When agencies or grantees are forced to address this broad category, the subpopulations contained within may be overlooked. We would suggest that ASPR consider creating a position of Director of Pediatric Preparedness and Response who is empowered and adequately resourced to work within ASPR, with its grantees, and with HHS partner agencies to improve our Nation's preparedness and response for children.

Healthcare System Preparedness, Response, Recovery, and Resilience

At baseline, our health care delivery system is fragile, decentralized, frequently uncoordinated, and regional. Financial drivers in the health care system are not aligned with the need for facilities to be prepared for emergencies and surges in the number and acuity of patients seeking care. Cost-reduction efforts within health care systems have led to skilled staffing shortages and leaner stockpiles of routine supplies, medications, and key equipment. This environment has caused hospital inpatient facilities to operate much closer to full capacity and emergency department overcrowding, driven largely by inadequate inpatient capacity, leads to poor surge capacity. So, when disasters occur, it's not hard to see why many communities struggle to respond and why some may never recover.

Changes to the economic environment are creating serious challenges for scientific research and innovation and are reducing public health system stability. In addition, the health care sector is in a State of rapid change, with adaptations underway to health care delivery models, health care systems, and health care financing. In this State of rapid change and uncertainty, with decreasing funds and increasing fiscal pressures, economic or service delivery disengagement by public and private sector safety net providers and other partners critical to health security (e.g., health departments, hospitals, academic medical centers, biotechnology and pharmaceutical industries) is reported from the field. In addition to the effect of economic change on individual sectors, these same stressors have the potential to further harm relationships among the various components of the larger system including Federal-state-local-private sector interactions. These relationships are critical to an effective response. [2]

With respect to children, the majority of ill and injured children seek care at the closest emergency department in their community. Eighty-nine percent of children in the emergency care system are seen in non-children's hospitals. [3] It is critical that all EDs have the appropriate resources and staff to provide effective emergency care for children but many see few pediatric patients per day—roughly 50 percent of U.S.

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[2] Ibid.

[3] Emergency Medical Services for Children National Resource Center. National Pediatric Readiness Project. Available: *http://pediatricreadiness.org/About—PRP/*

emergency departments provide care for fewer than ten children per day. On a nationwide level, AAP, along with the American College of Emergency Physicians, the Emergency Nurses Association, and other professional societies, issued guidelines on the care of children in the emergency department to aid all emergency departments in what to prioritize for children.

AAP thanks Senators Orrin Hatch and Bob Casey for their strong leadership on the Federal Emergency Medical Services for Children, or EMSC, Program, the only Federal program that focuses specifically on improving the pediatric components of the Emergency Medical Services (EMS) system. Under the leadership of the EMSC Program at the Health Resources and Services Administration, in partnership with several professional societies, we now have the National Pediatric Readiness Project, a multi-phase quality improvement initiative to ensure that all U.S. emergency departments have the essential guidelines and resources in place to provide effective emergency care to children.

Of the 4,146 emergency departments that participated in the 2013 National Pediatric Readiness assessment, the overall hospital Pediatric Readiness score was 69 percent but only 47 percent of participants responded that they have a disaster preparedness plan in place that addressed the unique needs of children.[4] The project found that the presence of a Physician and Nurse Pediatric Emergency Care Coordinator (PECC) was associated with a higher Pediatric Readiness score compared with no PECC. The potential for improving patient outcomes based on the findings of the National Pediatric Readiness Project is great. These findings also have important implications for the Hospital Preparedness Program (HPP) and ASPR's broader healthcare system preparedness efforts.

In order for the medical care system to respond, recover, and ultimately be resilient, preparedness planning must include not just public health and hospitals but also the primary care medical delivery system. While that system is largely in the private sector, it cannot be ignored. Primary care providers, such as pediatricians, are on the front lines of all emergencies. The administration of vaccines, provision of anticipatory guidance and appropriate screenings, and the counseling of patients and families are some of the vital functions of primary care, the continuity of which are all highly relevant to public health emergencies.

While the opportunity exists to improve further upon present disaster planning and response capabilities, we must also focus on recovery and the components of resiliency. Community resilience relies heavily upon the resilience the healthcare sector, a key pillar. As such, the Federal Government should support the ability of patients to return to their regular source of local medical care. After a disaster, medical offices and equipment are often damaged, and loss of power can lead to spoilage of vaccine doses. Lack of usable or safe office space and staff, housing, water, power, and telephone service have repeatedly hindered physician efforts in reestablishing practices. Further, local physicians may find themselves competing for patients with free or temporary clinics set up in the aftermath of the disaster. In the face of these circumstances, many physicians are forced to close their practices and leave the community. The Federal Government should develop formal incentives and assistance programs to provide systematic, long-term, financial stability to private physician practices after disaster strikes.[5,6] Collaboration between ASPR and the Centers for Medicare and Medicaid Services (CMS) is critical. As the Federal agency responsible for payment for medical services and for ensuring families affected by disasters seamlessly continue their insurance coverage under Medicaid and CHIP or become newly eligible for Medicaid or CHIP because of a disaster, CMS and ASPR must work closely together.

After an emergency, physicians are often eager to provide medical assistance to affected communities. While the National Disaster Medical System (NDMS) has an important role to play in our Nation's emergency medical response, it lacks the size and quantity of needed specialists to reach all communities that are or could be affected by disasters. AAP encourages ASPR to consider a more efficient infrastructure so that, in event of an emergency, physicians eager to provide volunteer medical services have a way to do so quickly.

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[4] Gausche-Hill, M., Ely, M., Schmuhl, P. A National Assessment of Pediatric Readiness of Emergency Departments. JAMA Pediatr .2015;169(6 :)527–534 .doi:10.1001/jamapediatrics.2015.138

[5] National Preparedness and Response Board. Assistant Secretary for Preparedness and Response (ASPR) Future Strategies Report.

[6] National Biodefense Science Board. Community Health Resilience Report.

Medical Countermeasures for Children

Significant strides have been made over the past ten to 15 years to develop medical countermeasures (MCMs) to address potential disaster hazards, including chemical, biological, radiologic, and nuclear threats.[7] Yet, major gaps still remain related to MCMs for children, a population highly vulnerable to the effects of exposure to such threats, because of their physiology and developmental differences from adults. Many vaccines and pharmaceuticals approved for use by adults as MCMs do not yet have pediatric formulations, dosing information, or safety information. As a result, the Nation's stockpiles and caches where pharmacotherapeutic and other MCMs are stored are less prepared to address the needs of children compared with those of adults in the event of a disaster.

Congress made important changes in the last PAHPA reauthorization to Emergency Use Authorizations (EUAs) that allow an EUA to be issued for preparedness purposes.

The Strategic National Stockpile (SNS) is currently underfunded to support the necessary stockpiling and replacement of MCMs as well as to support research, development, and procurement of pediatric MCMs. We must ensure that the SNS is adequately funded to meet these needs and that safety and dosing for children are considered.[8]

Recommendations for the Next Reauthorization of the Pandemic and All-Hazards Preparedness Act

- Reauthorize and Strengthen the HHS National Advisory Committee on Children and Disasters—AAP notes the important contributions of the HHS National Advisory Committee on Children and Disasters (NACCD) since this committee created it under PAHPRA in 2013. The NACCD contains numerous subject matter experts from the public and private sector. It has provided HHS with several thoughtful reports with recommendations for healthcare preparedness for children, surge capacity, strategies for human services and child-serving institutions, and a joint report with the NPRSB on youth leadership and resilience. AAP strongly supports the reauthorization of the NACCD and asks Congress to align the NACCD with the NPRSB by making it permanent and resourced. AAP has recommendations for additional areas of expertise that would be helpful to add to the NACCD such as mental or behavioral health, children and youth with special health care needs, schools and child care, trauma and critical care, among others. It is our hope that the ASPR will utilize the expertise of the NACCD and the NPRSB to enhance its preparedness and response efforts.
- Authorize the CDC Children's Preparedness Unit—AAP asks Congress to authorize the Children's Preparedness Unit (CPU) at CDC. 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. The CPU is an internal team of experts within CDC with a background in pediatrics, behavioral science, child psychology, epidemiology, biostatistics, health communications, and more that is providing leadership and technical assistance, training, and consultation with the CDC and to Federal, state, and local public health entities to improve preparedness and response for children including under the PHEP Program. Members of the CPU have been activated or utilized as part of a CDC emergency response and, as Dr. Redd noted to this committee, they leverage public-private partnerships to address gaps in emergency preparedness and response for children.
- Funding for Public Health and Medical System Preparedness and Response—HPP and PHEP are key to the foundational capabilities of healthcare and public health preparedness, respectively. These critically important Federal programs must be resourced at sufficient levels to ensure every community is prepared for disasters. HPP's highest level of appropriation was $515 million, yet the program has eroded to only $255 million, a vastly insufficient level given the task of preparing the healthcare system for a surge of patients, continuity of operations, and recovery. As Dr. Kadlec noted before the committee last week, we have a roughly $3.3 trillion health care system, so a Federal investment of only about $250 million is not realistic if we are to have a truly prepared and resilient health care system. AAP urges Congress to authorize HPP

[7] American Academy of Pediatrics DISASTER PREPAREDNESS ADVISORY COUNCIL. Medical Countermeasures for Children in Public Health Emergencies, Disasters, or Terrorism. Pediatrics, originally published online January 4, 2016; DOI: 10.1542/peds.2015–4273

[8] Ibid.

at a minimum of $474 million, the level authorized in the PAHPA legislation of 2006. PHEP, currently funded at $660 million, should be authorized at a minimum of $824 million, the level authorized in the 2006 PAHPA bill. Federal funding is crucial to maintaining state, local, and territorial public health preparedness capacity. Even small fluctuations in funding—such as the 2016 transfer of $44 million from PHEP for the Federal Zika response—have major impacts on workforce, training and readiness. [9]

We cannot let happen again what transpired during the Zika response where Federal agencies' ability to respond was hampered by delays in congressional action on emergency funding. A pre-approved standing fund for short-term scale-up of rapid, emergency response is necessary. Such a fund should be administered by the HHS Secretary and should supplement and not supplant existing, base public health and preparedness funds. Funding should not come at the expense of other health programs, either from discretionary health spending or by transfer. Such a fund should serve as an interim bridge between underlying capacity-building funds and emergency supplemental funds, if needed. While such a fund should have sufficient resources, it cannot be viewed as a substitute for future supplemental emergency funding.

- Public Health and Medical System Preparedness are Distinct and They Should Be nationwide with Strong Pediatric Considerations—Because disasters can happen anywhere in the country and universal risks such as influenza pandemics and mass shootings exist, it is essential that all jurisdictions have a baseline level of preparedness aided by the HPP and PHEP programs. Performance measures for both programs must include meaningful metrics that assess a jurisdiction's preparedness to identify and meet the needs of children. Given the important role pediatricians play in the response and long-term recovery and resilience of communities, pediatricians should be integrated into all health care coalitions to help serve as pediatric subject matter experts and to help integrate pediatric components into planning, including drills and exercises. While HPP and PHEP should continue to be aligned and coordinated, they must remain as separate, distinct programs. The two programs serve a different but complementary purpose: PHEP builds the capacity of state, local, and territorial health departments and laboratories to prevent, detect, and respond to emergencies, while HPP prepares the healthcare delivery system to provide essential care to patients by ensuring continuity of care during disasters. Both programs are needed to save lives and protect the public from emergency-related illnesses and injuries.
- Children with Special Healthcare Needs—The HHS emPOWER map allows every hospital, first responder, electric company, and community member to use the map to find the monthly total of Medicare beneficiaries with electricity-dependent equipment claims at the U.S. State, territory, county, and zip code level and turn on "real-time" natural hazard and NOAA severe weather tracking services to identify areas and populations that may be impacted and are at risk for prolonged power outages. This technology has the potential to save the lives of over 2.5 million Medicare beneficiaries who rely upon electricity-dependent medical and assistive equipment, such as ventilators and wheel chairs, and cardiac devices in our communities. However, emPOWER is currently limited to Medicare beneficiaries. AAP urges ASPR and HHS to conduct feasibility testing for piloting how emPOWER could be expanded to the Medicaid program so that millions of children and youth, including those with special health care needs can benefit from this technology.

Senator BURR. Dr. Krug, thank you.

As evidenced by the fact that I am not sure that we have had, in the past, a pediatrician before in PAHPA related hearings, it shows that we understand the need to get it right.

I might say it is probably one of the most challenging areas because it is hard to incorporate pediatrics in the cutting edge technologies that, on one side, we are pushing that that will always be a challenge to us and we need more subject matter experts to help us navigate through that.

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[9] *https://www.naccho.org/uploads/downloadable-resources/Impact-of-the-Redirection-of-PHEP-Funding-to-Support-Zika-Response.pdf*

I will recognize Members for up to 5 minutes starting with myself and move on a seniority basis.

Mr. MacGregor, Seqirus has worked for many years to make us better prepared in the event of an outbreak of pandemic flu. The facilities in Holly Springs, North Carolina are both a promise and a partnership between your company and the Federal Government that, if needed, we can flip a switch from the manufacturing of vaccines for seasonal flu to the manufacturing for pandemic flu.

What are the lessons learned from this partnership? And, how can we improve the partnership?

Mr. MACGREGOR. Thank you for the question.

I think the lessons we have learned thus far that the partnership has been a very good one since the very beginning. What has happened, really, in recent years is the commitment that has been made, and for which Seqirus and its predecessor companies have delivered, the funding has not kept up with what we believe is the threat going forward.

So whereas there was a period of time, and even though the funding for a pandemic flu, BioShield was not part of the original PAHPA legislation, there was emergency funds, supplemental funds that were provided for flu.

I think the big lesson we have learned since that time is as the funding has declined to very low levels, particularly since 2009, you start to question the commitment. And while we put a commitment forward, a partnership forward with BARDA, I think sometimes we feel that with the funding that is dedicated or earmarked for pandemic flu suggests that there is not a seriousness or as serious an interest taken to this particular threat going forward. I think that is one of the lessons we have learned.

I think communication, ongoing communication is another lesson we have taken. I think, for the most part, the communication between BARDA and our company, and BARDA and other companies that are in partnership with the Government, has been good, but there is always opportunity for improvement across the spectrum from NIAID all the way to the SNS.

It is not bad. There is still room for improvement there in harmonizing how it works across that entire spectrum.

Senator BURR. The jurisdictional lines were a little difficult at the beginning.

Mr. MACGREGOR. Yes.

Senator BURR. But I think we have gone through a lot of that.

I hope that my colleagues on this Committee will remember this year's flu season, the severity of it. We do not know yet, but as we get smarter at projecting what the threat is going to be, this is a great example that we are not smart enough to get it better than 32 percent right based upon the current numbers. And that we have got to look at technology that allows us to address seasonal flu in a way that encompasses all of the above options that might happen.

You mentioned BARDA. BARDA works to advance new and innovative technologies to better combat public health threats and has been extremely successful in advancing innovative approaches to the development of medical countermeasures such as platform technology.

What do you see as the greatest challenges to bringing these new, and innovative, technologies through the medical countermeasure pipeline?

Mr. MACGREGOR. Well, I think one example of what you mentioned, Senator Burr, is new and innovative platform technologies and the plant in Holly Springs is an example of this. This is cell-based technology in Holly Springs. It is not the more conventional egg-based which, I think, most people are aware.

The interaction with BARDA has been very strong in not only allowing us to continue to advance the effectiveness of cell-based technology—most recently through the partnership through efforts to improve the yields of cell-based technology that cannot only benefit in a pandemic setting—but actually will potentially benefit in a seasonal setting as well.

The benefit that ideally will come will not only be, hopefully, in vaccines coming sooner to market, but the other promise we hope with cell-based technology as an example of a platform—technology that is invested in by the Government—is that it offers the potential of providing a better match in the event of a mismatch season, as we are experiencing this year.

Senator BURR. Tom, let me turn to you, if I can.

Innovations and information technology have drastically improved our biosurveillance and situational awareness capabilities to monitor, detect, and identify public health threats in as timely a fashion as is possible. Though this potential exists, the Federal Government lags behind in its ability to leverage these technologies.

How can we improve the Federal programs to create a more cohesive and real time surveillance capability for public health threats? And just as an aside to that, do you believe that we use enough open source information outside of the mechanisms we have set up domestically and internationally?

Dr. INGLESBY. Sir, that is a very good question. People have been working on that for a long time.

There are many surveillance systems in the country right now that are aimed at that goal. They are not all brought together under one roof, which would be very difficult to do. I know it has been a goal of the Federal Government to try and consolidate and bring those systems together.

One of the things that we could do better is to get more information out of the healthcare system, to public health, during emergencies. We have a lot of advances in Electronic Health Records, but for the most part, public health agencies do not have any resources or analytics to be able to see what is going on in healthcare records around the country.

If we could do more to bridge that divide between public health and medicine, that is where a lot of the information, that is where the signals are going to come in during outbreaks from doctors and nurses seeing unusual things and feeding that information to public health, getting laboratory diagnostics, getting that information together.

I think closing that divide a little bit and also bringing together unusual sources of information like what is going on in the animal systems, combine that with human systems. Being able to trace

back foods when big food outbreaks arise; that is a very difficult challenge for us right now.

Senator BURR. We are much better at a lot of it than we were a number of years ago.

Dr. INGLESBY. Much better, but a lot of challenges.

Senator BURR. John is on the frontline and I feel confident that mechanisms are in place for that transmission of information. All we need is one breakdown.

It does make one wonder, in the overall scheme of things, why we are not layering on top of that a review of scripts written on a daily basis that gives us either confirmation of what we are hearing from the public health arena, or potentially a sign of an outbreak of something that we pick up in prescriptions that were administered the day before.

The unusual thing is that gives us great clarity as far as the geographical location of something all the way down the nine digit ZIP Code.

It seems like it is all of the above that we have to do.

Senator Casey.

Senator CASEY. Thank you, Senator Burr.

Dr. Inglesby and Dr. Dreyzehner, I will start with you.

Senator Burr talked about the flu this year. We are told that more than 17,700 cases of the flu have been confirmed just in Pennsylvania. Thirty-two people, including one child, have passed away because of that.

While this is a particularly bad flu season, it does not come close to what we would see on a much larger scale in an infectious disease emergency or, of course, a pandemic flu scenario. Our healthcare sector is already near capacity with this flu season. So we are woefully unprepared to respond to a mass casualty, biological event.

For both Dr. Inglesby and Dr. Dreyzehner, I would ask, how can we begin to prepare hospitals—let us just focus on hospitals—for a mass casualty, biological event?

I know that is a lot to bite off, but as best you can.

Dr. DREYZEHNER. Thank you for the question, Senator. I certainly welcome Dr. Inglesby's comments as well.

I think as has been said, fully funding PHEP and HPP to its prior levels would be hugely helpful. I think Dr. Krug made some really important points in terms of the financial incentives of the current system's just-in-time for supplies and for staffing. There is limited surge capacity and we are seeing that in Tennessee right now.

In fact, I had a call with our hospitals a couple of weeks ago. I have another call tomorrow. Some of the challenges that are——

This is a flu season that, I think, is more severe than we typically see. As, I think, Senator Burr pointed out, we do not know exactly what this will look like in comparison to other flu seasons.

I think one thing is true, we are reporting more. Many states are reporting all deaths. Our state is reporting child and pregnancy deaths. As Senator Alexander pointed out, we have already had several tragic preventable deaths.

As people hear about those things, there is a perception of greater severity. And when there is a perception of greater severity, people frequently visit places like emergency rooms.

One of the things we have been doing is messaging around, "If you are ill, you may need to call your healthcare provider, but you may not need to go to an emergency room." So all those kinds of things are a part of what we deal with in a flu season where there is a heightened awareness.

In terms of assuring that we are prepared, the amount of funding available to the HPP grant has been inadequate, really, for some time. And, I think as you pointed out in your comments, there is a need to bolster that.

I do not think it takes a great deal more, but certainly returning to earlier funding levels would be extremely helpful.

Senator CASEY. Dr. Inglesby.

Dr. INGLESBY. Yes, I would agree with everything he said.

I would add that, going back to the beginning of the hearing, the more that we can develop our flu vaccine technologies, universal flu vaccine being the ultimate goal, but modernization and rapid acceleration of the process being the interim goal, the less we will have sick people in hospitals. But in the meantime, we need a strong healthcare system preparedness program through HPP.

There could be other facets of that program, like having more regional centers, that could shoulder more responsibility in crises, take care of more contagious patients. We have a Level One trauma center system in the United States that works very well, but we do not have anything like that for infectious disease. That could be a model.

We have built biocontainment units in places around the country in response to Ebola, but most of those containment units can only take care of one, or two, or three patients at most. So if we want to try and raise the level of preparedness, we might think about creating some regional strength.

But at most hospitals, they are going to need to be able to take care of patients. They are going to need proficiency, personal protective equipment, and relationships with the other hospitals, and the public health agencies, and the surgery clinics, and the mediclinics where people are getting cared for in the community.

It is a network of care as opposed to only relying on the major, acute care hospitals and have to distribute that burden out to the community when there are major epidemics of flu or even pandemics of flu.

Senator CASEY. You mentioned, and I know I am going to be out of time in a moment, but I might come back to it after we have other questions.

But the Level One trauma center model, that is my word not yours, how do you think we incentivize that in the context of what, I think, in your testimony on Page 3, you refer to as, "specialized Disaster Resource Hospitals," another acronym, DRH?

I might ask you that question. I am out of time, but then I will come back later to Dr. Krug to add his comments on it.

Dr. INGLESBY. I think the way you would incentivize it is you could have some kind of competition for it, but you would have to provide resources for it because there is no, as we have said al-

ready here today, there is no "give" in the system. Hospitals are running very small margins, so they are not going to be able to build large entities or programs outside of the usual programs unless the Government says, "We want you to do this, and here is how."

Senator CASEY. Thanks very much.

Senator BURR. Senator Isakson.

Senator ISAKSON. Thank you, Chairman Burr.

Dr. Inglesby, you wrote of the national security agenda, the Global Health Security Agenda in your comments that was established in 2014.

Where is it housed today?

Dr. INGLESBY. It is in multiple agencies of Government, particularly the CDC and USAID.

Senator ISAKSON. Who is the quarterback for it?

Dr. INGLESBY. The quarterback for it, I think you would say, is the USAID and CDC directors.

Senator ISAKSON. Who are integrally involved.

Dr. INGLESBY. Yes.

Senator ISAKSON. In fact, when the Ebola outbreak took place, and you referred to some places around the United States that had containment areas already built and things like that.

Dr. INGLESBY. Yes.

Senator ISAKSON. From a modest standpoint, we were able to meet the threat at Emory University at NIH and a couple of other places with those first Samaritans, those first doctors who came back from, I think, Liberia which is where it broke out.

Dr. INGLESBY. Right.

Senator ISAKSON. That was enough at the time. But how much of that do you think should be built in preparation or to anticipate needing to have something like that happen again, maybe not for Ebola, but for some other infectious disease?

Dr. INGLESBY. Well, I think Emory was a national leader in that program, and I think if you were to speak to the leaders in that program, they would say that it would be difficult for them to take care of more than one or two patients in the current units.

I think we need to get better cost information about how much those units cost. It would be difficult to scale those by orders of magnitude by 10 or 100, but I think we could build more capacity in the systems, share the lessons that have been learned in those units, see if we can spread that responsibility out a bit further, because right now, it is a pretty small number of units that can care for any patients with that.

Senator ISAKSON. As in most cases, capital and money is the secret.

Dr. INGLESBY. And training, yes, exactly. Capital, money, training, and specialized people.

Senator ISAKSON. You talked in your testimony about a contingency fund or you recommended having some sort of a contingency planning funding for that.

Do you have any recommendations of where that ought to be and how much it ought to be?

Dr. INGLESBY. The contingency fund?

Senator ISAKSON. Yes.

Dr. INGLESBY. If you base contingency funding on what we have spent in other infectious disease emergencies, we typically have spent at least $500 million to $1 billion as a country in response to things like H9N1, Ebola, Zika, sometimes much more. And so, a fund that was somewhere in that range.

I think public health agencies, and others outside of our center, have called for a $2 billion contingency fund. That is closer to what FEMA uses for its disaster relief funding. I think that would provide a lot of acceleration in the public health response and emergencies.

Senator ISAKSON. And because biological threats and disease threats do not recognize national boundaries or oceans as barriers, it is something the whole world community has really got to participate in together. Right?

Dr. INGLESBY. Yes, absolutely.

Senator ISAKSON. And CDC is great at coordinating things like that and so is USAID, and they did a great job on the Ebola.

But that would be where the international agenda ought to coalesce a game plan and a contingency fund?

Dr. INGLESBY. Yes. I think the way the Global Health Security Agenda has worked, and one of its successes, is that it brings in different parts of government, including the finance sides of government and the security sides of government.

In the U.S., it is bigger than the CDC and USAID. There is participation by security, and by finance and economics, and that is the model they are trying to get other countries to represent as well.

Senator ISAKSON. Mr. MacGregor.

Mr. MACGREGOR. Yes.

Senator ISAKSON. Does the plant in North Carolina manufacture the flu vaccine?

Mr. MACGREGOR. Yes.

Senator ISAKSON. How are we doing on that? Do we still have enough, given the current epidemic that is going on?

Mr. MACGREGOR. Yes. We have been constantly enhancing the capability in that plant. So from a seasonal perspective, just looking at it from a seasonal perspective, we more than tripled our capacity into the market this year on a seasonal perspective.

That plant is also responsible, as I mentioned, in delivering one-third of the requirement in the event of a pandemic and responding within a 6-month period.

Senator ISAKSON. And you are cell-based?

Mr. MACGREGOR. It is cell-based. That is correct.

Senator ISAKSON. What is the shelf life of that vaccine?

Mr. MACGREGOR. Well, the shelf life of the vaccine from a pandemic perspective, the antigen is 5 years. Unfortunately, we do have antigen that is in the stockpile right now that is older than that from an egg and from a cell perspective. But that is the state of affairs right now as far as our cell-based vaccine is concerned. We also have to promise——

By the way, Senator, as I said, it offers the potential of being a better match in the event of a mismatched strain, so as an alternative form of manufacturing and the reason for the initial public-

private partnership. That is some of the promise that our company is trying to deliver on, on behalf of the government.

Senator ISAKSON. Thank you very much.

Thanks to all of you for your testimony.

Senator BURR. Thank you.

Senator Hassan.

Senator HASSAN. Thank you, Senator Burr.

Senator Casey, thank you for your leadership on this issue.

To our panelists, good morning, and thank you for being here.

Dr. Inglesby, I wanted to start with a question for you.

As we all know, Puerto Rico was recently devastated by Hurricane Maria and the island is still trying to rebuild from the disaster. The effects of that disaster are obviously widespread.

Hospitals in New Hampshire, and around the country, are dealing with, among other effects, medical product and equipment shortages such as I.v. saline bags because the storm devastated some of the manufacturers on the island.

So Doctor, what does this shortage say about our overall preparedness in the case of a future event or other types of emergencies where medical supplies cannot be easily replenished? What can we do here in Congress with this issue when we reauthorize PAHPA?

Dr. INGLESBY. Senator Hassan, yes, I agree with you completely that the Puerto Rico hurricanes and other storms have revealed how vulnerable our supply systems are.

One possibility to consider would be whether there are some critical supplies, such as saline bags, if they are single sourced to a part of the world, or some active products, or pharmaceuticals, if they are single sourced, whether or not they should be included in the national pharmaceutical stockpile.

That is not how the stockpile is configured or resourced now, so there would need to be additional resources for an additional mission.

But the stockpile has a great success in acquiring medicines and being able to deliver them to localities. So that would be one possibility if there were an additional purpose and funding for the stockpile.

Senator BURR. Senator, can I interject?

Senator HASSAN. Sure, yes.

Senator BURR. The time will not count against you.

Holly Springs is a great example, and the other two facilities, that when faced with a pandemic, we actually became visionary.

Senator HASSAN. Yes.

Senator BURR. And we thought, "What can we do to meet what we do not know?"

We went into a partnership with three different companies where we funded three-quarters of the facility of the plant, but with a condition written into it that at any point, we could turn it into what is in the Nation's best interest. And all three owners knew that and participated in it.

So it may be a model that we look at as we identify other things, but we have shown a degree of vision in the past.

Senator HASSAN. I think that is very helpful and I think the example of what happened on Puerto Rico after Maria really helps us focus on one of the next things we should be doing.

I also wanted to ask all of you, and I think I would start the question with you, Dr. Dreyzehner. I loved what you said about preparedness and response being about people and time, and obviously both demand resources.

New Hampshire uses its hospital preparedness funding to support a single statewide healthcare coalition that works to bring together public health and emergency management professionals to assure that the healthcare system preparedness is there across the spectrum of care from hospitals, to homecare, to long term care and beyond.

New Hampshire, like other states, relies on this funding to help make sure it is prepared for all kinds of emergencies, mass casualty incidents to hurricanes. Unfortunately, like many other states, New Hampshire has seen a significant decrease in hospital preparedness funding in recent years.

We do not know when the next emergency will happen or what precisely it is going to entail, so we need to make sure that the coalition in New Hampshire is not only collaborating regularly, but training regularly. It is hard to do that, though, when funding is dramatically reduced.

So I will start with you, Dr. Dreyzehner, but from all of you, do you agree that we need to increase investments in the hospital preparedness program and that it should continue to fund those efforts in all states?

Dr. Dreyzehner.

Dr. DREYZEHNER. So thank you for the question, Senator. I would say absolutely yes, if you think about who responds.

In my written testimony, I talk about three tiers.

Senator HASSAN. Yes.

Dr. DREYZEHNER. Professionals, people who do this every day. We have people that are highly trained and they are called upon if there is an actual emergency, like one you described, but they typically have different duties on a day to day basis.

For example, one of our emergency coordinators in Tennessee actually directs our Board of Emergency Medical Services.

Senator HASSAN. Right.

Dr. DREYZEHNER. But when we have an emergency, she is in the State Operation Center.

Then we have this third tier, which is kind of everybody else and the people that you are talking about. They are the public health nurses. They are the clinicians in the hospital. They are hospital nurses. They are people who are called upon whenever there is a need to surge.

Their training in training, and exercising, and actually responding, creating the relationships, the knowhow, "What do I do?" "Where do I go?" "Who do I talk to?" Those are the critical things. Those are the relationships built on trust that the HPP funding really helps solidify.

Unfortunately, when you reduce that funding, that is one of the first things that goes. Right? You try to preserve the positions. You try to preserve some of the things you have invested in, but the

more fungible assets are the very things you need more of. And I think you spoke to those very eloquently.

Senator HASSAN. Well, thank you. Just in the interest of time, I will ask the other three panelists any thing you would disagree with or add to what Dr. Dreyzehner just said about the funding?

Dr. KRUG. Just a point. It is about people.

The earlier question about how do we get the hospitals better prepared. They have to train and if you do not have trained people, your response will not be effective. That has been shown in many other industries, including healthcare.

With the focus evolving from hospitals to healthcare coalitions, which is actually, I think, an appropriate move, it is not just the hospitals that need to be trained. It is the entire community that needs to be trained.

As an emergency physician, can I just do a brief pivot?

Senator HASSAN. Yes.

Dr. KRUG. After oxygen, the elixir of life in how we care for patients is saline.

Senator HASSAN. Yes.

Dr. KRUG. So whether you have sepsis, because of a high-consequence infectious disease, or you have been in an explosion, or a bus crash, if you do not have saline, you lose lives.

So there could be nothing more fundamental to our emergency response, after oxygen, than saline.

Senator HASSAN. Well, I thank you.

Senator, I know I am over. I will just submit for Dr. Krug, a question about behavioral health needs, especially for children in disasters. The trauma that disasters impose on our children concerns me greatly.

Senator HASSAN. Last, just thank you for pointing out the importance of focusing on special needs populations. I am the mother of a special needs young man, and I thank you for raising that in your testimony very much.

Dr. KRUG. Thank you.

Senator HASSAN. Thank you, Senator Burr.

Senator BURR. Thank you.

Senator Smith.

Senator SMITH. Thank you very much, Senator Burr, and Senator Casey, and to the other Members of this Committee for your work and focus on emergency preparedness, and also to our testifiers here today.

In 2015, when I was Lieutenant Governor, and Minnesota was hit by an avian flu outbreak, which ended up costing somewhere in the neighborhood of $1 billion, it was the largest and most expensive animal disease response in the history, I think, of this country. Of course, it hit poultry growers incredibly hard.

Dr. Dreyzehner, I was really relating to what you were talking about how this safety net that we have is about people and not stuff because certainly as we responded to this catastrophe, we needed stuff. But we also really needed the people and the relationships that made our response work and function incredibly quickly, which was such an important part of it.

I am quite interested in this idea of a One Health approach and how we can build that kind of approach into our thinking about

emergency preparedness. I know that Senator Young from Indiana has raised this question just last week and probably, I have only been here for 2 weeks, so he has probably been talking about it for much longer. But raise this question of whether we need additional approaches or resources to do this.

So maybe I would like to just turn to Dr. Inglesby and also Dr. Dreyzehner. Could you talk a little bit about what tweaks you think we might need to the PAHPA legislation, and the PAHPRA legislation to address this question, this One Health approach, what we ought to be doing better there?

Dr. INGLESBY. Yes. First of all, I completely agree with the values and principles of One Health and think you are absolutely right that there are strong connections between animal and human health disease surveillance, outbreaks, zoonoses.

I do think that those principles, you will find those principles in Federal agencies. People believe there is a lot of acceptance and belief in One Health.

But I think you are also right that it is not really housed in a particular program. There are not large efforts underway to try and bring One Health together.

I do think that there is a national biodefense strategy that is now being written, or completed, by the White House and its purpose is to bring together animal health, plant health, and human health for biodefense. This is the first time a strategy has been written that way.

I do think that there was a lot of coming together in the agencies over the last year on this and I think it is improving animal surveillance systems. We do not have strong animal surveillance. If you talk about shortages in the workforce, the human health, public health workforce is strapped and the animal public health workforce is even more strapped.

Taking a look at those things, I am not sure that would be in the scope of PAHPA or not, but we do not have a lot of information coming from our animal systems. We do not have enough information and it does not crossover into human health very easily. So trying to create the bridges between the systems, that would be a good step.

Senator SMITH. Thank you very much.

Dr. Dreyzehner.

Dr. DREYZEHNER. Yes, thank you for that great question.

I think if I can make this point. As public health professionals, we think about primary prevention of flu, stopping it in the first place as a vaccine, as non-pharmaceutical interventions.

But I think we have to look ourselves and we have to think about, well, how do you primarily prevent the flu from ever occurring in the human population or another disease, for example, Ebola, occurring in the human population?

Well, doing things around the animal sources are critical. So the example you gave of avian influenza and stamping out avian influenza in poultry, we also have to make sure we circle the workers and we circle their families because that is primary prevention of a potential novel influenza strain in the human population.

One Health is, I think, an essential perspective and, I think, from my perspective, I would say from the Association of State and Territorial Health Officials' perspective, a deep interest in that.

Be very happy to work with you on crafting in PAHPA how to, specifically as Dr. Inglesby mentioned, bring agriculture professionals, public health professionals, the veterinary, the health world together to do a better job of keeping animal diseases in animal populations and not allowing transfer into human beings. Make one other point.

If somebody had come to Congress years ago and said, "We need some money to teach people how to properly prepare bush meat in Africa because we know they are going to eat it and how to properly gather fruit that may have been defecated on by bats." I think that would have been a pretty hard sell.

But when you consider all the money that we have spent on the Ebola outbreak that emanated from those practices, and lack of education around that risk, it would have been a relatively small investment.

Senator SMITH. Thank you very much, and I look very much forward to working with this Committee and Senator Young on this issue of One Health. I appreciate it.

I know I am out of time, but I might also just submit later to Dr. Krug. I am very interested in this question of how we respond to what is another epidemic seriously affecting children, which is the opioid epidemic especially in Indian country.

That will be for a later time, but I would very much appreciate your thoughts on that.

Senator BURR. Senator Roberts.

Senator ROBERTS. Thank you, Mr. Chairman.

I want to thank this Committee, both the ranking Member and our distinguished Chairman, for focusing on this issue.

Last month, over in the Agriculture Committee, we held a hearing on safeguarding American agriculture in a globalized world. Dr. Inglesby, you really hit the nail on the head with your comments.

One of our witnesses was General Richard Myers, four-star, President of Kansas State University, home of the now under construction National Bio and Agro-Defense Facility. We call it NBAF, for short. You can see why.

In his testimony, General Myers noted that because there were two Homeland Security Presidential Directives, HSPD's, in 2004—that has been some time ago—one for people, one for animals, there does not seem to be as strong of a focus at the executive level on crops, and livestock, and food. He suggested reasons why this is surprising.

I will enter his full testimony in the record at this point, if that is all right, Mr. Chairman.

Senator BURR. Without objection.

Senator ROBERTS. Thank you.

[The following information can be found on page 59 in Additional Material]

Senator ROBERTS. His reasons are, one, essentially every country that ever developed an offensive bioweapons program, including the U.S., created weapons targeting agriculture as well as people.

I would just like to insert at this time that we have had a lot of interest in this by former Senators Sam Nunn and Dick Lugar, the old Nunn-Lugar program on pandemic threats; and also by Tom Ridge and Joe Lieberman with regards to agro-terrorism.

I, myself, was in charge, at one time, of Nunn-Lugar funding as a Member of the Armed Services Committee. It was called the Emerging Threat subcommittee; went to a place called Obolensk, which is just north and west of Moscow thereby seeing one of the secret cities. We are not allowed in there now, of course, but we were then because they needed the money. We were focusing on security.

But in touring that area, I was a little stunned—not a little stunned—I was really stunned with regards to vast warehouses of pathogens that they were making ready with regards to attacking a country's food supply.

We ran an exercise at that particular time. It was called crimson sky. I think it was sort of a misnomer because you do not want to burn carcasses or anything like that. But it was hoof and mouth disease.

By the time Texas figured out that they would put a stop order from shipping cattle to Oklahoma, or Oklahoma would then to Texas say, "Do not ship any cattle in," in Kansas, and Nebraska, and South Dakota, and North Dakota, we had an epidemic on our hands.

We had to terminate thousands, if not millions, of cattle. All of our exports stopped. I mean, all of our exports stopped. There was a run on grocery stores all throughout the country. People finally discovered their food did not come from grocery stores.

It took us years to get back to a situation where we could literally feed not only this country, but a very troubled and hungry world. That was quite an experience for me and that is when we started on NBAF.

The General said first, as I have indicated, every country that ever developed an offensive bioweapons program also targeted agriculture.

Two, almost every pandemic threat today is a zoonotic disease that can spread from animals to people. Among the bioterror threats for which the Department of Homeland Security has issued a material threat determination, all except for small pox, are zoonotic, meaning they reach humans through animals.

The foreign animal disease threats could really devastate public health, as well, according to General Myers' testimony. Until NBAF is operational in the next four to 5 years, I regret that it is taking that long, there is no U.S. laboratory where livestock research can be conducted on Nipah and Ebola, swine being a host animal for both.

Mr. Chairman, I would like to work with you and all of our colleagues on this reauthorization, to ensure we are addressing and preparing for zoonotic threats.

I see I have 25 seconds to ask Dr. Inglesby if he would like to respond.

ASPR is responsible for leading the public health emergency medical countermeasure enterprise. This is supposed to be where all the coordinating agencies—the Department of Defense, the V.A.,

Agriculture, Homeland Security, along with all the first responders that are involved, along with HHS—to update our strategy and to implement our plan annually.

From your perspective, are we doing the job?

Dr. INGLESBY. I think we have a lot more work to do in the realm of agriculture, food, and crop safety.

I completely agree with what you said about the importance of animal vaccines, the shortage, with the lack of animal vaccines to protect herds against some of the most serious threats on the planet.

I agree with what you said about the threat to agriculture which, I think, both animal and plants, I think, have been relatively neglected over the last 15 years as we have begun to do other things around biological defense.

How to organize that in the government? I do not have a strong sense of how that should be organized. I do think it is complicated in that the USDA is responsible for the promotion of food and the business of food, and it is difficult, and perhaps could be difficult, to have all that protection of food in the same exact place.

But I have seen signs of life in the last 6 months around those programs that I had not seen in the last five or 10 years. So perhaps the program is becoming much stronger.

Senator ROBERTS. Well, Secretary Perdue and the Agriculture Research Service, obviously, would run NBAF. The construction of it is the Department of Homeland Security. In fact, they are responsible for any attack on the United States.

It has been very difficult to focus on this. Some years back on the Intelligence Committee, of which my distinguished friend is the Chairman, we were able to determine that what keeps you up at night that at least in the top ten was an attack on our food supply.

That is not the case today. I am talking with our CIA Director Mike Pompeo, who happens to be from Kansas. And so, we are trying to, at least, reassess that threat and I think it is a very real one.

I thank you all for your service.

I am over time. I yield back. Thank you, Mr. Chairman.

Senator BURR. Senator Roberts, you did not disappoint me. I knew there was going to be a question somewhere in that dissertation.

[Laughter.]

Senator BURR. Senator Baldwin.

Senator BALDWIN. Thank you, Chairman Burr and Ranking Member Casey.

This discussion today is important and timely. It brought into focus the sobering fact that we have experienced at least one health emergency every year in the 5-years that I have been serving on this Committee, from Ebola to Zika to the hurricanes this year.

I was serving, previously, in the House of Representatives during the 2009 H1N1 pandemic and also in 2004, when we saw a dangerous shortage of influenza vaccines due, in part, to our insufficient domestic production capabilities.

We are also in the middle of a particularly severe and deadly seasonal flu year. So I wanted to focus especially on our readiness for a pandemic flu outbreak.

I am concerned with the lack of sustained and predictable funding for the pandemic vaccine stockpile, and I am committed to working with my colleagues to advance a specific authorization for pandemic flu activities.

Mr. MacGregor, in your testimony, I was troubled that our pandemic flu stockpile does not match the current strains of influenza and is full of expired vaccine components due to underfunding. And it is especially concerning as we have the H7N9 bird flu circulating in China that continues evolve in ways that has the potential to trigger a global pandemic.

Are we adequately prepared for an outbreak of pandemic flu that could strike in the near term? And how would a pandemic in the middle of this severe seasonal flu season complicate our vaccine readiness?

Mr. MACGREGOR. Thank you for the question, Senator.

I think at the start of your statement, you immediately gave part of what would be my answer. I think your question and your comment about the stockpile, as it exists today, is a result of the underfunding that has occurred, particularly since 2009.

So with the funds that were provided, supplemental balances or emergency funds that were provided up to 2009, from 2005 through to 2009, it allowed for the building up of a stockpile of various pandemic strains, pre-pandemic strains allowing us to test and to understand how to manufacture. And this was, I think, a good partnership with BARDA and was fundamental to our preparation at that time.

Since then, the funding has really dropped off, as you commented and that is really what is behind the point I was making. There is product that sits in the stockpile today that was manufactured quite some time ago, in some cases, seven, 8 years ago.

Our ability, and the ability of the government, to replenish the stockpile, whether it be with antigen, or whether it be with adjuvant, which is also in the stockpile, has been diminished by the lack of sustainable funding to support BARDA and its efforts.

I would say in answer to your questions, because of that I do not believe we sit in a great state of readiness today. You do mention the H7N9 and we are, in fact, working with BARDA on developing an H7N9, as I imagine some other partners are as well.

Senator BALDWIN. Okay.

Mr. MACGREGOR. But we need that sustainable funding going forward in order to enhance our readiness.

Senator BALDWIN. This next question is both for you, Mr. MacGregor, and Dr. Inglesby.

My home State of Wisconsin has long been a leader in medical innovations that help grow our economy. Not only are we home to a world renowned flu scientist working to develop a universal vaccine, but we are also the hub for biomedical companies producing new technologies.

Stratatech, a company in Madison, Wisconsin is producing a new, regenerative skin technology to treat severe burns through a contract with BARDA to develop their tissue as a medical counter-

measure. Instead of painful skin grafts, they are producing living tissue designed to mimic human skin and promote tissue regeneration.

Dr. Inglesby and Mr. MacGregor, can you discuss why it is important to maintain our Federal investment in medical countermeasure research and development to foster innovation that keeps pace with the evolving and increasing chemical and biological threats?

Why do we not start with you, Dr. Inglesby?

Dr. INGLESBY. I think the reason why it is so important to continue investment is that for problems, like the one you described for patients with burns, for pandemic influenza, for other kinds of outbreaks, there is not necessarily a commercial market for those products.

Companies face a very difficult challenge, planning, a lot of uncertainty. If the Government can provide more clarity, both in the early phases in the research and in the development phase—and then potentially in the acquisition phase if that is the role for the government for a particular product—companies can then plan, can decide to make investments in this space as opposed to other commercially valuable opportunities that they might pursue otherwise.

I think it is going to continue to be a very important role for the government to play for products that we want that are not otherwise produced by the commercial markets.

Mr. MACGREGOR. I would certainly echo that comment from Dr. Inglesby.

It is a mechanism that needs to exist to have companies, innovative companies—like the one you mentioned and others that are Members of the Alliance for Biosecurity and more broadly bio—to be able to continue innovating in this space. There needs to be sustainable funding in this space.

The last comment I would make, just to add, it is interesting to hear from a number of colleagues in this space that, when you look at institutional investors and the like, where there used to be more of an attraction for them when the funding was more certain, that attraction has gone away. Little to no value is placed on MCM work in the current context because of the lack of sustainable funding.

Senator BURR. Senator Cassidy.

Senator CASSIDY. Thank you, gentlemen. I enjoyed your testimony, all of you. A couple of things. I enjoyed it so much because you agree with me. One of you spoke about the need to have healthcare professionals be able to go across lines and have liability protection. I was a practicing physician when Katrina hit. There was an orthopedist at the New Orleans Airport. The FEMA people would not allow him to set somebody's broken bones because he was from out of state and they were concerned about liability. So I think we need a Good Samaritan, which our Governors can say, "Listen, if you are from out of state and you are in good standing with your state, you have blanket protection." But I do think we need that on a Federal level as opposed to the patchwork. I will say that. I have introduced a bill with Senator King entitled the Good Samaritan Health Professionals Act that would do so. Second, I think Drs. Krug and Inglesby, you spoke Dr. Dreyzehner, of the

need to have a public health emergency fund. Senator Schatz and I have introduced something such as that would, just as FEMA has dollars, it does not need a special appropriation, but rather can go and when an emergency hits, the dollars are appropriated, and it cannot be encumbered and put in escrow by another effort. Those dollars are there. Still have accountability. To get a second trunch, you have to come back to Congress and get approval. GAO will make sure they do it. But we also take care of contracting because the CDC director said of Ebola, he had to get ten signoffs on travel vouchers for people to go over to West Africa and that slowed the response. He had to contract with NGO's for them to contract to get transportation for people and goods. We are trying to circumvent that and again, Senator Schatz and I have put something together as regard to that. Now, let me hit on some stuff which perhaps is a little bit more provocative. Dr. Inglesby, you speak about the need to maintain this international network. Theoretically, World Health is doing that. I am not sure we are getting bang for our buck with World Health. Now, you probably have relationships with them, so I do not mean to put you in a bad position. But if we are funding internationally World Health and the CDC is having to do it separately, that does not seem, in a time of scarce resources, wise use of resources. Thoughts?

Dr. INGLESBY. Yes, so the World Health Organization has some of the best experts in the world on diseases around the world, and they are kind of the normative agency for setting policy, and guidance around the world, looked up to it in the world. But they are not a strong, operational agency. They do not have resources to go and train the world or build labs around the world. They have some money for that, but their budget is constrained as well. They depend on donations.

Senator CASSIDY. If they had the money, do they have the capability of doing it?

Dr. INGLESBY. Not right now.

Senator CASSIDY. So, that seems like we are having to supplant an international organization with a Centers for Disease Control. I understand why we are doing it, but it almost seems like we are compensating for something which should have the responsibility already.

Dr. INGLESBY. Well, what I would say is that the CDC and about 65 other countries are all contributing in some way, some of them with a lot of money, some of them with just their experts. But the Global Health Security Agenda was a way of getting a large consortium of countries go out and help.

Senator CASSIDY. I get that and I am not objecting to it except insofar as it seems like World Health should be doing that. Let me move on.

Dr. INGLESBY. Okay.

Senator CASSIDY. Now, you mentioned about having regional areas of expertise. Let me go back to my formative experience with Hurricane Katrina. When the fecal material hit the fan, it just overwhelmed everything. Now, when I went to Haiti as a private citizen after the earthquake there, I was struck that the Israelis came in and they just plopped down a hospital, unfolded it, and every capability they needed was there in a field hospital. I almost

think since a public health emergency could happen in Baton Rouge, Shreveport, or Topeka, or you name it, how does every region have that kind of expertise? As opposed to a public health hospital that may sit up in your local V.A., which is already a government facility. Boom. "We commandeered. We are taking it over." It almost seems a better way to respond because then you would truly have expertise that is deployable in a moment. Any thoughts on that?

Dr. INGLESBY. I do think that we should be able to rely on the local institutions. So V.A.'s are a great source of strength in some cities. But the National Disaster Medical System and the DMAT teams, I think, are some of the teams that responded to Katrina, they responded to Harvey.

Senator CASSIDY. Let us go back to Ebola, which is very specialized. You had to take off your booties in a correct fashion or else you were exposed. This happened to the nurse in Dallas.

Dr. INGLESBY. Right. So the U.S. was not prepared to send doctors and nurses to Ebola. We sent public health specialists, but they did not take care of patients. They were not allowed to take care of patients.

Senator CASSIDY. But my point is, would it be better to have that sort of expertise that truly could go to a community and boom. "We are going to be the expeditionary force." I am sitting next to a Marine.

The healthcare expeditionary force that is going to be able to manage this and we do not have to have a lot of in-service because these people are hitting the door right now. We will give you in-service, but in the meantime, we will provide direct care and that way, whether it is Baton Rouge or Topeka or New York, we know that we have expertise deployed.

Dr. INGLESBY. Yes, I do think it would be very valuable. We have something like that on a much smaller scale called the DMAT teams.

Senator CASSIDY. Yes, but DMAT is more generic.

Dr. INGLESBY. Fair enough. I agree with you.

Yes, I do not think we have infectious disease-oriented, or Ebola, or contagious disease-oriented teams like the ones you are talking about. And I think nationally and internationally, it would be good for us to be able to build those teams.

Senator CASSIDY. I yield back. Thank you.

Senator BURR. I would like the record to show that North Carolina tried to deliver to Louisiana after Katrina a portable hospital.

Senator CASSIDY. Yes.

Senator BURR. And it was the Governor who would not sign the liability agreement. That put that hospital in Mississippi.

So we have this incredible surge capacity, I am learning about. It is just we have hurdles in the way.

Senator CASSIDY. Right.

Senator BURR. That will stop it dead in its tracks if it ever starts the motion of addressing collectively the problem. So these are things we can work out.

Senator CASSIDY. And let me just say we, in Louisiana, continue to be indebted to other DMAT's around the Nation who just so generously deployed. I cannot tell you the gratitude we feel.

Senator BURR. Senator Kaine.

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

An observation and then I want each of you to address a workforce question. So the observation is this.

When we reached a deal yesterday so the Government would open, there are really two components to the deal. One, a guarantee of a debate and vote around permanent protection for Dreamers, which is very important.

But the second half of it was, we have to get out of continuing resolution mania and get back to real budgeting again to fund these priorities and others.

One of the funding questions that we are now grappling with is the question of budgetary caps because of votes of earlier congresses that would impose such caps. When the caps were imposed, they were imposed equally on defense and non-defense.

All of your testimony, and the testimony of the equivalent panel last week, are about national security. This is national security.

I just came from a closed hearing about America's nuclear posture in the Armed Services Committee national security, but you are national security too.

One of the proposals floating around is that we would increase caps on the defense accounts but not on the non-defense accounts. You guys are non-defense, so you are national security, but you are not defense.

The Lynchburg, Virginia economy is based pretty heavily on companies that build nuclear reactors that go into carriers and subs. But those are under the control of the Department of Energy, not DOD. So that is a non-defense expenditure.

The point that I am making is as we grapple with these caps, it would be foolish to raise defense caps and non-defense caps because if we are not raising caps appropriately to fund emergency response, or we are not raising caps appropriately to fund the DOE programs that build nuclear reactors, we are not taking care of our national security.

That is my observation.

Second, workforce. The quote, Dr. Dreyzehner, in your testimony, written and verbal, it is about people. It is about people. And one of the things I love about this Committee is it is Health, Education, Labor, and Pensions. So PAHPA is within our Health jurisdiction, but in the Education jurisdiction, we are having a set of hearings about approaching the rewrite of the Higher Education Act. Programs like public loan service forgiveness. This is on the education side.

You all approach your jobs from different backgrounds and expertise, but share any concerns you have about the current public health workforce in this country as you look forward because we might be able to do something about that, not just in PAHPA. We might be able to do some things about that as we grapple with the Higher Education Act rewrite.

If you want to start, Dr. Krug.

Dr. KRUG. Thank you. Thank you for the great question.

As has already been said, this is about people. Yes, we do need more "stuff," but we really need more people. The budget environ-

ment today constrains the number of people that you can employ, which is why there is this just-in-time thing going on in healthcare, which is why we do not have a lot of capacity.

But in the end, there are not enough nurses, as an example, to staff all of the hospitals or all of the clinics. And some of those limitations are greater in certain communities than others. I will defer to my public health colleague, but I believe there is a public health workforce issue as well.

What we need to do through education, and maybe through some incentives, is to direct more of our future, young people, toward these important careers because these are careers where, in addition to taking home a paycheck, you are making a difference. You are serving the community. You are serving the public. You may not be a special Government employee, but you are still making a difference.

I think if we can redirect the flow, we will be better prepared to deal with a calamity.

Senator KAINE. Others who would like to address it? Mr. MacGregor and then Dr. Dreyzehner.

Mr. MACGREGOR. We will go down the line quickly.

Senator KAINE. Yes.

Mr. MACGREGOR. I think my main response in this would be some of the strain that comes on public health, as referenced by my colleagues up here, is the need to respond in an emergency.

I feel that a big part of the reauthorization discussion, the notion of sustainable funding really has, at its core, the avoidance of having to respond in an emergency that puts an undue strain on the public health system.

It has a bit drifted from your question about workforce, but I just wanted to make that particular point, because I think it gets to the sustainability question.

Senator KAINE. Thank you. Dr. Dreyzehner.

Dr. DREYZEHNER. Thank you, Senator. A very important question.

I think Mr. MacGregor said in his comments about medical countermeasures and the certainty around having a market for those. Dr. Krug mentioned that folks who are engaged in this area are highly committed, passionate, compassionate people, but they need certainty in the profession being there tomorrow. That has not been the case for the last 15 years.

There have been a lot of question marks raised about, "Will the area that I have devoted my life to, when called upon, be there?"

Really after 9/11 and anthrax, we developed our current, I think, more modern, more responsive, higher capacity public health and healthcare preparedness infrastructure.

But those professions that have evolved around that, many of them are now becoming senior, many of them are retiring. People are making decisions as to whether they want to enter the field, "Will there be a profession for me if I decide to enter the field or to stay in it?" So all those things are really important.

Sustaining and maintaining funding is very important, not pulling at the last minute to redirect it to some other priority is really important. You referenced that briefly.

I absolutely think your points are really important. I think the threat to the public health workforce is they are going to decide to go to something else and possibly they will retrain into healthcare where there is a little bit more stability. They have other options, but they really like these jobs.

These jobs are good jobs. They are important jobs in the areas where they exist, both in rural and urban environments. I think the Nation's national security would be well served to recognize the passion of these professionals, the experience that they have gained, the relationships that they have built, and the lives and property that they have saved in the last 15 years since this regime, PAHPA one and two, were reauthorized.

Senator KAINE. Mr. Chairman, might I ask Dr. Inglesby to respond briefly? Thank you.

Dr. INGLESBY. Yes, I would just echo the comments and say that the public health emergency preparedness program that supports so much of the public health workforce has come down pretty substantially since its start. Thousands of jobs have been eliminated in public health since we began this effort back after 9/11.

I think there is great excitement in the field. Young people want to work on these issues, both in medicine, nursing, and public health. They leave schools with pretty substantial loans. There are some loan forgiveness programs which need to be attended to, to draw people into the field.

But for the most part, I think people will come to these jobs if there is a field there, if there is support there. And right now, a lot of this money does come from the Federal Government. It supports jobs directly.

I think continuing these programs would help ensure that we have a workforce.

Senator KAINE. Thank you for that.

Thank you, Mr. Chair.

Senator BURR. Senator Young.

Senator YOUNG. Well, thank you, Chairman, and Ranking Member for this second in a series of hearings on a very important topic, public health threats.

I would like to turn to a topic of insurance for pandemics. I will be asking a question of each of you related to this topic.

But by way of background, in our last hearing, we heard Admiral Redd who, of course, is from the Centers for Disease Control and Prevention. He said that our strategy to address zoonotic diseases, those that spread from animals to people such as Ebola and the avian influenza, has been a reactive strategy.

It made me think. Are there any strategies that might take us from a reactive stance to a, to use a modern term, proactive one?

I found that last year, the World Bank launched the first pandemic bond to quickly finance public health emergencies. You may be familiar with this. So financing emergencies like pandemic influenza strains, something called corona viruses, filo viruses like Ebola, and others.

According to the World Bank, their pandemic emergency financing facility would provide over $500 million of coverage against pandemics in just the next 5 years.

My question to you is do you think Congress should experiment in the creation of similar financing structures like the pandemic emergency financing facility, or some other type of insurance mechanism to protect against pandemics?

Regardless of your thoughts on that, if there are other proactive strategies that you think we should turn to first, if you could volunteer that to me, I would appreciate it. We will start with Dr. Inglesby, please.

Dr. INGLESBY. I very much respect what the World Bank has done with the pandemic bonds. I have not studied it enough to understand whether there would be some value in doing that in the United States. It is an interesting and new question. I have not heard that before, so maybe I can get back to you with thoughts on that.

I think one alternative, which is less complicated but we talked about already, would be to establish a contingency fund that would only be used in the event of emergencies declared by either Congress of the Secretary of Health. We would have a fund that would be ready to go. It is kind of like an insurance policy. It would not be called insurance, but a fund available for rapid response.

Senator YOUNG. Thank you. Actually, I have done work like this, new financing mechanisms, related to a number of fields from healthcare to social policies. So I respectfully am of the opinion, this would not be all that complicated. It would be a way to capitalize a fund like those that have been invoked earlier. But thank you very much, doctor. Yes.

Dr. DREYZEHNER. Well, I would echo Dr. Inglesby's comments.

I think I am not sure I know what insurance means anymore, but the idea that, I think, funding is up in HPP back to their prior levels is insurance to make sure that people that need to be there when the balloon goes up are there and able to do what they do.

I think the contingency fund could be a very important piece of insuring that the unknown unknowns are insured against and they will certainly occur.

I would just echo what Dr. Inglesby said and I would say that our best insurance is making sure that we have adequate people, and relationships, and networks, and experts available at a moment's notice to respond.

Senator YOUNG. Thank you. Mr. MacGregor.

Mr. MACGREGOR. I would just add as well that if mechanisms such as these——

When you first mentioned it, I always thought more of in the event of protecting against the cost of pandemic once it hits. I would be more inclined toward financing mechanisms that, again, allow us to be more prepared in advance and not having to deal with the tragic aftermath.

Maybe just maybe what World Bank is proposing is something that could be more of a global kind of effort that cannot only benefit the U.S., but can benefit other countries as well. And by benefiting other countries, it actually contributes to preparedness we can have here.

Senator YOUNG. Thank you. Doctor.

Dr. KRUG. It is good to be last. I agree with all of the comments made by my colleagues. I would offer two, hopefully helpful, perspectives.

First of all, as one of the Members stated, if we could mitigate the problem and avoid the disease, that would solve a lot of problems, and so, that gets back to proactive vaccinations. And also locally and at a global level, looking at those vectors and trying to identify early on and prevent those diseases before they spread.

In the end, it is pretty clear to me, and I know you guys get this, that there is not money to go around to make this all work. We have all told you we need to improve funding for the core elements of the process because if you want to do it for less, that is what you are going to get. You are going to get less and that is what we are seeing today.

It is long overdue for a discussion with the public about the threats that we face, the reality of our resources, and how we can collectively make a difference. I think most Americans share some common values and I think our collective survival and making America stronger is something that most people would want to do.

In the end, there are not enough resources when the cavalry arrives, whether it is the state, local, or Federal Government to meet the needs of everybody in a town, a city, and whatnot.

If citizens were better prepared, if we began a discussion about the values and the culture with personal readiness and with the strong helping the weak, helping your neighbor, making sure that is okay, then we would not have to rescue everybody. Maybe we would be rescuing a few fewer, because there are going to be citizens who cannot do that for a variety of important reasons.

But if we can get back to the culture that, I think, I grew up with when I was in grade school where that seemed to be a value, I think that would help us both with this and probably with some other issues as well.

Senator YOUNG. Well, I thank you all. I threw a novel concept at you. If you have any additional thoughts that you would like to followup with my office about later, I would be appreciative.

Mr. Chairman, I would just note that point on community is something that has been invoked consistently, whether we are talking about the opioid epidemic, or social pathologies, the need for more community to help address a range of public issues that we are dealing with; so not an easy one to tackle, but an important reminder.

Thank you.

Senator BURR. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman.

When a public health emergency hits, the headlines are all about what is happening on a minute by minute, hour by hour basis. You do not get news alerts on your phone about the years of hard work that went into making the response to the disaster actually work when everything was on the line; so all the drills, the dry runs, the training. But I understand. These are the investments that we have to make in our Nation's preparedness and our response capabilities if we are going to be ready when an emergency strikes.

I want to talk about one specific type of investment today, and that is investing in the therapies, or the medical countermeasures,

that save lives when disaster strikes; so vaccines for anthrax, or Ebola, or influenza; products to protect us from radiation exposure; next generation antibiotics.

In 2004, Congress established a program called BioShield, and I think Senator Burr referred to this earlier and Senator Baldwin. I just want to dig in a little bit about this program. The idea was to accelerate development of medical countermeasures by investing in biomedical research.

Now, Dr. Inglesby, you are an expert on biosecurity. When a company develops a new drug or device, usually they go out and get a lot of funding from private investors.

Why do medical countermeasures need public investment from a program like Project BioShield?

Dr. INGLESBY. Senator, the reason why companies need that kind of support from the Government is because the products that we are trying to make for pandemics, like an anthrax vaccine or an Ebola vaccine that you referred to, they do not have a commercial market.

Senator WARREN. We hope.

Dr. INGLESBY. We hope.

Even in the event of a pandemic, it is going to be difficult for people to access those funds without the help of government. They are going to be in stockpiles. So what we need is sustained investment in those companies to get them to do this work.

Senator WARREN. So let us talk about that sustained investment.

When Project BioShield was created, it got $5.6 billion in guaranteed funding over 10 years. It was called an advance appropriation, and that means that Congress decided, in advance, that it was going to spend that amount of money. They did not come back every year during that 10 year period to decide whether or not they would actually put the money in as promised.

Now that changed in 2013 when the initial 10 year commitment ran out and Project BioShield has had to get its funds set aside on a yearly basis, just like everyone else, through the appropriations process.

Mr. MacGregor, you work in the biosecurity field at a company that makes flu vaccines. The authorization levels for Project BioShield, that is what Congress said we could spend on it, have stayed exactly the same since 2013.

Is that right?

Mr. MACGREGOR. Yes, since 2013. I mean, the authorization.

Senator WARREN. So authorization, I am going to go to this.

Mr. MACGREGOR. Yes.

Senator WARREN. The authorization stays the same, but appropriations levels, did Congress actually get that money out the door to you?

Mr. MACGREGOR. No.

Senator WARREN. No.

Mr. MACGREGOR. So for BioShield, I think the authorization is $2.8 from Fiscal Year 2014 and about $1.5 billion was actually appropriated. So there was a shortfall relative to what had been experienced in the initial period.

Senator WARREN. That is a pretty significant shortfall.

Mr. MACGREGOR. Yes.

Senator WARREN. All right.

What does that mean for companies like yours that are trying to make decisions about researching and developing these kinds of countermeasures?

Mr. MACGREGOR. Well, it calls into question again what the commitment is and I think for a lot of companies, it is very difficult in this space to do long term planning and to forecast in a way you would typically forecast, granted, in a commercial space. So it makes it very difficult to plan.

I think as well what has happened with this uncertainty, and I know I mentioned it before, but during that initial 10 year period, I think there was a lot of private investment. There was a lot of institutional investment in companies that were in the MCM space because there was a value that was seen there.

I have heard from a number of colleagues that investment, that pool of investment, has really dried up. And, in actual fact, there is really very little of any value that the market puts in the MCM space.

Senator WARREN. So this really worries me. You are telling me it is a market that only works if the Federal Government makes the investment and that the yearly appropriations process is not working in this field. I think that is what I am gearing from the two of you.

It just seems to me that keeping our Nation safe from these kinds of threats, it is one of the most important investments we can make. You cannot make up ground overnight on this, but you cannot do it once the threat is at your doorstep. We have to be in this for the long haul.

As this Committee works to reauthorize PAHPA, I hope that we can discuss the importance of providing robust, stable funding to researchers who are working to help us avert the next public health emergency.

Thank you, Mr. Chairman.

Senator BURR. Thank you, Senator Warren.

Let me just say to colleagues, I think Senator Casey and I have been in the trenches for a long time. We have written more letters to appropriators.

The definitive change was when Presidential budgets did not ask for the full BioShield money; a pivotal point. It was that lack of request. And unfortunately up here, as Senator Casey and I have found, even our letters to appropriators would not get them to fill a hole bigger than what the Presidential budget request was, and we have seen this steady decline.

But I think I can say on behalf of the Chairman, who is an appropriator, that this Committee has always said that we ought to appropriate at reauthorization levels.

You probably hit on the key thing that was, I think, the toughest thing to recognize, and that is: where is the Federal Government's responsibility at creating the incentive for people to create something that there is not a commercial market for?

I will say, though, hiding in the back of the room, is one of the authors who now works for the ASPR, and she has feverishly been writing notes. So everything you have said today is going to find its way back.

But I will tell you how difficult this was. When this was originally designed, trying to find somebody to be the spokesperson for disaster, we had to create a new position called the Assistant Secretary for Preparedness because nobody wanted to raise their hand and be in charge.

This is something that this Committee has got to be absolutely vigilant on from a standpoint of what the needs are because, I would say, that Mr. MacGregor is a great example. If this dries up, who wants to be in the vaccine space? The same reason that we have a shortage of antibiotics today, who wants to be in the antibiotic space? It is millions, and millions, and millions of dollars in development.

It is not only addressing this, I would tell you it is technologically trying to come into the 21st century. And our regulatory and reimbursement, as you look at gene-based platforms that may cure genetic defects in children on one side, and diseases that we have not been able to cure today that we can cure tomorrow.

How do you reimburse for that? You cannot do it based upon how much you have put into it. You have to look at it from a standpoint of how much we are saving over the life of living with that disease. This is foreign to government, but it is something that we have to tackle in a bipartisan way to get it done.

Senator Casey and I have just a couple more questions, and if Senator Warren has some, I will stick around as long as we need to.

Dr. Krug, identifying emerging public health threats is critical in determining how to prevent, treat, and mitigate its effect. One of the best tools that we have to gain this information is the diagnostic test.

In the midst of combating Ebola and Zika, determining the individuals in need of treatment helped to inform providers, and those on the frontlines, of the outbreak.

How do rapid, point of care diagnostics work to better inform providers working and are preparing for these public health emergencies?

Dr. KRUG. Thank you. That is a great question. They help immeasurably.

Imagine, for a moment, that you are in a scenario with multiple sick victims. And, I think, as one of my colleagues pointed out, your Ebola treatment center can maybe take care of, at most, three patients. Which of those three patients are you going to admit to the Ebola treatment unit?

With the older technology that we have with diagnostic testing, which took over 24 hours back when we dealt with Ebola as a treatment center, we had no other choice but to treat those patients until we knew for sure that they did not have the disease.

Fortunately, it came during a time of the year where we were not operating at peak hospital operating capacity. If that was today, I would not know what to do with this problem, because I would not know who to treat. And by treating somebody who might not actually have the disease and need the treatment, essentially prevent somebody else who needs that same treatment area and ICU bed, and that ICU care team meeting their need.

Both in a hospital setting, but also in the field, these diagnostics are terribly important. I mean, in the field the resources are more limited and so the fundamental decisions made in that setting are also vital.

Senator BURR. Tom, I want to turn to you since Dr. Krug mentioned Ebola.

Is this statement correct? "We learned enough with the Ebola crisis to understand our limitations, but we have done nothing to increase our capacity if it were to happen tomorrow."

Dr. INGLESBY. I think at a high level, that is probably true. There have been some lessons that have been built into the system, but we have not really changed resources that are available for the mission.

Senator BURR. But we learned enough to know that we have no, or very little, surge capacity for an infectious disease of that magnitude.

Dr. INGLESBY. That is true.

Senator BURR. Okay. Dr. Krug, let me come back to you.

From a pediatric standpoint, there have been a number of news reports, I do not know the accuracy of them, that suggest that young adults taking Tamiflu have had hallucinations.

How challenging does that make the avenue to try to expand these new treatments to the pediatric population?

Dr. KRUG. Well, thanks to that.

Senator BURR. And the acceptance by parents.

Dr. KRUG. Yes, thank you. You have hit the nail squarely on the head.

It is not just Tamiflu. In fact, the bigger issue is with vaccination. Because with the exception of maybe a glass of water, there are probably going to be side effects associated with almost anything, potentially anything, that you prescribe or give to a patient. Whether you use something or not is, hopefully, driven by evidence and that risk-benefit ratio of positive effects versus side effects.

Thanks in part to social media, everything that occurs that maybe did not occur the way it should have, and reports of adults who are having hallucinations with Tamiflu, make their way to places. And so that the average family that I care for that has a smart phone, they already know about this.

When I try and advise them that their child should have something, and it is driven by CDC guidance and the guidance from the American Academy of Pediatrics, they say to me, "But doctor, this medication will cause my child to have four heads." And it is like, "Well, I am not even sure that is true and if it is true, the likelihood of bad occurrence from the disease is probably much more likely than those four heads that you are worried about." So the point is that does make it more difficult.

I will say that the partnership that we have been able to have, and it is not just the American Academy of Pediatrics. There are other specialty societies as well in terms of partnering with a group like the CDC and getting out guidance, not only to practitioners, but information to families. So that at least on a reliable Website, there is, perhaps, counter information that makes it clear that if your child has an underlying medical problem, and they are in

their first day of illness with the flu that Tamiflu is probably a good idea.

Senator BURR. The challenging thing is to fulfill your wishes, which is increased pediatric indication, you have to have children willing to join clinical trials. And that means a parent that is willing to allow a child to do that.

We have done some unusual things by emergency use order, but I think you would agree with me that when you take somebody who is physically different than what a dose or a drug might have been approved for, you just do not know the reaction you are going to get.

There is a real interest in the Committee to make sure that pediatric indications are a normal process in the future.

Dr. KRUG. And it should be part of the process. There are ethical concerns whenever you are going to enroll a child in a trial. The concerns that you have to address are substantially greater than adults. And so, again, we are calling on this other hat that I have.

A very interesting discussion was, since we do not know if it was going to work, "Should we try and test the anthrax vaccine in children before an anthrax event occurs?" This was back when anthrax was high on the radar screen.

In the end, we deferred to the Presidential Commission on Bioethics, which essentially came to the conclusion that it was probably not ethical to do that.

So that is the dilemma. How do you do that? Again, in an industry where it is tough to convince people to develop things for which there is no market, the market is even smaller for children. And the risk to the industry to do something in children is substantially greater. So it is a steeper hill to climb.

Senator BURR. Yes. Brent, I want to turn to you just real quick.

I think it is safe to say that countermeasures are difficult things to develop. Those human efficacious studies are not feasible in some countermeasures. So the FDA finally, in 2015, set the way forward with the animal rule.

My question is this, what are the challenges in successfully bringing forward a medical countermeasure by relying on the animal rule as the pathway?

Mr. MACGREGOR. Well, it is a different approach for it to take from what we are accustomed to. And so, you are reliant on the data you generate from that rule being something that you have to extrapolate to being of use in humans.

I think it is beneficial in the sense that it allows us to bring medical countermeasures forward. So in that regard, it is good.

It is a rule that we have had, as an industry, to adapt to going forward, but I think as an industry, we are doing it. So it has been a good step forward.

Senator BURR. Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much.

I wanted to continue on the topic of children. I know we are almost out of time here. But Dr. Krug, in the last reauthorization, we were able to put in place a new,

National Advisory Committee on Children and Disasters, and appreciate your work and your testimony today.

The only question I have for you is, what are the areas of our preparedness planning where you see the greatest need for more attention to the needs of children?

I know you have answered different parts of this, but at least my wrap up would be there.

Dr. KRUG. Well, arguably in all facets. And again, we have made tremendous progress and the National Advisory Committee has certainly contributed in that direction.

From a healthcare perspective—and that is a narrow perspective because the whole process is bigger than healthcare—the healthcare industry is primarily put together to take care of somebody like me. Somebody not a child, somebody with underlying medical problems, toward the end of their life, I hope not.

The point is that with the exception of the facilities, and there are a smaller number that sort of specialize in children, the rest of the system does not. There is nothing wrong with it. That is how it works on a day to day basis.

We can build these specialty centers of greatness for disaster response, but every community, every institution, every clinic—because that is where the care may need to be provided—needs to be prepared to take care of all comers in the community. And that also, then, includes children.

In current operations, if you have a sick child, you put them in an ambulance and you send them to the children's hospital. Well, that is not going to work, first of all, if the children's hospital has been disabled by the event, or the nature of the disaster does not permit transportation, or everything is fine but they are already full to the gills.

So the challenge that we have, and the good thing is everybody likes children, so that is our little thing in our pocket. We have to get everybody better prepared to take care of children and one of the most important ways to get there is through training. Drilling and training, I think, would make us better in caring for all populations, and certainly for children.

Senator CASEY. Thanks very much.

Thanks, Mr. Chairman.

Senator BURR. Thank you, Senator Casey.

Thank you to our witnesses. I do want to highlight, just once again. In 24 years, I have done a lot of hearings. I found it almost impossible to have an agency witness at the table who testified and the private panel comes up second, and get an agency person to stay in the room to listen to the private sector.

This may be the first time I have looked and we have not had a government witness, but we have had agency folks who have attended to hear what the Members and the private sector say about the reauthorization of a program.

That is unusual. I hope it is a trend that is going to become the norm and not the exception. And I say that as a message to go back because I think your testimony is not only valuable to us, it is valuable to the agencies that are affected by the issues that you are here to talk about.

So I want you to know today, they got heard not just by us, but by the agency itself.

I thank all four of you for your willingness to be here today and for the insight that you have provided to the Committee.

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

[The information referred to follows]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF RICHARD B. MYERS [1]

Chairman Roberts, Ranking Member Stabenow, and distinguished Members of the Committee, I am honored to appear before you today on behalf of Kansas State University (K-State) for this hearing entitled, "Safeguarding American Agriculture in a Globalized World."

THREATS AND CONSEQUENCES

Food insecurity is an ever increasing global problem as delineated in a 2015 assessment by the intelligence community. [2] Hungry people are not happy people. America still feeds the world, so there is an urgent need to protect America's food crops, food animals, and food supply from naturally occurring and intentionally delivered biological threats. Either could be devastating.

One of the early discoveries when our troops went into Afghanistan in 2002 was a list of 16 pathogens al-Qaeda was planning to use as bioweapons. Only 6 of them targeted people. Another 6 were pathogens of livestock and poultry and 4 were crop pathogens. So, al-Qaeda wasn't just planning to attack people with biological weapons; they were going after agriculture and food as well.

al-Qaeda has always had a goal of destroying the U.S. economy, so bioweapons targeting crops, livestock and poultry is consistent with that objective. Moreover, natural infectious disease outbreaks could lead to the same outcome.

Consider the United Nations (UN) Food and Agriculture Organization (FAO) assessment that "just 15 crop plants provide 90 percent of the world's food energy intake, with three—wheat, rice, and maize—making up two-thirds of this." [3] Ninety percent makes the protection of food crops rather significant.

If wheat, rice, or corn are targeted successfully by al Qaeda or other bioterrorists or if there's a natural disease outbreak that devastates the global supply of any one of the three, the world will be in big trouble. The Wheat State takes such matters seriously.

Although it didn't turn out to be a global disaster, the pathogen Wheat Blast hitting Bangladesh in 2016 certainly wreaked havoc there. Wheat Blast can kill 100 percent of crops, and it likely got to Bangladesh in a shipment of grain from South America where it's endemic. The outcomes were devastating in areas of the country where it occurred, and even though infected fields were burned, there was a recurrence in 2017; the new outbreak spread to India too. The U.S. should consider restricting grain shipments here from South America to avoid a similar outcome.

With livestock, the Porcine Epidemic Diarrhea virus (PEDv) foreign animal disease (FAD) outbreak in the U.S. in 2013 highlighted biosecurity problems here that must be addressed. It resulted in over 8 million baby pigs dying, and significant financial losses incurred by producers drove up the cost of pork markedly. It's suspected PEDv came to the U.S. in feed products from China, but the FBI still hasn't confirmed whether the virus got here by accident or intentionally. There are reasons to suspect the latter. Either way, the impacts were substantial, and PEDv is now an enduring endemic problem to deal with in the U.S., not a FAD threat.

There are innumerable FAD threats that the U.S. must worry about today, and the top-line FAD concerns are those currently projected to be worked on in the U.S. Department of Homeland Security's (DHS's) $1.25 billion National Bio and Agro-defense Facility (NBAF) under construction on the K-State campus. These include the livestock-only threats, African Swine Fever (ASF), Classical Swine Fever (CSF), and Foot and Mouth Disease (FMD), along with the zoonotic threats, Rift Valley Fever (RVF), Japanese Encephalitis (JE), Nipah virus, and Ebola virus. Any of these and innumerable other FADs could ravage America's agricultural infrastructure, food supply, and economy if they hit the U.S. Furthermore, zoonotic FADs could dev-

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[1] General (Ret.), 15th Chairman of the Joint Chiefs of Staff

[2] Intelligence Community Assessment: Global Food Security, ICA 2015–04; September 2015

[3] See United Nations Food and Agriculture Organization: *http://www.fao.org/docrep/u8480e/u8480e07.htm*

astate public health as well, and until NBAF is operational in 2022/23, there's no U.S. laboratory where livestock research can be conducted on Nipah and Ebola.

FOUNDATIONAL EFFORTS

Defense of U.S. Agriculture and Food—Homeland Security Presidential Directive/HSPD–94

Delineating the federal role in bio/agrodefense post-09/11, President Bush issued Homeland Security Presidential Directive/HSPD–9, on January 30, 2004 to establish: "a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies."[4] Along with a number of other systems vital to U.S. survival and prosperity, the agriculture and food sector was appropriately noted to be "critical infrastructure."[5]

HSPD–9 Roles and Responsibilities:

A defined chain of command is critical to accomplish any national security mission. That's true for bio/agrodefense—defending the homeland agriculture and food system—just as it is for every other aspect of national defense. The leadership roles per HSPD–9 are as follows:

- Secretary of Homeland Security. As established in HSPD–7,[6] the Secretary of the Department of Homeland Security (DHS) "is responsible for coordinating the overall national effort to enhance the protection of critical infrastructure and key resources of the United States."
- Secretaries of Agriculture, Health and Human Services and the Administrator of the Environmental Protection Agency. The two Secretaries and the Administrator "will perform their responsibilities as Sector-Specific Agencies as delineated in HSPD–7:"[7]
- For the U.S. Department of Agriculture (USDA), sector-specific responsibilities mean agriculture and food (meat, poultry, and egg products);
- For the Department of Health and Human Services (DHHS), it means public health, healthcare, and food (other than meat, poultry, and egg products); and
- For the Environmental Protection Agency, sector-specific means drinking water and water treatment systems.

Thus, DHS was named to lead bio/agrodefense, with USDA, DHHS, and EPA supporting. Other departments and agencies also provide support with the HSPD–9 requirements that follow.

HSPD-9 Requirements:

- "Awareness and Warning"[8] . Knowing what's happening over-the-horizon—beyond U.S. borders—is vital if America is to be prepared to confront emerging biological threats; if the U.S. is to respond quickly and decisively to defeat the threat.
- HSPD-9 required the development of "robust, comprehensive, and fully coordinated surveillance and monitoring systems" for diseases of animals, plants, wildlife and people along with threats to food and water quality. This system was to include nationwide diagnostic networks for "food, veterinary, plant health and water quality." The Department of the Interior (DOI), USDA, DHHS, EPA and other departments and agencies would develop the systems.
- HSPD–9 required "intelligence operations and analysis capabilities focusing on agriculture, food, and water sectors." This would be led by the Attorney General/ Department of Justice (DOJ), DHS, and the Central Intelligence Agency (CIA) in coordination with USDA, DHHS, and EPA.
- HSPD–9 required the creation of "a new biological threat awareness capacity that will enhance detection and characterization of an attack." DHS was to coordinate with USDA, DHHS, EPA and other departments and agencies to carry this out.
- "Vulnerability Assessments". HSPD–9 mandated "vulnerability assessments of the agriculture and food sectors" and the identification of "requirements for the

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[4] Homeland Security Presidential Directive/HSPD–9—Defense of United States Agriculture and Food; Jan. 30, 2004

[5] As delineated in Section 1016(e) of the USA PATRIOT Act of 2001 [42 U.S.C. 5195c(e)]

[6] Homeland Security Presidential Directive/HSPD–7—Critical Infrastructure Identification, Prioritization, and Protection, December 17, 2003

[7] Homeland Security Presidential Directive/HSPD–7—Critical Infrastructure Identification, Prioritization, and Protection, December 17, 2003

[8] Homeland Security Presidential Directive/HSPD-9—Defense of United States Agriculture and Food; Jan. 30, 2004

National Infrastructure Protection Plan" that was to be updated every 2 years. The assessments would be done by USDA, DHHS, and DHS, with DHS responsible for the plan every 2 years.
- "Mitigation Strategies". HSPD-99 required:
- The prioritization, development, and implementation of "mitigation strategies to protect vulnerable critical nodes of production or processing from the introduction of diseases, pests, or poisonous agents."[9] This was a responsibility of DHS and DOJ working with USDA, DHHS, EPA, and other departments and agencies.
- The development of "common screening and inspection procedures for agriculture and food items entering the United States" and maximizing "effective domestic inspection activities for food items within the United States." This was a responsibility of USDA, DHHS, and DHS.

"Response Planning and Recovery". HSPD-9 required:

- Ensuring "that the combined federal, state, and local response capabilities are adequate to respond quickly and effectively to a terrorist attack, major disease outbreak, or other disaster affecting the national agriculture or food infrastructure." This was a responsibility of DHS in coordination with USDA, DHHS, DOJ, and EPA.
- Developing "a coordinated agriculture and food-specific standardized response plan that will be integrated into the National Response Plan." This was a responsibility of DHS in coordination with USDA, DHHS, DOJ and EPA.
- Enhancing "recovery systems that are able to stabilize agriculture production, the food supply, and the economy, rapidly remove and effectively dispose of contaminated agriculture and food products or infected plants and animals, and decontaminate premises." This was a responsibility of USDA and DHHS in coordination with DHS and EPA.
- Making "recommendations to the Homeland Security Council, within 120 days of the date of this directive, for the use of existing, and the creation of new, financial risk management tools encouraging self-protection for agriculture and food enterprises vulnerable to losses due to terrorism." This was a responsibility of USDA.
- Working with state and local governments and the private sector to develop:
  - "A National Veterinary Stockpile (NVS) containing sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy and that will be capable of deployment within 24 hours of an outbreak."
  - "A National Plant Disease Recovery System (NPDRS) capable of responding to a high-consequence plant disease with pest control measures and the use of resistant seed varieties within a single growing season to sustain a reasonable level of production for economically important crops."

Both were requirements of USDA in coordination with DHS and in consultation with DHHS and EPA.

"Outreach and Professional Development". HSPD-9 specified that the Secretaries shall:

- Work "with appropriate private sector entities to establish an effective information sharing and analysis mechanism for agriculture and food." This was a responsibility of DHS in coordination with USDA, DHHS and other appropriate departments and agencies.
- Support "the development of and promote higher education programs for the protection of animal, plant, and public health."[10] This was a responsibility of USDA and DHHS in consultation with DHS and the Department of Education (ED).
- Support the development of and promotion of "a higher education program to address protection of the food supply." This was a responsibility of USDA and DHHS in consultation with DHS and ED.
- Establish "opportunities for professional development and specialized training in agriculture and food protection, such as internships, fellowships, and other postgraduate opportunities that provide for homeland security professional workforce needs." This was a responsibility of USDA and DHHS.

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[9] Homeland Security Presidential Directive/HSPD-9—Defense of United States Agriculture and Food; Jan. 30, 2004

[10] Homeland Security Presidential Directive/HSPD–9—Defense of United States Agriculture and Food; Jan. 30, 2004

"Research and Development". HSPD-9 required:

- Accelerating and expanding "development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases." This was a responsibility of DHS, USDA, DHHS, EPA and other appropriate departments and agencies in consultation with the Director of the Office of Science and Technology Policy (OSTP), with DHS coordinating the efforts.
- Developing "a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases."This was a responsibility of USDA and DHS; DHS constructing the National Bio and Agro-defense Facility (NBAF) meets this requirement.
- Establishing "university-based centers of excellence in agriculture and food security."This was a responsibility of DHS in consultation with USDA and DHHS, but funding for these centers has been terminated by DHS.

The summary above does not include all the details in HSPD-9, but it does note departments and agencies responsible for each requirement. For almost every task, there were multiple departments and agencies involved which would make every task very complex. Nonetheless, all six requirements are vitally important to protecting U.S. agriculture and food.

Separating HSPD-9 from HSPD-10—Bioterrorism for the 21st Century [11]

As already noted, HSPD-9—protecting agriculture and food from bioterrorism—was signed on January 30, 2004, while HSPD-10—protecting people from bioterrorism—was finalized on April 28, 2004. There were likely sound reasons in 2004 to separate bioweapon threats to people from bioweapon threats to agriculture and food, but the result of that over the past decade and a half is that agriculture and food have received minimal biodefense attention or funding.

That's surprising for at least two reasons: (1) Essentially every country that ever developed an offensive bioweapons program, including the U.S., created weapons targeting agriculture as well as people; and (2) almost every pandemic threat today is a zoonotic disease that can spread from animals to people. As a result, significant federal funding should be focused on confronting and stopping these threats in the animal host; that's not being done.

The only statement regarding agriculture and food in HSPD-10 referenced "new programs to secure and defend our agriculture and food systems against biological contamination." [12] That's basically delineating a food safety role as a small part of HSPD–10. And, in fact, it was HSPD-7 that outlined homeland security obligations regarding food safety. [13] Responsibilities for meat, poultry, and egg products went to USDA; the agency responsible for inspecting those processing activities. Inspections for everything other than meat, poultry, and egg products is the responsibility of the Food and Drug Administration (FDA); a component within DHHS.

That might actually explain some of the disparities between HSPD-9 and HSPD-10, e.g., why HSPD-10 specifies "increased funding for bioterrorism research within DHHS by thirty-fold"to protect human health, while USDA got nothing for bio/agroterrorism research within HSPD-9 to protect plant and animal health. Food was delineated by food processing responsibilities for USDA and DHHS/FDA, with little focus on safeguarding agriculture pre-harvest activities, i.e., protecting food crops or food animals from infectious diseases or bioweapons. Thus, USDA and DHHS have nearly equal roles in HSPD-9 (with DHS leading), while DHHS has an appropriately dominant role in HSPD-10 (also with DHS leading) with USDA having a minor food safety role.

Infectious diseases and biological weapons target living things, people, plants, and animals. As noted above, bioweapon programs commonly included pathogens of plants and animals, not just people. Why? Because food-deprived or starving people are generally less fit to fight and more likely to surrender.

Evidently, al Qaeda knew this, since their bioweapons list included 10 pathogens targeting animals and plants, and only 6 targeting people.

U.S. Bio/Agrodefense Status Today

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[11] Homeland Security Presidential Directive/HSPD–10—Biodefense for the 21st Century, April 28, 2004

[12] Homeland Security Presidential Directive/HSPD-10—Biodefense for the 21st Century, April 28, 2004

[13] Homeland Security Presidential Directive/HSPD-7—Critical Infrastructure Identification, Prioritization, and Protection, December 17, 2003

U.S. biodefense efforts have been lacking for decades as pointed out in multiple reports; first by the Commission on the Prevention of Weapons of Mass Destruction (WMD) Proliferation and Terrorism,[14],[15] and then by the bipartisan Blue Ribbon Study Panel on Biodefense.[16],[17] The Commission looked at all WMD threats, and in their 2010 report card, biological risks received a failing grade; an "F." All four citations concentrated on biothreats to people, although the Blue Ribbon reports referenced threats to animals, primarily from a "One Health" perspective. The 2015 Blue Ribbon[18] report highlighted thirty-three major shortcomings requiring urgent attention by Washington, DC policymakers. The top three most problematic were: (1) no national leader; (2) no strategic plan; and (3) no dedicated budget. Unfortunately, none of these shortcomings have yet been corrected.

Since few elements dealt with agriculture, K-State raised the bio/agrodefense issue with Blue Ribbon Panel Members. That led to a Panel hearing on the K-State campus on January 26, 2017. The outcome of that was a special focus report entitled, "Defense of Animal Agriculture."[19] Since Senator Lieberman will be covering Blue Ribbon reports, the only other issue that should be noted from the hearing at K-State is that defense of plant agriculture was discussed as well. It's our understanding those threats will be addressed in a separate report.

Bio/Agrodefense Focus at K-State

As the Committee knows, protecting U.S. agriculture is a mission of America's land-grant universities; that began in 1862 when President Lincoln signed the Morrill Act. As someone relatively new to land-grant administration—but someone with a lifelong commitment to national defense —I'm convinced that the Nation's land-grant universities can and should play a significant role in U.S. bio/agrodefense. These institutions participate in protecting agriculture and food in their states each and every day.

Thus, we would encourage the Committee to integrate the land-grant universities into whatever solutions are developed. K-State stands ready to participate on the national team and lead when asked or when necessary. Protecting America's agriculture and food infrastructure is too important not to.

K-State is not new to this realm. Back in 1999 with encouragement from the Chairman of this Committee, K-State developed a 100-page "Homeland Defense Food Safety, Security, and Emergency Preparedness Program"[20] that detailed how to protect America's food crops, food animals, and food supply from biothreats. Later that year, K-State's President Jon Wefald testified before the U.S. Senate's Emerging Threats Subcommittee regarding the "Agricultural Biological Weapons Threat"[21] facing America. That Senate subcommitee was also chaired by Kansas Senator Pat Roberts.

The "Big Purple Book," as the 1999 program became known, documented the need for a biocontainment facility capable of conducting R&D on biothreats to food crops, food animals, and the food supply. Prior to September 11th and the anthrax attacks in 2001, little traction was gained for the need to build it. Post-09/11/2001, state and federal funding was obtained, and the Biosecurity Research Institute (BRI) at Pat Roberts Hall (PRH) became a reality.

The BRI/PRH is located immediately adjacent to the NBAF site and it includes five BSL-3Ag rooms that can be configured for research with cattle, pigs, sheep, goats and poultry. Work has been done on numerous species to date, including white-tailed deer in 2017 to determine their susceptibility to RVF. In addition to BSL-3Ag labs, the BRI/PRH has dedicated BSL-3 space for conducting research on crop and food pathogens. Wheat Blast R&D has been ongoing since 2009 and food

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[14] The Clock is Ticking: A Progress Report on America's Preparedness to Prevent Weapons of Mass Destruction Proliferation and Terrorism; Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, October 21, 2009

[15] Prevention of WMD Proliferation and Terrorism Report Card; Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, January, 2010

[16] A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts; A Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, October 2015

[17] Biodefense Indicators: One Year Later, Events Outpacing Federal Efforts to Defend the Nation; A Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, December 2016

[18] A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts; A Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, October 2015

[19] Special Focus: Defense of Animal Agriculture; Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, October 2015

[20] Homeland Defense Food Safety, Security, and Emergency Preparedness Program, March 22, 1999. See:*http://www.k-State.edu/nbaf/documents/1999-Homeland-Defense-Program.pdf*

[21] Agricultural Biological Weapons Threat, October 27, 1999. See: *http://www.k-State.edu/nbaf/documents/1999-US-Senate-Testimony.pdf*

safety research began soon thereafter. The latter included studies for the Army whereby eight 1-ton grinds of hamburger were done in October 2011 to validate whether food pathogens could be detected at the end of a commercial process. The breadth of food-related biocontainment R&D conducted under one roof makes the BRI/PRH unique-in-the-world.

K-State jump-started NBAF research in the BRI/PRH on RVF in 2013, JE in 2014, CSF in 2015, and ASF in 2016. We were able to do this because the State of Kansas agreed to fund $35 million for NBAF research in the BRI/PRH as part of our "best and final offer" for NBAF during the site selection competition. Research and development (R&D) continues on all four of these FADs, but the Kansas funding commitment will end in fiscal year 2019 when the last $5 million is appropriated. The majority of the research is conducted by K-State faculty, staff and students, but collaborators from the U.S. Department of Agriculture's (USDA's) Center for Grain and Animal Health Research (CGAHR) in Manhattan participate on some of the NBAF-related FAD projects. Moreover, CGAHR conducts other USDA BSL–3/3Ag biocontainment research in K-State's BRI/PRH as well. Going forward, federal support is needed for R&D on RVF, JE, CSF, and ASF to help mitigate these threats to U.S. animal health and public health.

Until NBAF is fully operational in 2022/23, USDA has no biocontainment facilities where R&D can be conducted on zoonotic FADs. Moreover, DHS stopped funding CSF and ASF research in 2017 at the Plum Island Animal Disease Center (PIADC); an antiquated facility unsafe for work with zoonotic diseases. Consequently, training the NBAF R&D workforce is highly reliant on the BRI/PRH until the new DHS facility becomes operational.

PROPOSED PATH FORWARD

The importance of implementing the requirements outlined in HSPD-9[22] to safeguarding American agriculture in a globalized world cannot be overstated. They are all critically important, but strides made to implement them in the early years have eroded today.

K-State believes that statutory authorization—with clearly delineated and enforceable accountability—along with the appropriation of funds to support the following key provisions in HSPD-9 will advance this crucial humanitarian and economic mission.

(1) Enhance Intelligence Operations and Analysis Capabilities—Leverage "awareness and warning"intelligence information to conduct federal, state, and local agriculture and food "vulnerability assessments." Advanced warning of over-the-horizon biothreats is vital, but today, the U.S. is often minimally aware and insufficiently warned. One reason appears to be insufficient numbers of bio/agrodefense subject matter experts (SMEs)—veterinarians, animal scientists, crop scientists, plant pathologists, etc.—with high-level security clearances to assess classified intelligence.

(a) Security Clearances—Increase the number of food crop, food animal, and food supply SMEs with high-level security clearances (TS-SCI) to monitor bio/agrodefense threats worldwide.

(b) Sensitive Compartmented Information Facilities (SCIFs)—Increase the number of SCIFs with secure communications that have agriculture/food SME analysts and/or cleared SME advisors with TS-SCI clearances.

(c) USDA Clearances—Increase the number of USDA personnel with TS-SCI clearances. It's unknown how many bio/agrodefense SMEs there are within the intelligence agencies, but there are nowhere near enough within USDA. Conversations in 2016 with the USDA's chief scientist and a USDA intelligence analyst confirmed their frustrations with an inability to convey critical classified information within USDA to make it actionable. This creates huge federal impediments to safeguarding agriculture, particularly when DHS stopped meeting their HSPD–9 responsibilities in 2016/17. Undertaking "vulnerability assessments,"[23] developing "mitigation strategies," conducting "response planning and recovery," and defining time-critical "research and development" strategies are virtually impossible when there is limited awareness and no warning. This must be rectified immediately.

(d) Intelligence Fusion Centers (IFCs)—Increase the number of state IFCs with agriculture and food SMEs with TS-SCI clearances. The Kansas IFC (KIFC) appears to be the only such center of over 70 nationwide that has a biothreat team

[22] Homeland Security Presidential Directive/HSPD-9—Defense of United States Agriculture and Food; Jan. 30, 2004

[23] Homeland Security Presidential Directive/HSPD-9—Defense of United States Agriculture and Food; Jan. 30, 2004

with cleared SMEs capable of assessing the full range of biohazards to food crops, food animals, the food supply, and people. These include a DVM and PhDs from K-State and MDs from the University of Kansas Medical Center as well as SMEs from multiple state agencies. These SMEs allow the KIFC to assess global intelligence for the purpose of preventing bioterrorism attacks and preparing for natural infectious disease events emerging globally. Thus, the KIFC focuses "left of boom" (prior to an attack or outbreak) rather than "right of boom" (after the event) like other fusion centers. This model should be emulated beyond Kansas, because it allows state-specific planning with regard to "vulnerability assessments, mitigation strategies, and response planning and recovery."

(2) Emerging FAD Threats—Exploit "awareness and warning" telligence information regarding newly emerging biothreats to establish bio/agrodefense "mitigation strategies"at USDA CGAHR prior to NBAF becoming operational and fund "research and development"in the BRI/PRH.

(3) Zoonotic Animal Disease Research—Establish federal threat "mitigation strategies"[24] for zoonotic FADs at USDA CGAHR prior to NBAF becoming operational and fund RVF and JE "research and development"in the BRI/PRH.

(4) Non-Zoonotic Foreign Animal Disease Research—Expedite federal threat "mitigation strategies"for non-zoonotic FADs by moving the research portfolios for ASF and CSF from USDA PIADC to CGAHR and funding ASF and CSF "research and development"in the BRI/PRH until NBAF becomes operational.

(5) Private-Sector Outreach—Enhance private-sector "outreach and professional development"by leveraging the Nation's land-grant universities that interact routinely with private-sector agriculture producers and food processors nationwide.

An implementation problem for HSPD-9 was the expectation that the Federal Government would be able "to establish an effective information sharing and analysis mechanism"with private-sector agriculture producers and food processors. Having the Federal Government show up at the door is likely to be viewed with distrust and skepticism. In some instances, State Government might be a somewhat better alternative, but this is an area where the Nation's land-grant universities could serve as the facilitators/trusted brokers.

(6) Higher Education Programs—Support the development of higher education programs as called for in HSPD-9 "outreach and professional development."

(a)

For Capacity Building—'In veterinary medicine, public health, and agriculture."

(b) For Protection—"Of the food supply."

(7) Surveillance Systems—Increase support for "awareness and warning" surveillance systems to provide early detection of U.S. disease outbreaks.

(a) For Food Animals—the National Animal Health Laboratory Network (NAHLN)

(b) For Food Crops—the National Plant Diagnostic Network (NPDN)

(c) For Wildlife—Unknown

(8) Agriculture Response and Recovery—Support agriculture/food "response planning and recovery"systems for the purpose of reestablishing full operations following infectious disease outbreaks.

(a) For Food Animals—By utilizing and expanding the USDA National Veterinary Stockpile (antigen bank) as called for in HSPD-9 "response planning and recovery"and endorsed by livestock producer groups and animal health companies.

(b) For Food Crops—By designing a National Plant Disease Recovery System as called for in HSPD-9 "response planning and recovery" and endorsed by crop producer groups and related stakeholders.

(9) FAD Advance Development and Manufacturing (ADM)—Improve "response planning and recovery"[25] by creating FAD ADM capabilities for producing vaccines and other countermeasures against livestock-only and zoonotic FADs similar to ADM capabilities for human infectious diseases.

(10) Screening/Inspecting Agriculture and Food Items—Validate existing screening technology "mitigation strategies" and develop new/improved technologies.

(11) National Livestock Readiness Program (NLRP)—Ensure DHS in standing up the NLRP to help meet the requirements of the fiscal year 2017 "Securing Agriculture and Food Act" (Public Law 114–328) in support of HSPD–9.

(12) National Biodefense Strategy (NBS)—Confirm that the NBS — Section 1086, fiscal year 2017 National Defense Authorization Act (Public Law 114–328) —

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[24] Homeland Security Presidential Directive/HSPD-9—Defense of United States Agriculture and Food; Jan. 30, 2004

[25] Homeland Security Presidential Directive/HSPD-9— Defense of United States Agriculture and Food; Jan. 30, 2004

includes agriculture (animal health and plant health) and that bio/agrodefense components are adequate and implemented effectively.

(13) Biodefense Leadership—Support the Blue Ribbon Study Panel on Biodefense's proposal to centralize bio/agrodefense leadership.

BIO/AGRODEFENSE BOTTOM LINE

The bottom line today regarding bio/agrodefense is that "the clock is ticking"[26] as stressed by the WMD Commission back in 2009. Much must be done to safeguard American agriculture in a globalized world—the U.S. agriculture and food critical infrastructure is not well protected from potentially catastrophic biological events.

Bioterrorist attacks on America's food crops and/or food animals could devastate the U.S. economy, and the global economy wouldn't be far behind. America still feeds the world. Natural disease outbreaks could lead to similar outcomes.

Food shortages in the U.S. may not occur immediately, or ever, depending on the effectiveness of the attack or the magnitude of the outbreak. Nonetheless, there could still be hugely problematic outcomes for America and the world.

Well-conceived Presidential Directives have not gotten the job done; neither did the Patriot Act nor the Homeland Security Act that preceded the directives. Key components of American critical infrastructure—agriculture and food—are vulnerable to terrorist attacks with bioweapons and undeliberate infectious disease outbreaks, and the U.S. is unprepared to confront these threats.[27]

Congress must act before it's too late.

Senator BURR. This hearing is adjourned.

[Whereupon, at 12:10 p.m., the hearing was adjourned.]

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[26] The Clock is Ticking: A Progress Report on America's Preparedness to Prevent Weapons of Mass Destruction Proliferation and Terrorism; Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, October 21, 2009

[27] Bodin, Madeline; "U.S. Remains Unprepared for Agricultural Disease Outbreaks," Emergency Management, November 13, 2017