S. Hrg. 114–639

THE FEDERAL PERSPECTIVE ON THE STATE OF OUR NATION'S BIODEFENSE

HEARING

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

APRIL 14, 2016

Available via the World Wide Web: http://www.fdsys.gov/

Printed for the use of the
Committee on Homeland Security and Governmental Affairs

U.S. GOVERNMENT PUBLISHING OFFICE

22–772 PDF WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

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CONTENTS

WITNESS

THURSDAY, APRIL 14, 2016

ALPHABETICAL LIST OF WITNESSES

APPENDIX

THE FEDERAL PERSPECTIVE ON THE STATE OF OUR NATION'S BIODEFENSE

THURSDAY, APRIL 14, 2016

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 10:02 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Ron Johnson, Chairman of the Committee, presiding.

Present: Senators Johnson, Portman, Ayotte, Ernst, Sasse, Carper, McCaskill, Tester, Booker, and Peters.

OPENING STATEMENT OF CHAIRMAN JOHNSON[1]

Chairman JOHNSON. Good morning. This hearing will come to order. I certainly want to thank all of the witnesses for taking the time to attend and for taking the time to write your thoughtful testimonies. We appreciate it. It will all be in the record.

This is an important hearing. I guess I would consider this our second hearing on this subject. We had Governor Tom Ridge and Senator Joe Lieberman here, earlier, with their Blue Ribbon Study Panel on Biodefense, which is a very well-thought-out document with a lot of detail. Probably the main takeaway from that was the fact that we just have no central authority to kind of accumulate all of the data, to accumulate the budgets, and really to direct potential activity—particularly in the event of a significant outbreak, whether it is—and, of course, we have dealt with Ebola and avian influenza. We have had hearings on both of those—and, now, the Zika virus.

In Wisconsin, we have something—and I cannot pronounce it—Elizabethkingia meningoseptica. I think I might have actually gotten that right. It has infected about 59 people, already 18 people in our State. I appreciate the work the Centers for Disease Control and Prevention (CDC) has already done on that, responding very quickly to a letter I sent. It sounds like you have really taken that very seriously and have been trying to find the common cause. Very interesting, I guess. Troubling in many respects, but, anyway, this is an important hearing.

I do ask consent that my opening written statement be entered in the record. But, as with any hearing, the main goal is to lay out a reality, so we all understand really what we are facing here. And,

[1] The prepared statement of Senator Johnson appears in the Appendix on page 37.

when it comes to the different types of biothreats, these can be very serious.

Maybe the good news about all of them is that the same types of procedures, processes, and kind of management structure can be put in place to respond to just about any of them, because the threats are always changing, as we are seeing just the different type of pathogens and the different biological threats that I just listed.

So, again, I appreciate all of your work and effort in this. I appreciate you coming here.

With that, I will turn it over to Senator Carper.

OPENING STATEMENT OF SENATOR CARPER[1]

Senator CARPER. Thank you, Mr. Chairman. I understand there is a vote at 10:30.

Chairman JOHNSON. Yes.

Senator CARPER. Do you want to just keep rolling, or do you want us to recess for the vote? Do you have to think about it?

Chairman JOHNSON. It would probably be nice to keep rolling if we could, so why don't we try—you and I will tradeoff. Thank you.

Senator CARPER. OK. Good. So, when the vote starts, I will leave—with the Chairman's concurrence—and go vote and come back right away. And, you guys can just keep talking. And then, we will start asking questions.

Thank you all for coming. Mr. Chairman, thank you for bringing this together. This is an even more important hearing, given what is going on with the Zika virus. But, as the Chairman has said, last fall we convened a hearing to examine a report by this Blue Ribbon Study Panel on Biodefense chaired by a couple of our good friends—Joe Lieberman and Tom Ridge. And, one of the main points in their report was, there ought to be somebody in the Administration, one senior person, to lead it. They thought the Vice President would be a pretty good one, and so we will see. We had a meeting with the Vice President and the two co-chairs, and we will see where that leads.

But there is a lot of work to be done, and, fortunately, the panel provided recommendations to further enhance our ability to prevent, to detect, to respond to, and to recover from a biological incident.

Today, we have the opportunity to discuss those recommendations with the heads of several agencies—senior people in several agencies, who would be responsible for implementing some of the recommendations of the earlier panel. I am eager to hear your thoughts and also hear how you believe we can further improve our country's biodefense system. This is an important conversation to have in the context of recent global events, including a couple that are emerging even as we speak.

Ebola continues to threaten West Africa, and—after claiming thousands of lives—the spread of the virus has declined significantly, thanks in no small part to the investments that America has made in the health systems of the countries that were hardest hit by the epidemic. I think it is one of the proudest chapters in

[1] The prepared statement of Senator Carper appears in the Appendix on page 39.

our Nation's history as of late, and I am very proud of the work that was done, including by some of you and the folks that you lead. But, that said, the recent news of more cases in Guinea and Liberia underlines the need to continue supporting our international partners in their efforts to combat this disease.

We are also almost one year removed from a significant outbreak of highly pathogenic avian flu, which decimated some parts of our Nation's poultry industry. The Chairman's State was badly affected, as were a number of others in the Midwest. And, while infections of poultry have been limited in number so far this year, thank God, we must remain vigilant and continue to enforce good biosafety practices at poultry farms across the country to safeguard against another epidemic.

Meanwhile, we are quickly approaching the beginning of mosquito season in most parts of the United States. Unfortunately, this presents us with a new threat—this one in the form of the Zika virus that we are hearing a whole lot about. The virus has spread explosively throughout Central and South America. It has already reached Puerto Rico and other U.S. territories and is expected to spread further as the weather warms. The World Health Organization (WHO) estimates that as many as 4 million people in the Americas could contract Zika by the end of the year. Researchers continue to learn more about the virus every day—but it is clear that the health impacts can be devastating, particularly for pregnant women and their unborn children. We have all heard that the CDC has just recently confirmed this week something that a lot of folks have speculated for a while—that the Zika virus is a cause of severe birth defects.

While most of the Zika cases diagnosed in American citizens to date have been traced to travel abroad, we must be prepared for the virus to present itself locally to us. So, it has been encouraging to see a proactive, coordinated response from the President and his Administration to this threat. For example, Federal agencies are helping State and local governments enhance their capacity to better detect and track the virus. There are also significant mosquito control efforts underway in areas that are most at risk.

We also know that medical countermeasures and vaccine development are being rigorously pursued. We applaud that. To help fund these efforts, the Administration announced last week its intent to redirect almost $600 million from other programs—including funds originally designated for Ebola—and spend it on Zika response efforts. I believe the President made the right call in this instance. I am glad he has done this. While these efforts continue, Congress should continue to carefully consider the President's request for additional resources to combat this threat.

In addition, we must ensure that our public health officials have the tools that they need to protect us from Zika and to prepare us for future threats. But, at the same time, we should not let our foot off of the gas when it comes to our efforts to contain dangerous diseases such as Ebola and avian influenza.

With that, we welcome each of you. Thank you for your service, and thank you for your testimony today.

Chairman JOHNSON. Thank you, Senator Carper.

It is the tradition of this Committee to swear in witnesses, so if you will all rise and raise your right hand. Do you swear the testimony you will give before this Committee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. HATCHETT. I do.

Dr. REDD. I do.

Mr. SHEA. I do.

Mr. FIROVED. I do.

Mr. CURRIE. I do.

Chairman JOHNSON. Somebody has a snappy tune there.

Our first witness is Dr. Richard Hatchett. Dr. Hatchett is the Acting Director of the Biomedical Advanced Research and Development Authority (BARDA) and the Acting Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS). That is a big title. Among his many past roles, Dr. Hatchett has served at the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), on the White House National Security staff, and in the White House Homeland Security Council (HSC) as the Director for Biodefense Policy. Dr. Hatchett.

TESTIMONY OF RICHARD J. HATCHETT, M.D.,[1] ACTING DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. HATCHETT. Chairman Johnson, Ranking Member Carper, and distinguished Members of the Senate Committee on Homeland Security and Governmental Affairs, good morning. Thank you for inviting me to testify on the state of our Nation's biodefense. I am Richard Hatchett, Acting Director of the Biomedical Advanced Research and Development Authority, and my testimony today will focus on steps taken by the Office of the Assistant Secretary for Preparedness and Response to strengthen our Nation's health security as well as the contributions of my own office toward that end.

We have made substantial progress in the past 10 years to advance the State of our national biodefense. Thanks to the support of this Committee and others in Congress, we have established BARDA and continue to make critical investments in biodefense and our health care system. However, as highlighted by recent challenges, such as Ebola, Middle East Respiratory Syndrome (MERS), and Zika, there remain gaps in our preparedness.

As this Committee is aware, a recent report by the Blue Ribbon Study Panel on Biodefense has indicated that the United States is underprepared for biological threats and that the Nation is dangerously vulnerable to biological events—whether natural, intentional, or unintentional in origin.

Where the civilian, public health, and medical response to such events is concerned, the ASPR is charged, by statute, to play a strong leadership role. The ASPR serves as the principal adviser to the Secretary of Health and Human Services on all matters related

[1] The prepared statement of Dr. Hatchett appears in the Appendix on page 41.

to Federal medical preparedness and response for public health emergencies. The ASPR chairs the HHS Disaster Leadership Group (DLG), which convenes in response to complicated emergencies, and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates medical countermeasures development efforts across the interagency. The ASPR is the author and custodian of the National Health Security Strategy (NHSS), which focuses on protecting public health during an emergency. The ASPR oversees 2 critical programs that support medical response.

The first, the Hospital Preparedness Program (HPP), enhances medical preparedness and resiliency at the community level through its support of health care coalitions.

The second, the National Disaster Medical System (NDMS), deploys medical personnel and related assets when local resources are overwhelmed.

The PHEMCE, for its part, promotes the development and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear threats (CBRN), pandemic influenza, and emerging infectious diseases. PHEMCE coordination and decisionmaking encompass all stages of the medical countermeasure life cycle, from identifying requirements and developing target product profiles through product development to distribution and dispensing. The PHEMCE has an outstanding record of success and is now being studied as a model for global preparedness against emerging infectious diseases.

To date, at least 23 medical countermeasures that BARDA has supported have been approved, licensed, or cleared by the Food and Drug Administration (FDA) under PHEMCE's purview. Of these, 15 have been approved since 2011 and 5 have been approved in the last 12 months. 17 products—ranging from anthrax antitoxins and smallpox vaccines to anti-neutropenia cytokine therapeutics for acute radiation syndrome and an array of products for the management of thermal burns—have been added to the Strategic National Stockpile (SNS) under Project BioShield, with another 7 anticipated between now and the end of fiscal year (FY) 2018.

Overall, since the year 2000, the FDA has approved 89 medical countermeasures for CBRN threats and pandemic influenza, as well as 17 supplemental changes to already approved applications and 71 modifications to diagnostic devices. This investment in preparedness has already paid dividends. Because of the workforce and capabilities we have developed over the last 10 years, we are much better prepared to respond quickly to emerging threats.

The PHEMCE, for example, facilitated the rapid development and deployment of vaccines, therapeutics, and diagnostics during the Ebola epidemic and is now fully engaged in the response to Zika.

We know, from experience, that a well-coordinated PHEMCE response is a critical enabler of a rapid science and industry response. The PHEMCE succeeds not because a set of government offices succeeds, but because response efforts across the whole of society are supported and coordinated. To respond effectively to threats as diverse and unpredictable as the biological threats we face, nothing less than a whole-of-society response will work.

Thank you again for the invitation to speak with you, and, at this time, I would be happy to address any questions you may have.

Chairman JOHNSON. Thank you, Dr. Hatchett.

Our next witness is Dr. Stephen Redd. Dr. Redd is the Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention. Dr. Redd, who has been part of the Public Health Service for over 30 years, is responsible for all of the CDC's public health preparedness and response activities. Is it pronounced Dr. Redd?

Dr. REDD. Yes, sir.

Chairman JOHNSON. OK, great. Thank you. Dr. Redd.

TESTIMONY OF STEPHEN C. REDD, M.D.,[1] DIRECTOR, OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. REDD. Chairman Johnson, Ranking Member Carper, and distinguished Members of the Committee, my name is Stephen Redd. As you have just heard, I am the Director of the Office of Public Health Preparedness and Response at the CDC, and it is my pleasure to appear today to discuss the work the CDC is doing to prepare and respond to threats to the health of the public.

As you know, the CDC works to protect the public's health by helping communities improve readiness and response. This is for chemical, biological, and radiation emergencies—whether those are naturally occurring events like the Ebola epidemic or the Zika virus epidemic, intentional, or accidental.

There are two key programs at the CDC that enable us to prevent, detect, and respond to public health threats: the Public Health Emergency Preparedness (PHEP) Program and the Strategic National Stockpile. Both programs had their origins before September 11, 2001 (9/11) and the anthrax attacks of 2001. They were greatly expanded after those events in recognition of the need to improve the ability of the public health system to respond in scale and in speed.

The Public Health Emergency Preparedness Program's overall aim is to prepare the Nation to respond to public health emergencies. Since 2002, $10 billion has been devoted to this effort. The program funds 62 awardees: all 50 States, 4 large cities, and 8 territories. And what it actually funds are staff: epidemiologists, laboratory experts, and risk communication experts as well as emergency operations centers, laboratory equipment, planning and exercising efforts, and efforts to respond—or to correct things that are identified in exercises and natural events.

The Strategic National Stockpile is the national repository of lifesaving medicines, vaccines, and medical supplies, such as mechanical ventilators. Currently, the stockpile holds over $7 billion in assets. It operates as part of the Public Health Emergency Medical Countermeasure Enterprise, which you have heard about. The stockpile procures, stores, and delivers supplies in times of emergency.

[1] The prepared statement of Dr. Redd appears in the Appendix on page 59.

Both the Public Health Emergency Preparedness Program and the Strategic National Stockpile were instrumental in the Ebola response and are being used now as part of the Zika response. So let me now turn to Zika.

As of yesterday, 41 countries have reported local transmission of the Zika virus. In the continental United States, over 300 travel-associated cases have been reported. About 1 in 10 of these are in pregnant women. 7 have been acquired through sexual transmission. There currently are no local transmissions by mosquitoes, but the problem exists here because of these travel-associated cases and sexually-transmitted cases. In Puerto Rico, there is transmission from mosquitoes—over 300 cases. About 1 in 6 of these are in pregnant women.

Just to talk about some of the things that we are doing in the response to Zika, you heard from Senator Carper that yesterday the CDC authored a publication that concluded that the Zika virus infection causes severe birth defects. That article also identified a number of the outstanding scientific questions.

On April 1, we convened the Zika Action Plan Summit in Atlanta. This brought together State and local health officials to review the latest scientific information and to jump-start planning at the State and local levels.

We also issued travel guidance for women who are pregnant within 72 hours of identifying the virus in the brains of children and fetuses that had died. We have developed laboratory tests. We are working closely with local health departments and we are implementing mosquito control measures with the government of Puerto Rico to prevent transmission to pregnant women.

Public health threats are ever present. Due to the investments from Congress, the Nation is better prepared to prevent, detect, and respond to health emergencies than we were before the events of September 2001. And, at the CDC, we are on the frontlines to protect Americans from health threats wherever those threats occur. From recent experience, we know that we will be called upon to respond in the future.

Thank you.

Chairman JOHNSON. Thank you, Dr. Redd.

Our next witness is Mr. Kevin Shea. Mr. Shea is the Administrator of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). Mr. Shea carries out the agency's broad mission of protecting and promoting American agriculture, regulating genetically engineered organisms, administering the Animal Welfare Act, and carrying out wildlife damage management activities. Mr. Shea.

TESTIMONY OF KEVIN SHEA,[1] ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Mr. SHEA. Thank you, Mr. Chairman, Senator Carper, Senator Ayotte, and Senator Booker. I appreciate you all being here today to hear us.

[1] The prepared statement of Mr. Shea appears in the Appendix on page 70.

At APHIS, over 8,000 men and women work around the world to protect American agriculture and natural resources against plant and animal pests and diseases. We want to keep them out of the country, but if they do get into the country, we have the expertise and the tools to detect them, to control them, and, hopefully, to eradicate them.

Although the crux of our mission is plant and animal health, we understand that, of course, there is a crucial link between plant and animal health and human health. Our partnerships with the CDC and other Federal and State agencies emphasize this "One Health" (OH) approach.

Animal health can affect human health and human health can affect animal health. That is why it is so important that we communicate and coordinate with each other. That is why the emphasis on "One Health" in the "National Blueprint for Biodefense" is so important and why we strongly support it and appreciate that they emphasized it.

I want to highlight just a few examples of what APHIS does with our partners.

First, we created, within our Veterinary Services Program, a One Health Coordination Center (OHCC). This center works closely with our internal veterinarians to make sure that they are considering the human health aspects of animal health programs.

At the same time, they work with their counterparts in the human health arena to make sure those agencies have an understanding of how what they do can affect agriculture and animal health. Because this communication is so important, we have embedded an APHIS veterinarian in Atlanta with the CDC to exchange information literally every day.

We always share information with our partners about our well-established zoonotic disease surveillance efforts, and when we have information about potentially damaging diseases, we share that quickly. Of course, this Committee knows—as the Chairman and Senator Carper alluded to earlier—you all know the devastating impact avian influenza had last year on our producers, but also the impact it had on the availability and price of eggs and turkey. 1,000 APHIS employees and thousands of contractors and State employees did the important frontline work to control that disease, but, behind the scenes, our partnerships with the groups with us today were there and were very important. Our scientists shared information with the CDC about avian influenza—about the virus. We had no reason to think that that virus was going to be a human health threat, but avian influenza viruses mutate. And so, we were constantly supplying information to the CDC so they could develop candidate vaccines if indeed it ever should have jumped over to be a human health problem.

We also are working very closely with our colleagues in the Fish and Wildlife Service to test wild birds. And, the good news is, we tested 43,000 wild birds over the last 9 months and have found no more examples of high-path avian influenza in those birds. So, that is some hopeful information.

We spent a lot of time assessing our efforts in controlling avian influenza last year as well as on our capability to detect it. And, we compiled a very substantial, very large new planning document

on what we can do to prevent avian influenza from becoming a huge problem again. And, we had a chance to test that out already. In Indiana, in January, there was indeed one case of highly pathogenic influenza and 9 cases of low-pathogenic avian influenza associated with that. We were able to get on top of that, immediately, to wipe that out, and we have had no cases of avian influenza other than that since last June 17.

Something we learned, in all of our review, was that we need to rebuild our capacity to respond to large animal health emergencies. We have 200 fewer animal health professionals—veterinarians and animal health technicians—than we had 10 years ago. We need to rebuild that workforce. And Secretary Tom Vilsack certainly recognized that, and, in the President's budget request for FY 2017, there is a proposed $30 million increase for animal health emergency response because we realized just how lucky we were to get on top of avian influenza after all of the damage that it did do.

Mr. Chairman, this concludes my testimony, and I appreciate the opportunity to be here. I would certainly be happy to answer any questions.

Chairman JOHNSON. Thank you, Mr. Shea.

Our next witness is Dr. Aaron Firoved. He is the Director for the National Biosurveillance Integration Center (NBIC) in the Office of Health Affairs (OHA) at the Department of Homeland Security (DHS). He previously served as the Senior Biodefense Advisor to the Assistant Secretary for Health Affairs and Chief Medical Officer (CMO) of the Department.

Dr. Firoved?

TESTIMONY OF AARON M. FIROVED, PH.D.,[1] DIRECTOR, NATIONAL BIOSURVEILLANCE INTEGRATION CENTER, OFFICE OF HEALTH AFFAIRS, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. FIROVED. Sir, we have generations of people being called "Firewood" in my family. [Laughter.]

Chairman Johnson, Ranking Member Carper, and distinguished Members of this Committee, I want to thank you for inviting me to speak with you today. I appreciate the opportunity to testify on the Department of Homeland Security's role in biodefense, and it is an honor to sit beside my colleagues from HHS, the U.S. Department of Agriculture, and the Government Accountability Office (GAO). As you mentioned, I am the Director of the National Biosurveillance Integration Center. I am a microbiologist by training. I have done some work with anthrax at the NIH. And, I understood biodefense policy through service to this Committee, so I want to thank you. These experiences have given me a broad understanding of the biological threat to our homeland and a strong commitment to help improve our Nation's biodefense and progress.

The threats and risks posed by emerging infectious diseases and the use of biological agents by terrorist organizations, violent extremists, and rogue States will continue to challenge our ability to warn, prepare, and protect the homeland.

[1] The prepared statement of Dr. Firoved appears in the Appendix on page 77.

In the wake of these threats, the Department of Homeland Security remains fully engaged and proactive in characterizing the threat, providing warning of emerging and imminent diseases, and ensuring that the critical missions of the Department will continue, unabated, should a biological event occur.

For example, during our recent Ebola virus disease outbreak in West Africa, DHS provided intelligence analysis to the interagency, State and local governments, and first responders. We directed research to better characterize the threat of Ebola persistence and fill gaps in public health and operational responses. And, we coordinated and implemented the enhanced screening for more than 42,000 international passengers at 5 airports.

Today, we continue to build upon these lessons learned from the responses to Ebola and apply them to other biological threats, as we tackle the emergence or reemergence of viruses like Zika, where we are ensuring that our partners continue to have timely information, our workforce is informed of protective measures, and the health interests of detainees in our care and custody is provided for. We must remain vigilant and innovative as biological threats continue to evolve and as new threats emerge.

The DHS Office of Health Affairs coordinates the Department's biodefense activities to understand and meet these threats, today, and to be ready for the threats that will emerge, tomorrow. OHA synthesizes biological threat information from multiple sources and takes a true "One Health" approach to biodefense and emergency response.

For large-scale biological events, having knowledge as quickly as possible allows for informed decisions that can save American lives. And to this end, the Department's operational biodetection and biosurveillance programs are critical to our Nation's biodefense.

The National Biosurveillance Integration Center is uniquely situated within DHS to provide a fusion of human health, animal health, and environmental data to ensure our Nation's decisionmakers have timely, accurate, and actionable information.

To accomplish this, we monitor thousands of data sources and leverage the expertise of 14 Federal departments and agencies, who are members of our charter—including those that you see at this table here—and then integrate this array of information into reports on biological incidents that could potentially cause economic damage, social disruption, or loss of life.

Reports by my good colleagues at GAO and the Blue Ribbon Study Panel on Biodefense have acknowledged the progress that NBIC has made in delivering daily situational awareness to our partners, but we still have a lot of work to do to fully realize the vision that this Committee helped to start with comprehensive biosurveillance integration.

To address this, we are developing new collaboration tools, pursuing innovative data sources and methods, and fostering greater stakeholder engagement.

DHS's BioWatch Program provides Federal, State, and local leaders with actionable information on detection of a biological agent to enable a coordinated and effective response. One important and frequently overlooked benefit of our BioWatch Program is how we work with each local jurisdiction to ensure that the decisionmakers

are familiar with how the coordinated response will unfold should the detection of one of these agents occur. There is no other program that provides this layer of biological defense.

The DHS Science and Technology Directorate (S&T) is currently collaborating with OHA on enhancements to the BioWatch Program that will shorten the time needed to detect biological agents as well as address other short-term and long-term capability needs.

One of our most critical roles is in the integration of local public health with emergency management, law enforcement, and intelligence community (IC) partners—and their preparation and response to biological events. One initiative we are developing in coordination with HHS is the "First Responder Vaccine Initiative." We are evaluating the feasibility of a voluntary pre-event anthrax vaccination program for first responders using the anthrax vaccine scheduled to rotate out of CDC's Strategic National Stockpile. I want to thank this Committee for moving on S. 1915, Senator Ayotte's legislation authorizing this pilot program.

I thank you for your time, and I look forward to answering your questions.

Chairman JOHNSON. Thank you, Doctor.

Our final witness is Chris Currie. Mr. Currie is the Director of Homeland Security and Justice at the Government Accountability Office, where he leads the agency's work in evaluating emergency management, national preparedness, and critical infrastructure protection issues. In this role, Mr. Currie has led the reviews of numerous Federal programs as well as efforts to prevent, plan for, and respond to natural and manmade disasters and terrorist attacks. Mr. Currie.

TESTIMONY OF CHRISTOPHER P. CURRIE,[1] DIRECTOR, HOMELAND SECURITY AND JUSTICE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. CURRIE. Thank you, Chairman Johnson, Ranking Member Carper, and other Members of the Committee who are here today. I really appreciate the opportunity to be here, and, today, I would like to talk about GAO's work on biodefense.

Defending the United States from naturally occurring or manmade biological events is a massive and difficult effort. Leadership and coordination are critical to such a large and fragmented effort, not only at the Federal level, but across levels of government and the private sector. The number of Federal departments at this table today, alone, demonstrates this point.

In a hearing last fall, your Committee heard the findings and recommendations of the Blue Ribbon Study Panel on Biodefense. Our work through the years has come to many similar conclusions and recommendations. Today, I would like to talk about this work—ranging from coordinating the entire biodefense enterprise down to improving various specific programs.

At the highest level, the Blue Ribbon Study Panel on Biodefense concluded that there is no central leader, no comprehensive national strategic plan, and no all-inclusive dedicated budget for bio-

[1] The prepared statement of Mr. Currie appears in the Appendix on page 82.

defense. Our work has also found that there is no national strategy or single focal point for biodefense.

As an illustration, there are over two dozen Presidentially appointed officials with biodefense roles. Over 5 years ago, we recommended that the Homeland Security Council within the White House develop a strategy and designate a focal point for coordination.

They did issue a strategy in 2012 for biosurveillance and designated offices within the White House as focal points—and this is progress and it shows a commitment to coordinating biodefense efforts. However, it just does not go far enough.

The biosurveillance strategy does not identify resource and investment needs, which is critical to help prioritize resources across such a complex enterprise. We have heard that the National Security staff created a more specific implementation plan of the strategy. However, we do not know the extent to which it is actually being used across government and across these departments. Thus, we do not know if it will operationalize coordination and prioritization of resources, as we think it should.

We have also identified challenges with specific agency biodefense programs, such as those within DHS. Our report last October found that 12 years after the BioWatch program was first deployed, there is still not reliable information about its capabilities. This is because it was put in the field so quickly without performance requirements.

We have also found that, because BioWatch was not fully tested, its uncertainties and limitations are unknown. We recommended that DHS not pursue upgrades until it establishes system performance requirements and tests against those.

I would also like to talk about our work on the National Biosurveillance Integration Center—also within DHS. NBIC was set up, in law, to be the integrator, analyzer, and innovator of biosurveillance information across the entire Federal Government. However, it has never fully met this bar. NBIC has implemented our recommendations to strengthen collaboration within its partners, like CDC, HHS, and USDA. However, we reported last year that persistent challenges still get in the way.

For example, most of its primary Federal partners—those like CDC and HHS—told us that NBIC's products and activities did not add value, did not provide new meaning, or did not help them identify biological events quicker. NBIC also still has difficulty getting the data it needs because partners either will not share it or there are restrictions to sharing that data.

The challenges that NBIC faces are not easy to address by DHS, alone. We have identified options for policy or structural changes to help NBIC better fulfill its mission. However, these options may require changes in law—and it is not clear that even these would address the challenge.

This brings me back to the bigger issue. As we and the Blue Ribbon Study Panel on Biodefense have noted, investments in specific programs should be evaluated in terms of cost and benefit, but they should also be prioritized against other programs across government as part of a national biodefense strategy.

Another critical part of this prioritization should be using the most recent threat and risk information to guide decisions. This is implemented to ensure that our limited resources are directed to the most important areas. Without a strategy that bridges across departments, it is difficult for decision-makers in Congress and those in the executive branch to make resource decisions above the traditional agency-by-agency approach.

This concludes my prepared remarks. I would be happy to answer your questions.

Chairman JOHNSON. Thank you, Mr. Currie.

I want to kind of go back to this within the specific agencies to get just sort of an update on exactly where we are. I want to start with the USDA. Mr. Shea, the last avian outbreak occurred between December and June, and that was basically migratory birds flying south, correct?

Mr. SHEA. Correct.

Chairman JOHNSON. But, obviously, in June, they are also flying back. I just kind of want to get to—to what extent have we dodged this bullet? Have we gone through now, basically, 2 additional migratory patterns without this hitting us again?

Mr. SHEA. Mr. Chairman, it is still too soon to say. What ended up being the final end to the outbreak last year really was due to the onset of warm weather. Once the temperatures get consistently above 70 degrees, the virus pretty much will not survive.

Chairman JOHNSON. Very similar to human flu, then.

Mr. SHEA. Yes.

Chairman JOHNSON. OK. So we were kind of getting it coming and going then—migratory birds coming up, coming back—but then temperatures got to a certain point, and that outbreak ended.

Mr. SHEA. Exactly. And also, what happens with the migratory birds, when they are flying south, they pretty much have a clear path. They just keep going. When they are heading north, they can slow down. For example, what happened last year—and the reason we thought it was so bad in Iowa and Wisconsin—was that the birds were heading north, but the weather was still too cold. They got to a spot where the lakes were still frozen and hung out.

Chairman JOHNSON. I live on one of those lakes, so, yes, OK, I got it. So, that is pretty good news, though.

Now, the outbreak in Indiana—is that typical, where we just on occasion see these small, little outbreaks and stuff and we can respond quickly? Or is that——

Mr. SHEA. It is typical to find low-pathogenic avian influenza outbreaks. They happen from time to time. What we believe happened here was probably a low-pathogenic virus that may have mutated on just the one farm. The local surrounding area where we had 9 or 10 other infected premises were all low-pathogenic.

Chairman JOHNSON. OK. But, again, that was probably spreading out by migratory birds. That was just spread within that localized flock, hopefully.

Mr. SHEA. It may have started with a migratory bird, but have spread as you suggest.

Chairman JOHNSON. OK. I want to kind of revisit Ebola. I will go to Dr. Firoved. Has that been totally wiped out? Has that been

completely contained? Are there any active cases right now in Africa that we are aware of?

Mr. FIROVED. Unfortunately, we have seen cases reemerge in Guinea and Liberia. So, I will defer to my colleague from the CDC, but, there is some active tracing going on.

Chairman JOHNSON. Dr. Redd, tell me what happened there. Did we get to a level of zero and it is just coming back, or what?

Dr. REDD. So, the widespread transmission that was seen in 2014 and 2015 has been contained. What we have seen, repeatedly, in Liberia, Sierra Leone, and now, in Guinea, are very small clusters, identified after a few cases—with very rapid response, and by implementing the measures that brought the disease under control when it was more widespread. Unfortunately, this is not unexpected. The latest case we believe is from sexual transmission. A person that had Ebola in the past transmitted that disease through the route of sexual transmission, and then a small cluster occurred. And, I think that this outbreak is now being worked on very hard, both in Guinea and in Liberia—and those cases in Liberia are connected to the ones in Guinea.

The thing that is different now is that the response is very vigorous. Large numbers of contacts are being identified and traced to be sure that, if one of those people does become sick, they will be put into isolation and given treatment very quickly.

Chairman JOHNSON. Because of the tragedy that occurred there, is the general population far more educated on this as well as—in addition to the public health and safety officials who know how to respond? Is it a combination of that, or is it primarily—tell me what worked. What lessons have we learned?

Dr. REDD. Well, I think, to go back to the lessons, the situation that is occurring right now is not that different than what occurred in March through April 2014, in terms of where the disease is occurring and the location. The thing that is different is that we have a much more vigorous response—so, both in Guinea and in Liberia, there is the capacity to identify those cases quickly and respond, and there is an international presence that is able to respond.

And, to go back to 2014, the things that did not happen that needed to happen concerned the ability of those governments to rapidly identify cases, to respond effectively to them, to call for help when the response was not going well, as well as for the international community to be able to respond. That is basically the structure of the Global Health Security Agenda (GHSA) which is being implemented in those countries and in other countries in Africa, Asia, and the Americas.

Chairman JOHNSON. So, again, you are basically describing real progress, in terms of public health and the work of safety officials. Has there been any progress just in terms of information to the general population where these things—let us face it, Ebola breaks out in these African countries.

Dr. REDD. I think that there has been, and I think that, particularly, at that inflection point, depending on the country, in 2014 and 2015, it is likely that a lot of the control was actually implemented outside of official channels, that communities understood the risk that Ebola caused and took measures into their own hands, in terms of isolation facilities, local care, etc.

I think this is actually a really important question that we need to have better hard data on, but it appears that that was an important part of the response—in addition to the community mobilization and communication efforts that took place.

Chairman JOHNSON. I hate that I am going to ask this, but—what was the final mortality rate? How many people were really affected? Because, when this first broke out, we were projecting literally a few months from then there being a million people.

Dr. REDD. Yes, sir.

Chairman JOHNSON. So, how did we finally contain this?

Dr. REDD. It did not reach a million people, and that estimate of a million people was in the absence of any control measures. So, I think in some ways, even though the number was massive, it was not what——

Chairman JOHNSON. It did not hurt to get the public's attention so we could respond. We ended up with tens of thousands?

Dr. REDD. Tens of thousands of cases and 10,000 or so deaths. And, just for context, the total number of cases, in all of the outbreaks up to that point, was around 2,500. So, around 10 times more cases than had ever occurred, and one of the things—just thinking about the sexual transmission side of it—we probably have twice as many male survivors as there were total cases before this outbreak.

Chairman JOHNSON. Is that pretty unusual? I mean, was that because of additional treatment? Hydration? So, how many people were infected? How many people died? What was the survival rate?

Dr. REDD. Yes, I mean, I can give you the exact number from reports.

Chairman JOHNSON. I just looked at——

Dr. REDD. But, 25,000. And, 12,000 deaths—something like that.

Chairman JOHNSON. From how many people infected?

Dr. REDD. 25,000. So, about a 50-percent mortality rate, overall. And, when I give those numbers, I have to say that the quality of that information, particularly early in the outbreak when medical services were overrun—many deaths occurring in the community——

Chairman JOHNSON. I understand. I am just trying to get some sense——

Dr. REDD. Just in order of magnitude.

Chairman JOHNSON. Where are we at, in terms of the development of a vaccine? Because Ebola has been around. We were working on a vaccine. It just was not really a top priority. I would imagine it has become a priority. Are we making progress, in terms of a vaccine?

Dr. REDD. Yes, sir. I will answer that question, specifically, and then I will turn to my colleague from BARDA. A vaccine is actually being used now to control the outbreak in Guinea and Liberia. There were 3 clinical trials of different vaccines that were undertaken. The ones in Liberia and Sierra Leone, the vaccine got there after the disease was on the down trend, so they were not able to show effectiveness. They were able to measure the safety of the vaccine. A trial conducted in Guinea using a different strategy to use the vaccine and to measure its effectiveness did find the vaccine to be effective—and this was a containment strategy where a

case was identified and then the cluster of contacts and the contacts of the contacts were vaccinated to prevent onward transmission. And, that study did show effectiveness.

Chairman JOHNSON. So, what level of effectiveness? I realize it is just a ballpark, but, I mean——

Dr. REDD. Yes, I would have to get back to you——

Chairman JOHNSON. Was it pretty darn effective?

Dr. REDD [continuing]. On the exact number. I think that there are some questions about whether a person was exposed or not. It was not shown to be effective—or it was not tested to be effective before the period of 6 days after exposure. So, after that period of time, it did demonstrate effectiveness. I can come back to you with the exact number on that.

Chairman JOHNSON. OK.

I actually have the luxury, because I am here by myself, to keep asking questions.

Did we ever get to the bottom of the infection of those nurses in Texas? We were, again, assuming that we kind of had this understood and we were going to take precautions—and yet, we still had——

Dr. REDD. Yes, sir. Well——

Chairman JOHNSON. So, did we ever solve that mystery, in terms of how those nurses got——

Dr. REDD. I am not sure we totally solved it. What we did do was put in place a different plan for personal protective equipment, which included very specific guidance on what types of protective equipment were needed and also put in place a strategy to train people to use that personal protective equipment before needing it. Then, there was the additional specificity of, when a person is being treated for Ebola, including things like observers to make sure that a person does not accidentally, when they are taking the equipment off—kind of a risk period—that something did not happen. And then, also following those individuals after the person was gone. Similar to the returning travelers that Dr. Firoved mentioned—tracking them daily until the potential incubation period was over.

Chairman JOHNSON. So, from the start of that outbreak to kind of the final conclusion of it, it seems like, certainly, the procedure was, "We can handle this in hospitals to the point where now let us do it in very specialized hospitals." Is that kind of the process and procedure in place now, that we are going to have basically "Centers of Excellence" here, and, hospitals are going to have to be ready, because they would have to respond properly—but then transport individuals that proved positive?

Dr. REDD. So, for Ebola that is the system that is in place. I think a lot of the discussion is about other diseases that there might be more cases of and trying to adapt that system, so that we have the right care for people who have these very severe effects. I think I would pass it to Dr. Hatchett.

Chairman JOHNSON. And, by the way, Ebola is obviously a unique disease, but the procedures in place, those are good procedures for a number of types of situations?

Dr. REDD. Yes, sir. I think there are a couple of characteristics about Ebola that are different, and that probably is, primarily, the

small number of cases and the need for the very rigorous infection control procedures. If there were a large number of cases, the system that we have in place would have to be changed.

Chairman JOHNSON. Right. It would be overwhelmed.

Dr. REDD. We are sort of in the kind of dozens of cases level of capability.

Chairman JOHNSON. Dr. Hatchett, can you kind of speak to the progress of the vaccine—and, obviously, the effectiveness—but also to our ability to produce it?

Dr. HATCHETT. Of course. Would you like me to touch on the Ebola treatment centers?

Chairman JOHNSON. Sure.

Dr. HATCHETT. So, just to answer that question and then to go back to the vaccine question, through ASPR's Hospital Preparedness Program, with the assistance of the funding that was provided by Congress in the Ebola supplemental, we have established a tiered system, nationally, of Ebola treatment centers. There are now 9 regional Ebola treatment centers. There are 3 education and training centers at the pinnacle of that system, and then there is a system of feeding hospitals—I believe the number is 73—State or local Ebola treatment centers that can manage patients, temporarily, before they can be transferred to the 9 centers that are fully equipped. And then, there is a larger system of assessment hospitals. I believe the number is over 200, nationally.

Chairman JOHNSON. OK. Thank you.

I have to go vote. I am going to turn it over to Senator Carper. Hopefully, I can get back here, and we can kind of follow up.

Dr. HATCHETT. I will talk about the vaccine.

Senator CARPER [PRESIDING.] Mr. Currie, unfortunately, I had to leave as soon as you started to speak—and it was not cause and effect, but we trade off like this. We usually have 15 minutes in which we can vote, so this way we can keep things rolling and not unduly delay you. But, just take a minute and give me the—over in the House of Representatives, people give 1-minute speeches, and so, I will ask you to give us your best 1-minute speech, please.

Mr. CURRIE. I will do my best, sir. So, I think from my oral statement, there were 2 big areas I wanted to focus on. First, was what I called the 60,000-foot level, the coordination across the biodefense enterprise. And then, the second piece was looking at some of the specific programs at DHS that we have looked at. Of course, we have done a lot of work at HHS and USDA as well.

But, let me focus on the 60,000-foot level. I think a problem that we have identified through the years—and so has the Blue Ribbon Study Panel on Biodefense—is the lack of a unified strategy at the top—at the Federal level—to guide all of the departmental efforts and resources. And, all of the departments work really hard and do a very good job of doing their individual missions. The problem is, there is nobody above that has the authority or the ability to actually drive resource decisions and priorities. And so, that makes it very difficult to know if we are addressing the top priorities. And so, that was a key point from my opening statement.

Senator CARPER. All right. As you know, we talked a little bit—I mentioned the Blue Ribbon Study Panel on Biodefense co-led

by Joe Lieberman and Tom Ridge. And, one of their recommendations spoke—or at least attempted to speak to the point you have just made. Let me just ask all of you, with respect to the recommendations—I think they made 33 recommendations, and a major recommendation was that the Vice President should be sort of the person to lead this. What current and planned activities are each of you taking, or planning to take, to address the recommendations contained in the report? What do you think about the recommendations for the Vice President, in this case, Joe Biden, leading this effort for the next 9 months and then, presumably, whoever succeeds him leading afterwards?

Mr. CURRIE. I can start.

Senator CARPER. Yes, please.

Mr. CURRIE. We have not taken a formal position on whether the Vice President's Office is the right place to place that responsibility or not. But, we understand why the Blue Ribbon Study Panel on Biodefense made the recommendation that the Vice President serve that role, because it needs to be somebody in a position of authority that can guide all of the Federal departments, each with their own powers and responsibilities, to do things and spend money a certain way.

We made our initial recommendations along those lines to the National Security staff within the White House, and so I think—and our goal there was, again, to try to put it at a level that was above the departmental level.

So far, I think we have been a little underwhelmed at the efforts that have come out of the response to that recommendation. There have been some strategies developed. The problem is that, even within those offices, they still have trouble dictating exactly what the other Federal departments are doing.

So, I am not sure what the right entity is, but I think the problem is consistent across our work and the Panel's work.

Senator CARPER. All right. Thank you. Thank you very much.

Others, please? Dr. Hatchett, what current or planned activities are you all taking, or planning to take, to address the recommendations contained in the report?

Dr. HATCHETT. Thank you, Senator, for the question. We certainly participated in the process that led to the development of the report. We participated in the meetings. We read the report, with interest, when it came out. We feel that we have actually undertaken activities that address or parallel some of the recommendations in the report. I just mentioned the establishment of the Ebola treatment centers and the national hospital system for managing diseases that require high containment—that, in some ways, is similar to a recommendation within the report.

We are not responding directly to the report, but we certainly feel that it has been a valuable contribution to the national discussion on this issue.

Senator CARPER. What do you think of the point of Mr. Currie—the point that the Blue Ribbon Study Panel on Biodefense recommended the Vice President be anointed to follow up and implement the recommendations of the report? If not the Vice President, how about the junior Senator from, maybe, New Jersey? [Laughter.]

He does not have much going on now. He has finished his book and he has finished his book tour. He is looking for stuff to work on. No, I am just kidding.

Dr. HATCHETT. So, we feel that we have effective cross-government mechanisms in place, already, to ensure that threats can be identified and responded to appropriately within the statutory sphere of the Assistant Secretary for Preparedness and Response, which is public health and medical preparedness and response. We actually have mechanisms in place which reduce the need for a central oversight figure. We have two very effective coordinating bodies that are interagency bodies where we work with our colleagues at the CDC, the FDA, the Department of Defense (DOD), etc.

The first of these is the Disaster Leadership Group, which the Assistant Secretary for Preparedness and Response convenes and which responds to complicated emergencies. That addresses policy issues that will arise. In recent months, for example, we have convened two different Disaster Leadership Groups—one to address the Flint, Michigan water crisis and another to address the emerging Zika crisis.

Within the domain of medical countermeasures, we have a very effective coordinating body, the Public Health Emergency Medical Countermeasures Enterprise. In my oral testimony, I cited some of the successes that we have demonstrated. That entity has really evolved——

Senator CARPER. I am going to ask you to hold it right there. Otherwise, these guys will never have a chance to say a word. Dr. Redd.

Dr. REDD. There are a number of recommendations that pertain specifically to the CDC. I could go through those now or we could submit written answers to that.

Just quickly, recommendation 15 is a collaboration with the Department of Homeland Security on anthrax vaccination. We are providing the vaccine for that pilot—or would if the pilot started—from the Strategic National Stockpile. There is a recommendation to develop and implement a medical countermeasure response framework. We actually are working with State partners through the Public Health Emergency Medical Countermeasure Enterprise to implement improvements on the distribution and dispensing of the stockpile.

There is a recommendation to allow for forward deployment of SNS assets. That was number 23.

We are working closely with New York City on really kind of a project management formula that—when they are ready to administer product from the stockpile—we get it there that quickly—so, matching the delivery from the stockpile to the local capacity. And, we will be working with other health jurisdictions to marry their capability and our capability.

There is a recommendation to overhaul the Select Agent program. I think that would kind of fall into the overall category of a high-level policy decision. We are doing a lot of work to improve the Select Agent program within our authority, improving the inspection process, the process to report incidents that are identified

at the facilities, and the communication and transparency aspects of that.

There actually have been 3 recent——

Senator CARPER. Dr. Redd, I am going to ask you just to hold it right there. What I think I am going to ask you is, for each answer for the record, give us the status of your implementation—those that you have begun implementation on, those that you have completed implementation on, and those you have no intention of implementing. And, you can also use that as an opportunity to respond as to whether or not you think the Vice President is the better person to oversee the implementation as opposed to Senator Booker, who I suggested as a possibility. When he asks his questions, maybe he can cast some light on it.

But, just raise your hands. How many of you think that we need somebody like the Vice President who can sort of oversee the implementation that—without that, we are not going to make the kind of progress we otherwise would need? How many think that? If you do, raise your hand.

[No response.]

And, if you do not, raise your hand.

[All hands raised.]

All right. Thank you.

Let the record show Booker: 2 and Joe Biden: 0. But, I saw there were several people leaning toward Joe as well. All right. Senator Booker.

OPENING STATEMENT OF SENATOR BOOKER

Senator BOOKER. I have lost many votes before. This is one that I am very happy to not win, if possible. So, I want to thank you very much for holding this. I think this is an urgent hearing and there are a lot of very consequential realities at stake. And, I want to thank the folks before me because your dedication to the health, strategy, strength, and security of our country is really admirable.

I have some very New Jersey-based concerns—and, perhaps, I could start with Dr. Hatchett on the end. So, a lot of the dollars that are received through our State for homeland security issues are based upon formulas. The Hospital Preparedness Program is a program that, recently, New Jersey has seen a significant cut to.

Now, it is a little incongruous to me because, in the risk profiles, which are calculated by the Department of Homeland Security, we have actually seen increases in some areas. For example, in fiscal year 2016, the Department of Homeland Security recognized New Jersey's vulnerability to a targeted violent attack and heightened the State's risk score to "threat." DHS also raised our Urban Area Security Initiative (UASI) grants—UASI vulnerability, moving it from 11 to 7 on the risk index. So, we see that New Jersey, when it comes to risks—terrorist attacks, bioattacks, and the like—is getting more severe, but yet, at the same time, somehow, in the formula, we are being cut from the HPP program.

And so, I am just wondering what the reason for the cut is, given that the Department of Homeland Security sees us—and you understand that New Jersey is—I live 10 miles from Manhattan. In fact, Manhattan is moving their back offices and a lot of their in-

frastructure to New Jersey, which, again, DHS sees as heightening our risk.

And so, I am wondering, is this, in your opinion, problematic? Is it incongruent, as I see it? Or, do you see it in a different way?

Dr. HATCHETT. So, I cannot speak to the particular case of the New Jersey allocation, but I can say that the Urban Area Security Initiative risk scores are figured into the Hospital Preparedness Program formula. And, that formula and those allocations are reviewed annually, and so they are adjusted annually.

There are many factors other than risk score which go into the formula—certainly population, etc. Given that I am not, myself, personally responsible for the Hospital Preparedness Program, we can certainly get back to you with a more detailed response.

Senator BOOKER. Yes, I would really appreciate that—and, maybe, we can even meet on it, because if it is population, New Jersey is the most densely populated State in America. If it is critical infrastructure, we have the most dangerous, they say, couple of miles—there are chemical companies, you name it. I just do not understand how we could be going down, especially when other areas of the Federal Government are seeing us as being at a higher and higher risk for these problems. So, I would really appreciate it.

Dr. HATCHETT. Yes, sir. We would be glad to do that.

Senator BOOKER. Thank you. Thank you very much.

Let me go really quickly over just some of my concerns, in general, about Zika and some of the other elements.

Dr. Redd, can you explain to me the process for the New Jersey Public Health Emergency Preparedness Program, the PHEP Program—the award was increased this year. However, because the CDC is looking at additional money to allocate for Zika, we have seen money being taken away from the States, including New Jersey, which raises concerns, for me, that we are just moving around a finite pool that has urgent needs, as opposed to allocating new money, and that that might be weakening our preparedness. So, can you explain to me the process for cuts? And, were they just sort of blunt cuts across the board or really are we looking at the crises and the concerns for safety and security?

Dr. REDD. Let me start by saying that I agree with your underlying point, which is that this is a new threat and we need the supplemental appropriation to be passed—and that would address the problem in the way that it needs to be addressed.

Senator BOOKER. That is a very profound statement that I want to repeat one more time. You agree that this is a new threat and that we should be making supplemental new funding, as opposed to taking away urgently needed dollars from currently existing programs?

Dr. REDD. Yes, sir.

Senator BOOKER. Thank you for that.

Dr. REDD. We completely agree with that.

Senator BOOKER. That is definitely an important statement. Thank you.

Dr. REDD. So, in the absence of that, there is a very difficult decision that the Administration had to make as to whether we would respond to the current threat or not—and the only way to respond

to the current threat was to identify funds that could be used now. I think your description of a blunt instrument is correct—that there was an across-the-board cut to the Public Health Emergency Preparedness Program. It was a little complicated as to how each dollar amount was arrived at for every grantee, but every grantee lost funding.

Senator BOOKER. OK. But, there is obviously a better way to do it. Can you speak to me a little bit about—and maybe some other people might want to chime in. We seem to often be very reactive to crises. Do we have some kind of predictive analytics to better know what is coming before it dominates the headlines and fear is being—could we be doing a better job heading some of these crises off?

Dr. REDD. I think that is a very big challenge and I think it is one that we continue to work on.

To take the particular case of Zika, there are many aspects of this that are unprecedented. It has been 50 years since an infectious disease has been identified as the cause of a birth defect. There has never been a birth defect caused by an infection transmitted by a mosquito. So, if we were to use the historical record, this is not something that we would have predicted. I think that there is a need to be able to forecast more effectively than we have been able to do.

A totally different problem than with Ebola—although the event that occurred in West Africa was also not predicted. I think that for that event, had we had in place the systems that are being put in place now, we would not have had the event that we had. We might have had something that is similar to what we are seeing now with a very rapid detection and response to a problem.

Senator BOOKER. OK. I am going to submit one more question for the record because I have to go, but it is more about just general preparedness. I like the idea, as was said in the testimony, that preparedness is not an event—it is an ongoing process. But, I do worry about the States—having run a lot of tabletops for a lot of things, I worry about our overall State and Federal working coordination and preparation for a lot of the problems that I think are going to be seen more and more—not just here in the United States, but also threats coming from overseas.

Thank you.

Senator CARPER. Thank you so much, Senator Booker. Senator Peters.

OPENING STATEMENT OF SENATOR PETERS

Senator PETERS. Thank you, Senator Carper. And, thank you to our panelists for your testimony here today. I certainly concur with my colleagues. We appreciate you being vigilant and on the job each and every day. These are serious threats, and we appreciate your dedication to it.

In addition to being on HSGAC here, I also serve on the Commerce Committee. And, I am currently the Ranking Member on the Space, Science, and Competitiveness Subcommittee. I am currently working with Senator Cory Gardner on a working group that is going to be reauthorizing the America Competes Act. And, from my perspective, if we are going to increase our biodefense preparedness

and work to counter diseases which can pose a threat—either intentionally or naturally—we need to fund basic scientific research and consider it both a national and, really, a homeland security priority for us.

Last year, in a hearing examining the Blue Ribbon Study Panel on Biodefense, this Committee heard that that report found that federally funded scientific investigators are more likely to engage in early-stage research, versus in the private sector, where the focus is on specific product goals and end-user needs—and that this was a cause for Ebola medical countermeasures not being available when they were needed.

When looking at the America Competes Act, the working group examined global biomedical research funding trends and found that private investment in the United States correlates very closely with government investment. When government investment in research and development (R&D) shrinks or it stagnates, the private sector pulls back as well. And, when government grows its investment, the private sector tends to follow suit. And yet, Federal R&D spending has fallen below 1 percent of GDP, which I believe is unacceptable for our future and R&D is important for biodefense as well as the seed corn for innovation.

So, given the correlation between Federal and private sector investment in basic science, I am a big supporter of robust Federal funding for basic research and believe that research can certainly contribute to the next big thing—whatever that next big thing is. It also sparks new industries, creates jobs, and builds the economy, but, as we are discussing today, I think it also improves our biodefense preparedness as well. So, the challenge is in deciding the right ratio of basic to applied research—and appropriate funding levels for each—and the proper role of the private and public sectors.

So, first, to Dr. Hatchett and Dr. Redd, could you explain how your agencies make use of basic science research, kind of your sense of where we are, where our needs are, and what you would like to see?

Dr. HATCHETT. Sure. Yes, thank you for that question. Just to be clear, I am the Acting Director of the Biomedical Advanced Research and Development Authority. As our name implies, we work in the area of advanced research and development. As we understand that term, it means when we are working on medical countermeasures. These are medical countermeasures that have reached the clinical stage of development, where many of the problems relate to the clinical testing of the product as well as to scaling up manufacturing and working out manufacturing issues, so that we can be able to produce the products on a large scale.

We have to depend on our colleagues at the National Institutes of Health and the Department of Defense to fund that basic research. We do not fund basic research. And, it is very important for us to coordinate our efforts with them so that, as they cultivate products and bring products forward through the earlier stages of discovery and development, we are ready to transition those products to advanced development.

In the case of the Ebola vaccines—and Ebola therapeutics, for that matter—Ebola obviously had been on our threat list for some

time. It is one of the material threats that the Department of Homeland Security has identified. NIH and the Department of Defense had been supporting basic research on countermeasures and had been moving those countermeasures forward through the development cycle.

When the Ebola epidemic started in 2014, none of those products had reached the stage where our organization was—that they were ready to be developed by our organization. Within a very short span of time, within about a year, we were able to transition 12 products from that preclinical development to advanced development—and many of those products have actually been tested in West Africa. So, we do have a strong system as it relates to biodefense for supporting product development and translating products from basic research—and I could not agree with you more about the importance of basic research.

Senator PETERS. Thank you. Dr. Redd.

Dr. REDD. Yes, sir. If we had a panelist from NIH, you would have kind of a good description of the proportion of basic research and the proportion of applied research and practical application. So we do some basic research ourselves, but, predominantly, our mission is to protect the health of the public and to use the tools that are available to make sure they are effective and to make sure that they are disseminated. So, we are more on the end-user side of that spectrum from basic research to use.

Senator PETERS. I realize that, but, I guess, the follow-up question is: So do you believe that we need to be putting more into basic research, as these threats seem to be developing, and, in some ways, at an accelerating rate—that we are probably doing ourselves a disservice if we are not putting more resources into the very foundational level of science?

Dr. REDD. I think we do. I think we also need to make sure that we do not have a bottleneck at that development stage and we are able to get things through the system quickly to find out if they are going to be useful in large populations and be effective. And, some of those kinds of questions are difficult or are not possible to answer at the basic level.

Senator PETERS. Right. Would any of the other panelists like to weigh in?

Mr. FIROVED. Sure. At the Department of Homeland Security, we have the Science and Technology Directorate, and it is critical to helping the Department meet the needs of its stakeholders—whether they are first responders—helping make improvements to the BioWatch program—and it relies on a diverse university program as well—the "Centers of Excellence" to help us meet those needs. And, just recently—since we have been talking about Ebola—some basic understanding that has significant ramifications for biodefense have to be answered still. So, some of the questions were: How persistent is Ebola on surfaces? How long does it remain infectious? And so, in a study that was conducted with our partners, we were trying to understand what it does on the carpet of an airplane or on surfaces that our employees might encounter in an airport.

And so, this kind of basic research has real, serious implications for our day-to-day operations—so it is critical.

Senator PETERS. Thank you. I appreciate it. Thank you very much.

Senator CARPER. Thank you, Senator Peters.

Looking at the list of folks, Senators Ayotte and Tester were here when the gavel came down. They may come back. Next on the list is Senator Ernst. If we are looking for somebody who has previous military experience, a colonel—and maybe you could be next for us. Then, Ben Sasse, if he returns, and then Senator Portman and Senator McCaskill.

OPENING STATEMENT OF SENATOR ERNST

Senator ERNST. Thank you, Ranking Member. I appreciate it. And thank you, gentlemen, for being with us today.

This question is for anyone on the panel, please. I want to follow up on a question that was asked earlier by Ranking Member Carper. One of the Blue Ribbon Study Panel on Biodefense's top recommendations was the development and implementation of a comprehensive national biodefense strategy. This Administration has failed to present a comprehensive strategy in a number of areas—whether it is defeating the Islamic State of Iraq and Syria (ISIS) or countering the use of social media—which has led to disparate efforts that lack focus. And, as the Blue Ribbon Study Panel on Biodefense concluded, the United States is underprepared for biological threats and it is critical that the Administration establish a comprehensive biodefense strategy.

Could Mr. Currie or anyone else on the panel speak to the importance of this recommendation?

Mr. CURRIE. Yes, ma'am. Absolutely, we think it is very important—and our findings and recommendations have been really similar to the Blue Ribbon Study Panel on Biodefense's findings and recommendations.

I think it is important to note that it is not easy. Part of the reason it is so difficult to do this—and this links also to their recommendation of providing the Vice President the authority to do this—is because it has to come at a level that is above the cabinet and the Department level because Departments cannot tell other Departments what to do. It is very difficult to allocate resources between the Departments and identify resources priorities—for example, deciding that we want less resources in one Department's program versus more in another. And, that is exactly why such a global national strategy across the Federal Government is so important. But, it is very difficult to do.

Senator ERNST. Yes, and we understand the difficulty, but also the importance and necessity of doing that.

Would anyone else like to respond?

Dr. HATCHETT. Yes, ma'am. Thank you for the question. While the Office of the Assistant Secretary for Preparedness and Response has not developed a strategy for the parameters that are described in that report, I do think it is important to point out that they did leave the development of a National Health Security Strategy. The first National Health Security Strategy was completed in December 2009 and an updated version of the strategy was completed in December 2014.

The National Health Security Strategy is a broader strategy. It does not just look at biodefense. It also focuses on securing the Nation's health security—as the title implies. It has 5 major strategic objectives. The first is to promote the development of resilient communities that are capable of responding to incidents of all kinds, including biodefense-related threats. The second is to promote the development of a robust medical countermeasures enterprise. The third is to promote comprehensive health situational awareness, so that decisionmakers can respond appropriately. The fourth is to promote integration of public health, health care, and emergency management systems across the Nation at the different levels of government. And, the last strategic objective is to promote global health security, so that we can address issues like the Ebola epidemic.

So, that is an overarching strategy that governs a great deal of what we do in biodefense. And, in developing that strategy, we did work with stakeholders at all levels of government and with our interagency partners.

Senator ERNST. That is wonderful. Very good. Great first step.

For Administrator Shea, thank you very much for being here. How do we integrate information about animal and human health without creating or perpetuating misunderstandings and fear among consumers, both here at home and abroad? We do see this, where, perhaps, the Chinese or other governments will push away any commodities, like produce that they feel might do them harm—or they can make that up. So, what are your thoughts on that?

Mr. SHEA. I think it is very important that we stick to the science and we work with our colleagues on the human health side to be clear about the science. And, a really good example of that, of course, that affected your State, was what was being called "swine flu" in about 2009, when we should have called it by its proper scientific name, "novel influenza A (H1N1)." And, it is so important to do that because the industry, which so important in Iowa, of course, was put at a real disadvantage because of the fear of an influenza that really should not have been attributed only to swine. So, that is why it is so important that the science be integrated and that we speak with science. And, that is why I think it is important that we have someone embedded at CDC—which we do—and that we work, on a daily basis, to make sure those messages go back and forth.

Senator ERNST. Very good. And, also, you spoke about the swine flu. We can talk a little bit about the avian flu, but, yes, go ahead, sir.

Mr. FIROVED. Thank you. I also wanted to point out that there are some robust communications that go on between these entities. Within our center, we actually also have a liaison with APHIS within the USDA, and it has proved to be critical for producing this "One Health" message. And, in one case just this last fall, we were seeing some erroneous news reports come up about a resurgence of avian influenza that just were not at all accurate. But, working through the National Wildlife Health Center (NWHC), also with the Department of Interior, as well as our colleague at APHIS with the USDA, we are really able to push through those agencies, able

to tamp down these stories, and really able to prevent a story from gaining legs that could have economic consequences.

And, so I think that the "One Health" approach is so critical to everything that we do—and we need to continue to bridge this divide.

Senator ERNST. Great. Yes, sir?

Dr. REDD. Just briefly—to support the Administrator here, we have a very intense scientific interchange with USDA on influenza and also for foodborne diseases. So, there are some pockets of just very close collaboration.

Senator ERNST. Very good. Well, I appreciate that so much. And, we spoke about this earlier—or we heard about it earlier—but, as you know, last year the poultry sector was rocked by the Asian highly pathogenic avian influenza (HPAI), commonly called "bird flu." And, this was very devastating in Iowa, where it resulted in the death of over 30 million birds and inflicted $1 billion of damage to our economy in Iowa. It was one of the worst foreign animal disease outbreaks in our Nation's history. And, the livestock sector is also regularly impacted by these diseases—and they struggle to control them—with new ones popping up each year. We have talked about some of that. And, it is not inconceivable that an ill-intentioned actor could purposefully introduce an equally dangerous and contagious pathogen into the United States to really mess with our food security, our trading relationships, and our economic security.

And, I know I am going a little over time, but, to that end, what is the USDA doing to prepare for the threat of bioterrorism? Can you give us a broad overview on that?

Senator CARPER. Mr. Shea, I am going to ask you to suspend your answer just for a second. I am very much interested in your answer, but Senator Portman has a dead stop right now and he needs to go.

Senator ERNST. OK.

Senator CARPER. If we can just yield to him for a moment, and then we will go back to you.

Senator ERNST. Thank you. Yes.

Senator CARPER. Thank you.

OPENING STATEMENT OF SENATOR PORTMAN

Senator PORTMAN. Thank you, Senator Ernst, and thank you, Senator Carper, and thank you for having this hearing—you and the Chairman. This is an incredibly important area. I have a number of questions I am going to be submitting for the record, probably to each of you—at least to three of you—as I see you there. But, I want to focus on a single issue, Dr. Hatchett, if I could. We talked a lot about Ebola today. We have also talked about the Zika virus. And, they are very different. My understanding is that the way in which someone becomes contagious with Ebola creates a health problem in and of itself, whereas, with Zika, it is not as easily transmitted from person to person. However, it is transmitted from mosquitoes to people very easily. And, I just wonder what you think we could do, in terms of leveraging all of our assets—including one that happens to be situated in Youngstown, Ohio, which is the 910th. It is the airlift wing there that provides aerial spraying

for our country. They do incredible work on our firing ranges. They do work with regard to oil spills. But, they also do work with regard to mosquito infestations. Do they have a role here with regard to Zika, particularly, in spring in the southern part of the country, where we can see, unfortunately, a movement from Latin America up toward the United States?

Dr. HATCHETT. Senator, thank you for that question. Vector control, which is what you are referring to, in terms of controlling mosquito populations, is an area that CDC, I think, has primary responsibility for, so, if I could yield to my colleague to let him address your question.

Dr. REDD. It is hard to give a global answer to that question. The variability of mosquito control districts in the United States is remarkable. Some localities have really finely honed enterprises, while others have hardly any at all. I think that there could be a role for that airwing in locations that do not have the capability and need it.

Something that we think is really important, that the Zika virus outbreak is pointing out, is the need to really revitalize those mosquito control efforts—not only for control, but really just to understand what is going on—that part of what those mosquito control districts do is capture mosquitoes and speciate them, and we just do not have the information that we need right now in the United States to make the best decisions.

Senator PORTMAN. Well, thank you, Dr. Redd, and thank you, Senators. I want you to know the 910th is ready and willing—and they, again, do outstanding work. And, I think it would be a way to leverage some of those DOD assets to address a very real, potential biological issue that we are currently facing—just as we did with Ebola over the last couple of years.

Thank you.

Senator CARPER. Senator Ernst.

Senator ERNST. Thank you, Ranking Member. I will go ahead and just submit the questions for the record in the interest of time.

Senator CARPER. Well, go ahead and respond to the question. It was a good question.

Senator ERNST. I have a hard stop also.

Senator CARPER. That is OK. I would like to hear the answer, and then we will go—actually, it is a great question, so go ahead. Just briefly.

Senator ERNST. Yes, bioterrorism efforts.

Mr. SHEA. OK. Of course, we work very closely with our colleagues in Homeland Security's Customs and Border Protection (CBP), who actually conduct inspections of things and people as they are coming into the country. So, that is our very first line of defense—looking for things.

But, after that, what is important, of course, is finding any outbreak quickly. And so, surveillance is really the key. We have surveillance on farms, in markets, and in feedlots—everywhere. And, that surveillance comes not only from USDA people, but, more abundantly, from State people and from private veterinarians who we accredit at USDA. And, when they find a disease, they are duty-bound to report that to us. So, that is really the key—surveil-

lance, prevention, keeping these things out of the country, and getting on it right away.

Some other things that are going on, of course—at DHS, they are developing countermeasures at the Plum Island Animal Disease Center (PIADC)—soon to be relocated, but they are working very hard there to find countermeasures and detection methods. So, all of those things are in place now.

Senator ERNST. Just to follow up with that then, as we are preparing for potential incidents, is it important that we have stockpiles of vaccinations or other veterinary supplies then, to safeguard?

Mr. SHEA. Absolutely. We do have a veterinary stockpile, but it certainly is not robust enough to handle a really huge outbreak of foot-and-mouth disease, for example. We do have a good capacity now for the avian influenza vaccine, but we do not have a huge stockpile of some of the others.

Senator ERNST. Thank you.

Chairman JOHNSON [PRESIDING.] Senator McCaskill.

OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. Thank you.

I understand that there are several advisory committees involved in the material threat assessment process and the material threat determination process that include nongovernmental experts. These determinations are, in fact, the guidance that DHS uses when considering a particular chemical, biological, radiological, or nuclear weapon to be a threat and allows HHS to use the BioShield funding for countermeasure procurements.

So, my question to you, Doctor, is: Is anyone on these committees associated with any of the companies that are actually getting the funds for the research and development on possible countermeasures?

Mr. FIROVED. The Science and Technology Directorate is the organization that runs the terrorism risk assessments and the material threat assessments. While I have been involved in the process, I am not knowledgeable as to the membership that they rely on when they put those together.

Senator MCCASKILL. If you would get that for the record, that would be helpful.

Mr. FIROVED. I will, absolutely.

Senator MCCASKILL. I have had a hearing on this, in previous years, with the person that you just referenced and was frustrated with what I thought—and I am going to go into that a little bit because I think it is relevant to the hearing today—about what we are warehousing and why, as well as what we are spending money on.

If you look at the funding decisions, the priorities, and the tradeoffs, we spent $1.4 billion on anthrax countermeasures, alone. 2 of the investments were for anthrax antitoxins that cost $3,100 and $8,200 per dose. We also bought 10 million doses of BioThrax, which only has a 4-year shelf life. And, we bought that vaccine in 2005. And then, we bought another 18.75 million doses 2 years later. Now, all of that money is—I mean, I understand you have to spend money to be prepared, even if you do not use it. I get that.

But, it appears to me that anthrax investment is crowding out other countermeasures in terms of funding. And, I would like someone to address that, because, while we had one anthrax attack, it seems to me that the cupboard is bare in a lot of other areas where we need to have BioShield funds being used. And, I would appreciate it if someone would address that, especially since Dr. Lurie, when I talked to her about anthrax, basically said that it is a therapeutic that, potentially, could be effective against an antibiotic-resistant anthrax infection. There was not even certainty that it would be. Dr. Hatchett.

Dr. HATCHETT. Yes, ma'am. Good to see you, ma'am. Thank you for the question. Your question has multiple parts. I will try to be brief and address all of them.

With respect to the anthrax antitoxins, we do have very limited treatments for anthrax disease. And, we now have 3 licensed anthrax antitoxins, so FDA has judged that, based on the best available evidence, those products are likely to be safe, effective, and produce a survival benefit against anthrax. Anthrax certainly is one of our top threats—and we have made very substantial investments to secure the Nation against future anthrax attacks.

To address your question about whether it is crowding out other products, I have to say it is not. We—as the Office of the Assistant Secretary for Preparedness and Response—as you know, are the stewards of the Project BioShield funding. Over the last 12 years, we have added 17 products to the Strategic National Stockpile using Project BioShield funding. Those products include products, yes, to treat anthrax—both vaccines and antitoxins—but also antivirals and vaccines to treat smallpox, antitoxins to treat botulism, drugs and treatments for acute radiation syndrome (ARS), exposure to chemical nerve agents, and, most recently, we have added 4 products to the Strategic National Stockpile to address the risk of thermal burns that could be associated with explosions, bombings, or the detonation of an improvised nuclear device (IND).

We have a number of new products that we will be procuring this year. We anticipate adding as many as 5 new products to the Strategic National Stockpile this year. Only 2 of those are for anthrax, but they also include treatments for smallpox and acute radiation syndrome. And, we may add as many as 5 new products next year.

So, we have been able to buildup a diverse portfolio of medical countermeasures against CBRN threats.

Senator MCCASKILL. Does the smallpox purchase include IMVAMUNE?

Dr. HATCHETT. We have purchased significant amounts of IMVAMUNE over the last several years.

Senator MCCASKILL. Is it not a problem that a scientific journal, "Biosecurity and Bioterrorism," said, unequivocally, that there is no apparent programmatic use for this vaccine at this time? In fact, 7 years after the initial procurement, it is not recommended—the advisory group—the World Health Organization's advisory group—said it is not recommended for emergency use.

Dr. HATCHETT. I would respectfully disagree with the statement that it has no programmatic use. IMVAMUNE was created, specifically, to be a vaccine that we could give to immuno-compromised populations or persons who had relative contraindications for the

existing smallpox vaccine—and that includes persons with a history of atopic dermatitis. That is a substantial number of people who could have a potentially severe reaction to the other available smallpox vaccines.

Senator MCCASKILL. That makes sense. I just am concerned because the World Health Organization's scientific advisory group of experts noted, in 2014, that it was not recommended for emergency use—and we have spent $650 million on it. I hope that would always raise the hackles of somebody sitting in this chair who is trying to figure out what is going on. I mean, why are we spending that kind of money when, clearly, there are real questions about its efficacy and its Section 5.

Dr. HATCHETT. We also have very substantial stockpiles of the Acambis vaccine, which can be administered in an emergency use setting. The potential concern about the IMVAMUNE vaccine is that it requires 2 doses to achieve immunity. For those people who have been exposed to persons with known smallpox, there is no absolute contraindication for the existing vaccine. And, if it is given up to 3 or 4 days after exposure, it can protect individuals who have been exposed to smallpox, and so, that may be the basis of that discussion. But, IMVAMUNE clearly is efficacious and clearly meets an unmet medical need for a large segment of the population.

Senator MCCASKILL. I know I am out of time. I have one more. Do you mind?

Chairman JOHNSON. You are doing a good job.

Senator MCCASKILL. I want to make sure that we have time.

I get that we are reliant on small start-up companies for developing some of these drugs because of the nature of the market and the nature of the research. And, the economics do not make sense for some of the big guys. So, I get that we have to fund a lot of this. But, what I do not get is—take ABthrax, for example. We gave Human Genome Sciences $130 million for late-stage development activities to support approval of the product, including support for non-clinical, clinical, and manufacturing facilities—as well as funds for the licensing and approval process. I mean, this was our baby—the taxpayers' baby.

Well, then we have to turn around and buy it from them for $3,000 a dose. Most people in Missouri do not understand that—why we would pay for the development of a drug and then have to pay $3,000 a pop for the drug after we paid to develop it.

Dr. HATCHETT. So——

Chairman JOHNSON. Good question.

Dr. HATCHETT. Yes, it is a good question. I will say that the pricing of medical countermeasures is complex. A factor that we have to take into consideration is that, because these products do not have commercial markets, we have to provide a sustaining revenue that will allow for the manufacturing base to remain intact. And, the price that you quoted for a monoclonal antibody therapeutic is very clearly in the middle of the range for other—there are dozens of licensed monoclonal antibody therapeutics for many other indications, and the prices for those products range from slightly less than the amount that you mentioned to substantially more. So, I would argue that it is a fair price for the product.

Senator MCCASKILL. Have we explored whether it would be cheaper to do this ourselves? We are paying them to develop the drug, and then we are the only customer, and so, we are continuing to pay them—I mean, it seems like, to me, that we are guaranteeing a profit for something that is wholly owned by the government.

Dr. HATCHETT. If I could just say that we do look at different business models for how we support biodefense countermeasures. In a related domain, for emerging infectious diseases, we have a similar market failure problem. And, we are thinking through different potential approaches to how we can support companies and how far we would like the private sector to carry products and, potentially, what options we may have to ensure that we can have those products when we need them—which might include the scenario you mentioned.

Senator, if I could mention another thing that I think you would be interested in. In framing your question initially, you did talk about the shelf life of products. And, BARDA does have a total lifecycle cost containment initiative that we have been supporting for many years, where we look at the products that we are developing and try to find ways to reduce that long-term carrying cost to the taxpayer. And so, for example, you mentioned the IMVAMUNE product—the smallpox vaccine. BARDA has supported the development of a lyophilized—or freeze-dried—version of that product which will have a longer shelf life——

Senator MCCASKILL. Which will help the shelf life—that is terrific.

Dr. HATCHETT. And, we are doing that across the board. And, we are looking across our entire portfolio to see how we can reduce those costs.

Senator MCCASKILL. Well, I have been involved in this other investigation where a guy named Martin Shkreli figured out that there was a limited market for a certain drug, and he went out and bought it, and then he jacked the price up. So, maybe, we need to take a page out of his book and jack the price down. Maybe, we figure out what the price is to buy the drug that we paid to develop and continue to manufacture it ourselves and drive that cost way down, because, now, we are taking out the profit that the private company is making from our investment. I mean, believe me, I do not quarrel with a private company being able to make money off of their investment. But, it seems weird that we are making the investment and then they can profit off of theirs for the life of the company. That is the kind of deal that any businessman would like to get.

Dr. HATCHETT. Yes, ma'am, thank you. We are always looking at ways that we can be better stewards of the taxpayers' money. We recognize our responsibility and we recognize that we do provide a great deal of that up-front investment. And so, we can take that for——

Senator MCCASKILL. Yes, I would love you to take a look at that, because I am not sure this business model makes a lot of sense for the taxpayers.

Dr. HATCHETT. Thank you.

Senator MCCASKILL. Thank you, Mr. Chairman.

Chairman JOHNSON. Thank you, Senator McCaskill. Senator Carper.

Senator CARPER. Thank you, Mr. Chairman.

I want to come back to Mr. Shea. Just briefly, I want to follow up on Senator Ernst's question with respect to the avian influenza outbreak. Senator Johnson's State was hit hard—and a number of other States in the Midwest were hit hard—especially their turkeys and laying hens, and we saw that happen, I think, between November 2014 and May and June of last year. And, we fully expected the East Coast—the "Atlantic Flyway"—to be hit this winter—and it just has not happened. And, we have been pretty good with biosecurity. But, why do you think we have escaped this blow?

Mr. SHEA. Of course, all of the scientists will tell me it is all speculative, but some of the reasons seem to be something like this:

First, the virus circulating in the water fowl may have mutated to a less virulent form, and, therefore, when they are dropping the virus, it is simply not catching on like it did last year in a highly pathogenic form. So that is a possibility.

Another possibility is that the biosecurity has improved—and I think it has improved dramatically, certainly in Delmarva, where poultry is so important, and throughout the Midwest and all of the places where poultry is. And, poultry is in so many places, of course. I think biosecurity is much better.

So, I think those are some of the things that seem to have led to it.

Senator CARPER. All right. Thank you.

I do not know who to ask this question to, but I will start with you, Dr. Redd. Would you talk to us about what the difference—or similarity—is between how Ebola is transmitted from 1 human being to another, as compared to the Zika virus, please?

Dr. REDD. Sure. I will start with Zika. It can be transmitted by an infected mosquito, it can be transmitted by sexual transmission, and it, probably, can be transmitted by blood transfusion. There is no instance where that has occurred, but it is a possibility based on the way other similar viruses can be transmitted in blood.

Ebola is not transmitted by mosquitoes. It can be transmitted by sexual transmission, but its primary route of transmission is through contact. So, by coming into physical contact with the body secretions of a person who is infected—where the virus multiplies to very high titers—and then, it is really just through that direct contact.

Senator CARPER. Thank you. The CDC announced this week, as was described earlier, that the Zika virus is now confirmed to be a source of significant brain damage to developing fetuses. There are a lot of policy consequences that flow from that. But, just take a minute or 2 and talk to us about what actually happens to the brain of—and it does not happen to all pregnant women. Why is that? But, what is actually happening in the brain of the developing fetus? And, what is the capability—if a child is born alive, what are some of the consequences there?

Dr. REDD. So, a couple of points. This declaration is not changing what we are doing. Actually, part of the reason behind making this declaration was to try to make it easier to move quickly and, particularly, to take away any of the confusion people might be having

when they are deciding whether or not they should put insect repellent on. There is no question, now, that those preventive measures are very important to prevent something that is confirmed.

When a fetus is infected, the brain is actually infected, and that was—an early finding was actual—on microscopic slides, you can see brain tissue and the virus right there. What we think happens is that the brain actually—because of this infection—actually shrinks, so that you have a normal fetus, then there is an infection—that brain gets infected and it gets smaller—and that is what causes the small heads.

It is actually—even though the term "microcephaly" just means small head, the kind of—in these severe cases, it is actually a very particular kind of malformation that was very rare up until this point, where the plates of the skull of the fetus are actually overlapped because of that collapse. The skin has ridges in it—and that is not part of kind of regular microcephaly. So, it is actually a very specific finding.

Now, even though there is evidence that the Zika virus causes this malformation, there are many questions—and you actually pointed out several of them. It does not seem that every pregnant woman who gets bitten by a mosquito has this very severe adverse effect—and we do not know why that is. We do not really know—there is a likelihood that there is a certain time during pregnancy that poses the greatest risk. That is a little bit of the speculation. We also suspect that there are other adverse events that can occur, which is typical of other birth defects. They rarely are just a single thing. And, we do not really have good information on that entire spectrum of disease.

Senator CARPER. Do we have any idea of the degree to which a baby born with this disease—this brain disease that you have described—to what extent does it impair their ability to function?

Dr. REDD. It really depends on the severity—and that is the question of the spectrum of illness. For the ones that are very severely affected, I mean, there are deaths right at the time of birth. So, that would be kind of the extreme—or deaths before birth. And, I think you can go all the way down the line—that there may be much less severe findings in what, right now, look like normal births.

Senator CARPER. OK. And, for the panel, a last question. What good, just common-sense, practical advice can you give to people who are going to be traveling to parts of this country or to other countries, and are concerned about possible infection? What good advice can you give people?

Dr. REDD. Well, our advice—that has expanded to include more places where the virus is actively being transmitted—is if you are pregnant, it is probably not a good idea to go. If you do go, use mosquito-prevention measures—an effective insect repellent, insecticide on your clothes, long sleeves, light-colored clothing, and do what you can to avoid being bitten by a mosquito.

Senator CARPER. Any other advice from anybody else?

[No response.]

All right. Thank you. Thank you very much, Mr. Chairman. Thank you all.

Chairman JOHNSON. Thank you, Senator Carper.

Just really quickly, there is only 1 species of mosquito that carries this. Is that true or not?

Dr. REDD. There is 1 vector that is presumed to be the predominant vector. They are both Aedes mosquitoes. There is Aedes aegypti, which is thought to be the predominant vector. Aedes albopictus is thought to possibly also be a vector.

Chairman JOHNSON. So, what is the status of the program to use genetically modified mosquitoes to, basically, make the population sterile in order to reduce the population of those?

Dr. REDD. I will have to get back to you with the specifics on that. I think there are a number of—well, there is a programmatic approach of using indoor residual and outdoor residual spraying that is being used in Puerto Rico for pregnant women to prevent mosquitoes—basically killing mosquitoes right there—and also putting larvicides in potential breeding spaces of those mosquitoes as well as removing potential breeding spaces.

There are a number of kind of experimental—or less widespread—uses, and, in all of this, we really need to learn the effectiveness of these measures because this is a very difficult mosquito—not to kill at an individual level, but to be sure that there are enough mosquitoes being killed to reduce transmissions.

Chairman JOHNSON. OK. Can anybody else speak to the status of using genetically modified—OK. So, it is just experimental at best.

Let me close out the hearing. I will just kind of go down the panel. Based on the Blue Ribbon Study Panel on Biodefense's conclusion that we do not have a strategy—we do not have any kind of functioning leadership here, both budgetary as well as operational—you are all involved in these organizations. I have been at organizations that have a very well defined strategy and you know it. I have been at organizations that do not have a strategy—I am kind of in one right now—where you also know it. So, I want to get your evaluation and—if you are saying you agree with GAO—if you agree with the Blue Ribbon Study Panel on Biodefense, you do not have to say a whole lot more. But, if you disagree, just quickly tell me—what is the disconnect, in terms of what GAO and the Blue Ribbon Study Panel on Biodefense are talking about—a lack of strategy, a lack of coordination, and a lack of unity of effort? I will start with you, Dr. Hatchett.

Dr. HATCHETT. Thank you. I think the problem of biodefense is a tremendously far-reaching problem, and it stretches to all sectors of society—actually, to all parts of government. Within the domain that we work in, which is public health and medical preparedness and response, I feel that we do have strong strategies, we do have strong collaborative mechanisms, and we have adequate structures in place to respond to the emergencies that we are presented with.

Chairman JOHNSON. Dr. Redd.

Dr. REDD. So, I think there is a policy process to make the kinds of changes that are being proposed—and that involves the legislature and the Executive Branch. And, this is a recommendation that needs to be looked at very carefully.

Chairman JOHNSON. Mr. Shea.

Mr. SHEA. I certainly agree with them. I would say that so many great things are going on between our respective agencies and I

think, if those could all be brought together, probably—certainly—it would be to our advantage.

Chairman JOHNSON. OK. Dr. Firoved.

Mr. FIROVED. Sure. I think that we are certainly taking to heart the Blue Ribbon Study Panel on Biodefense's recommendations. We are trying to implement as many of them as we can. I think there are strong strategies. I think there are strong coordination mechanisms. We have touched on a few of them today, but there are many more. We are never going to be done. I think one of the things that strikes me is, after 9/11, when we were talking about interagency coordination to address it, so that we could connect the dots, there was one anecdotal story that someone stood up and said, "I thought we were going to do this after Pearl Harbor." And so, this is a task that is never done. And, we will always have to strive and we are always going to have to grow and build these capabilities.

Chairman JOHNSON. Listen, I come from a manufacturing background. It just gets into your genes—continuous improvements. So, everything always can be improved.

Mr. Currie, just a final comment. Again, the gentlemen here think there are certainly strategies—certainly areas for improvement. Is that a pretty accurate assessment from your standpoint?

Mr. CURRIE. Probably not surprising to hear we think strategy is important. And, I do not want to take away from some of the efforts that have been done. The public health strategy that Dr. Hatchett mentioned, I think, is probably the closest thing to such a comprehensive strategy. I think if I had to nail 1 key thing that is not being done that makes it difficult, it is this idea of being able to prioritize investments and prioritize efforts. Within each area, you can do that because the agencies and departments have control of those areas. But across, you cannot.

Chairman JOHNSON. Yes, so, at the agency level, you think you are doing a pretty good job of prioritizing, but, again, it is that top-down allocation of resources.

Well, again, thank you all for your time, your testimony, and your answers to our questions. The hearing record will remain open for 15 days, until April 29 at 5 p.m., for the submission of statements and questions for the record.

This hearing is adjourned.

[Whereupon, at 11:51 a.m., the Committee was adjourned.]

APPENDIX

Chairman Johnson Opening Statement
"The Federal Perspective on the State of Our Nation's Biodefense"

Thursday, April 14, 2016

As submitted for the record:

Today, we look forward to learning the perspective of federal agencies on the state of our nation's biodefenses. We hope to learn how key federal agencies are fulfilling their responsibilities in this area, and what steps they are taking to improve preparedness and response.

To be fair, biodefense is an unwieldy topic. We face threats ranging from natural outbreaks of infectious diseases to accidental releases of high-risk pathogens, or purposeful, malicious attacks.

Over the last two years, our nation — and at times the entire world — has faced several major biological incidents.

Ebola certainly caught the nation off-guard. Our public health officials first told the nation that every community hospital could handle Ebola infections. Shortly thereafter, new cases were transferred to just a handful of specialized hospitals. There also were issues surrounding waste management, adequate supplies of personal protective equipment, and tracking travelers to countries in West Africa.

In terms of animal health, last spring's spread of highly pathogenic avian influenza through the Midwest, including Wisconsin, revealed significant gaps in preparedness. There were staffing and equipment shortages, and a lack of understanding of the pathogen itself.

The Zika virus now threatens the nation. A recent study concluded that dozens of major metropolitan areas across the southern half of the United States are at moderate to high risk of susceptibility to the Zika virus.[1] As was the case with Ebola, officials have changed their tune from their initial approach. The deputy director of the Centers for Disease Control and Prevention recently said, "Everything we know about this virus seems to be a little bit scarier than we initially thought."

Given the serious potential consequences of exposure to the Zika virus, including the heart-breaking impact this virus is having on pregnant women and their babies, it is natural for American families to be concerned about the risks. I am supportive of moving $510 million that was earmarked for Ebola response to Zika-related activities.

With this background, our purpose today is to examine the state of the federal government's approach to biodefense.

In October 2015, we held a hearing to look at the findings of the Blue Ribbon Panel on Biodefense. The panel co-chairs, former Governor Tom Ridge and former Senator Joe

Lieberman, testified that the biodefense activities of the federal government lacked strategic direction and leadership, among other findings.

According to the panel's tally, our government spends about $6 billion every year on biodefense-specific activities — a number of panel members had to compile themselves, since it is not one provided by any single agency.

We need to work together to identify and close gaps in our preparedness and response, and that is why I am pleased to have representatives of key agencies here today.

I want to thank our witnesses for joining us this morning and look forward to their testimony.

Statement of Ranking Member Tom Carper
"The Federal Perspective on the State of Our Nation's Biodefense"

Thursday, April 14, 2016

As prepared for delivery:

Thank you, Mr. Chairman, for holding this timely hearing on federal biodefense efforts, particularly in light of the current threat posed by the Zika virus. Last fall, this Committee convened a hearing to examine a report issued by the Blue Ribbon Study Panel on Biodefense. We heard then from our good friends, Senator Joe Lieberman and Governor Tom Ridge, about our country's capabilities to confront biological threats and how those capabilities could be strengthened. Needless to say, there is a lot of work to be done. Fortunately, the panel provided a number of recommendations to further enhance our ability to prevent, detect, respond to, and recover from, a biological incident.

Today we have the opportunity to discuss these recommendations with several of the agencies that would be responsible for implementing them. I'm eager to hear our witnesses' thoughts on the Panel's findings and to also hear how they believe we can further improve our country's biodefense system. This is an important conversation to have in the context of recent global events, including several emerging, widespread outbreaks. Ebola continues to threaten West Africa. After claiming thousands of lives, the spread of the virus has declined significantly, thanks in no small part to the investments America made in the health systems of those countries that were hardest hit by the epidemic. That said, the recent news of more cases in Guinea and Liberia underline the need to continue supporting our international partners in their efforts to combat this disease.

We are also almost one year removed from a significant outbreak of highly pathogenic avian flu which decimated some parts of our nation's poultry industry. While infections of poultry have been limited in number so far this year, we must remain vigilant and continue to enforce good biosafety practices at poultry farms across the country to safeguard against another epidemic.

Meanwhile, we are quickly approaching the beginning of mosquito season in most parts of the United States. Unfortunately, this presents us with a new threat, this one in the form of the Zika virus. The virus has spread explosively throughout Central and South America. It has already reached Puerto Rico and other U.S. territories and is expected to spread further as the weather warms. The World Health Organization estimates that as many as 4 million people in the Americas could contract Zika by the end of the year. Researchers continue to learn more about the virus every day, but it's clear that the health impacts can be devastating, particularly for pregnant women and their unborn children. In fact, the CDC has now confirmed, what many have long speculated, that the Zika virus is a cause of several severe birth defects.

While most of the Zika cases diagnosed in American citizens to date have been traced to travel abroad, we must be prepared for the virus to present itself locally. So it's been encouraging to see a proactive, coordinated response from the President and his Administration to this threat. For example, federal agencies are helping state and local governments enhance their capacity to

better detect and track the virus. There are also significant mosquito control efforts underway in areas most at risk.

We also know that medical countermeasures and vaccine development are being rigorously pursued. To help fund these efforts, the Administration announced last week its intent to redirect almost $600 million from other programs - including funds originally designated for Ebola - and spend it on Zika response efforts. I believe the President made the right call in light of this threat. While these efforts continue, Congress should continue to carefully consider the President's request for additional resources to combat this threat. In addition, we must ensure that our public health officials have the tools that they need to protect us from and prepare us for Zika and future threats. But at the same time, we should not let our foot off the gas when it comes to our efforts to contain dangerous diseases such as Ebola and avian influenza.

With that, let me welcome our witnesses. We look forward to an informative and productive conversation on how to better integrate and strengthen our biodefense programs. This is an important hearing, not just for our committee, but for our nation. Bring it on!

Written Testimony Committee on Homeland Security and Governmental Affairs

"ASPR's Role in Biodefense"

Statement of
Richard J. Hatchett, MD
Acting Deputy Assistant Secretary and Acting BARDA Director
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

For Release on Delivery
Expected at 10:00 a.m.
Tuesday, April 5, 2016

Chairman Johnson, Ranking Member Carper, and distinguished Members of the Senate Committee on Homeland Security and Governmental Affairs – thank you for the opportunity to testify on behalf of the Office of the Assistant Secretary for Preparedness and Response in support of our recent progress enhancing coordination, building community resilience, and responding to threats against the health and well-being of our nation. I am Dr. Richard Hatchett and I serve as the Acting Director of the Biomedical Advanced Research & Development Authority (BARDA) and as an Acting Deputy Assistant Secretary for Preparedness and Response. BARDA is a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR). The ASPR, Dr. Nicole Lurie, serves as the principal advisor to the Secretary of Health and Human Services (HHS) on all matters related to federal medical preparedness and response for public health emergencies.

Securing our nation against biological threats is a challenging endeavor. The array of threats for which we must be prepared is vast. Such threats include bioterrorist agents such as anthrax, smallpox, and botulism; evolving and emerging threats causing substantial regional disruption such as Ebola and Zika; and highly communicable diseases with pandemic potential such as influenza. In the last fifteen years, the world has experienced the first pandemic in 40 years, devastating outbreaks of foot-and-mouth disease, anthrax attacks, the re-emergence of cholera in the Western Hemisphere, the largest Ebola epidemic ever recorded, and the global dissemination of vector-borne viral diseases such as Chikungunya and Zika. However, thanks to lessons learned from previous responses, biomedical breakthroughs, and sound strategic investments, we have improved our preparedness for and capability to respond to a wide-range of threats regardless of their origin and properties. We have read with interest the report and

recommendations of the Blue Ribbon Study Panel on Biodefense, which we know to be of interest to this Committee. With that in mind, I would like to update you on some of the areas in which ASPR and BARDA have progressed in recent years.

In the wake of the 2001 anthrax attacks and subsequent disasters such as Hurricane Katrina, Congress and the Executive Branch reevaluated the preparedness and response strategy of our nation. In 2006, Congress passed and President Bush signed the Pandemic and All-Hazards Preparedness Act (PAHPA), which established both ASPR and BARDA. ASPR will celebrate its tenth anniversary on December 19 of this year. Within ten years, ASPR has significantly enhanced the preparedness of our nation.

ASPR has made numerous improvements to ensure national health security and to protect the American people. One such improvement is the development and continued refinement of the National Health Security Strategy (NHSS), which unified a patchwork of public health and medical preparedness, response, and recovery strategies. The NHSS works to ensure that the nation is prepared for, protected from, and resilient in the face of public health threats. Originally released in 2009 and updated in 2014, the NHSS is the first strategy specifically focused on protecting public health during an emergency. It envisions resilient and strong communities with sustainable health and emergency response systems. The NHSS, with its accompanying implementation plan, lays out actionable goals and objectives to achieve these ends.

ASPR has the authority to deploy federal public health and medical personnel; oversees the advanced research, development, and procurement of medical countermeasures; coordinates the integration of federal preparedness and response activities for public health emergencies; and provides logistical support for the federal component of medical and public health responses. In light of these responsibilities, the ASPR has provided leadership over the last seven years in response to a number of public health and medical emergencies including the 2009 H1N1 pandemic, the Deepwater Horizon oil spill, Superstorm Sandy, and the recent Ebola and Zika epidemics. Most recently, in January, Dr. Lurie was designated the lead federal official in response to the Flint, Michigan water crisis.

In executing her responsibilities, the ASPR serves as the chair of two interagency coordinating bodies, the Disaster Leadership Group (DLG) and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The DLG is convened on an as-needed basis to respond to emergencies while the PHEMCE is a standing virtual enterprise that coordinates the entire life cycle associated with the development and procurement of medical countermeasures. Both were created explicitly to improve coordination and collaboration within the Department and with our external stakeholders, including nonprofits, other federal departments, the private sector, and the international community. The DLG, comprised of decision makers from across HHS, including representatives from the Office of the Secretary, NIH, the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and other HHS operating and staff divisions with incident-specific responsibilities, serves as the Department's main policy-making body during emergency responses. Under the scope of its policy-making responsibilities, the DLG advises the Secretary on critical preparedness matters, addresses

ongoing response activities, and mitigates the lasting effects of disasters. The PHEMCE is comprised of ASPR, NIH, CDC, and FDA as well as the Departments of Homeland Security (DHS), Defense (DoD), Veterans Affairs, and Agriculture.

The PHEMCE has been uniquely successful in promoting the development and acquisition of medical countermeasures for chemical, biological, radiological and nuclear (CBRN) threats, pandemic influenza, and emerging infectious disease threats. PHEMCE activities are governed by the PHEMCE Strategy and Implementation Plan (SIP). The PHEMCE SIP is updated annually and describes the PHEMCE's governance and decision-making structure. One of the most important functions of the SIP is to provide clarity and guidance about PHEMCE objectives to our external partners and stakeholders.

PHEMCE coordination and decision-making encompass all stages of the medical countermeasure life cycle from identifying requirements and developing target product profiles through product development to distribution and dispensing. Agencies take responsibility and are held accountable for activities within their mission space and PHEMCE coordination establishes common priorities, facilitates joint decision making and information sharing, and ensures smooth transitions as products move from stage to stage of development. The PHEMCE has an outstanding record of success and is now being studied as a model for global preparedness against emerging infectious diseases. It was established in 2007 and its processes have been iteratively refined and improved over the last 9 years. At least 23 medical countermeasures developed under its purview have been approved, licensed, or cleared by the FDA by the FDA. Of these, 15 have been approved since 2011 and five have been approved in the last 12 months.

The PHEMCE facilitated the rapid development of vaccines, therapeutics, and diagnostics during the Ebola epidemic and is fully engaged in the current response to Zika.

Operationally, the PHEMCE establishes product specific requirements for CBRN medical countermeasures based on Material Threat Assessments developed by DHS. NIH and DoD support discovery and early stage development of product candidates by academic and industry partners, preparing them for transition to BARDA. In turn, BARDA supports and assists product candidates through advanced research and development until they are ready for acquisition under Project BioShield. After procurement, medical countermeasures are maintained within CDC's Strategic National Stockpile (SNS) or within virtual stockpiles maintained by commercial vendors (in so-called vendor-managed inventory). If advanced development data leads to FDA approval of a marketing application, the financial responsibility of purchasing medical countermeasures for stockpile and delivery transfers from BARDA under Project BioShield to SNS. During evolving public health emergencies such as the 2009 H1N1 pandemic, the Ebola outbreak, and the current Zika crisis, NIH, BARDA, and DoD may shift into response mode, interfacing with other federal agencies and manufacturers to develop, produce, and test products for FDA review and approval and (where necessary) distribution by CDC to state and local health departments.

The ongoing response to the Zika epidemic illustrates how these coordinating bodies function and interact in a crisis. As was also the case with Ebola, the PHEMCE response was initiated well before we had a recognized problem with either virus in the US. In the case of Ebola, PHEMCE processes began to gear up in the spring of 2014, and for Zika, it was early December

2015. A subcommittee of the PHEMCE, the medical countermeasures Senior Steering Group, has met almost weekly throughout both crises. The Zika DLG convened for the first time on January 5, 2016 and meets at least twice weekly to coordinate and guide the policy approach to Zika and to coordinate the major strategic workstreams. These workstreams focus on maintaining situational awareness, communications and stakeholder outreach, international engagement, enhancing laboratory tests and diagnostics capacity, vector control, improving availability and access to contraceptive and other health services, addressing the particular needs of territories with ongoing transmission (especially Puerto Rico), promoting domestic preparedness in states at high risk of autochthonous transmission, ensuring blood/tissue/organ safety, and accelerating the development of effective medical countermeasures such as vaccines, therapeutics, and pathogen reduction technology for blood. The PHEMCE Senior Steering Group meets once weekly and has focused on the three major areas of emphasis within countermeasures development based on the special characteristics of the Zika epidemic (diagnostics, vaccine, and pathogen reduction technologies). Interagency participation facilitates coordination of effort and rapid problem solving. This is exemplified by the rapid generation of vaccine and diagnostics landscapes, efforts to ensure the integrity of the blood supply, and prospective monitoring of contraceptive and insecticide supply chains.

A well-coordinated PHEMCE response is a critical enabler of a rapid science and industry response. Last month, ASPR hosted the General Assembly of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), which consists of 23 globally recognized research funding institutions. This meeting focused largely on lessons learned from the Ebola response and planning for research on and development of medical countermeasures against

Zika. A couple of weeks ago, HHS sponsored another major international meeting, "Zika Virus in the Americas: An HHS Expert Consultation to Accelerate the Development of Countermeasures" that was attended by nearly 700 people and included representatives from academia, industry, and major international partners. These meetings and associated outreach activities have allowed the PHEMCE to better understand the needs of our partners and to identify and address major barriers and rate-limiters for countermeasure development.

To best support information flow within the PHEMCE and DLG, as well as across the interagency response components, ASPR supports operational coordination through staff in the Secretary's Operation Center (SOC). ASPR supports the surveillance of emerging threats and critical incidents, nationally and internationally, 24 hours a day, seven days a week using staff and technologies in the SOC. Staff monitors information from federal, state, local, territorial, tribal, private-sector, non-profit, and international partners to identify potential or emerging threats to public health and facilitate the rapid implementation of response activities when necessary.

The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) requires HHS to develop a five-year budget plan for the medical countermeasure enterprise. This multiyear plan is a tool for strategic project coordination, product transitions between agencies, communication of priorities and resources to partner stakeholders, and assistance with long-term forecasting. The goal of the multiyear plan is to outline PHEMCE programmatic estimates on a five-year rolling basis and to identify the hand-offs in the development cycle in anticipatable budget terms. This forecast allows agencies to understand the dynamic effects of PHEMCE

decisions on their own strategic planning and those of downstream partners. Additionally, this tool communicates PHEMCE commitments and priorities to our industry partners. By coordinating resources and priorities, we can ensure an active medical countermeasure industry that meets our essential needs for a nimble and flexible response capability.

Created in 2006 by PAHPA, BARDA supports advanced research, development and procurement of countermeasures—vaccines, therapeutics, antiviral and antimicrobial drugs, diagnostics, and medical devices—that mitigate the medical consequences of man-made CBRN agents of terrorism and naturally-occurring and emerging threats like the 2009 H1N1 pandemic, the 2013 H7N9 influenza outbreak, and the recent Ebola epidemic. BARDA is the only federal agency that is exclusively focused on promoting the advanced development of medical countermeasures. Advanced development includes critical steps needed to transform a candidate to a product that is ready to use. These steps include optimizing and validating commercial scale manufacturing processes; optimizing product formulations, storage, and product longevity and effectiveness; creating, optimizing, and validating assays to assure product integrity; conducting late-stage clinical safety and efficacy studies; and carrying out pivotal animal efficacy studies.

PAHPA directed BARDA to promote countermeasure and product advanced research and development. Since its creation, BARDA has built a comprehensive and formidable advanced development product pipeline that has supported close to 200 medical countermeasure development projects. Seventeen products, ranging from anthrax antitoxins and smallpox vaccines to anti-neutropenia cytokine therapeutics for radiation illness and an array of products for the management of thermal burns, have been procured under Project BioShield with another

seven anticipated between now and the end of FY 2018. BARDA has supported the development and manufacturing of 18 influenza vaccines, antiviral drugs, and diagnostics that were either used in the 2009 H1N1 pandemic or stockpiled to enhance preparedness for H5N1 and H7N9. To better serve the needs of special populations, BARDA has funded the development of a smallpox vaccine (Modified Vaccinia Ankara) suitable for use in immunocompromised individuals as well as pediatric formulations of drugs like Prussian Blue (a treatment for internal radiation contamination) and solithromycin (an antibiotic candidate under investigation).

To address its core mission of developing medical countermeasures against CBRN threats and pandemic influenza, BARDA has honed its processes and procedures, supported the development of critical product development support services and infrastructure, and assembled a world-class workforce expert in all aspects of product development. These product development capabilities have allowed BARDA to pivot to address emerging threats when a rapid response is required. For example, BARDA advanced multiple vaccines and therapeutics and an innovative lateral flow diagnostic into clinical trials during the response to the Ebola epidemic and more recently has mobilized to support the development of vaccines, diagnostics, and pathogen reduction technologies for Zika virus.

BARDA has vigorously pursued innovations to reduce the time and cost of countermeasure development. Investments have yielded a next generation anthrax vaccine candidate by coupling an expression system with rational genetic design technology using a novel bacterial expression system; the objective of which is an anthrax vaccine with increased stability and production

yields, and thus a lower overall product cost. BARDA partnered with industry to use synthetic biology technology to generate influenza vaccine seed strains. In 2013, this technology was pivotal in making pre-pandemic H7N9 bulk vaccine for stockpiling in record time. In 2014, BARDA began working with industry partners to develop new Ebola monoclonal antibodies rapidly using the latest innovations in monoclonal antibody development. These new Ebola antibody candidates have now been tested in non-human primate challenge studies and could move into clinical trials later this year. BARDA has kept a keen eye on and supported innovative technologies that may enhance existing medical countermeasures or generate new transformative medical countermeasures at lower costs and with longer shelf lives.

BARDA has established its medical countermeasure development pipeline by collaborating closely with federal partners, primarily NIH, CDC, FDA, and DoD, and by establishing public-private partnerships with industry and academia. BARDA has established partnerships with almost 100 pharmaceutical and biotechnology companies and more than 25 academic and other institutions since 2006. BARDA established the first and largest pre-pandemic influenza vaccine stockpile in the world, one that could, if necessary, vaccinate tens of millions of Americans in the event of H5N1 or H7N9 pandemics. Using the Other Transaction Authority granted by PAHPA, BARDA has established novel portfolio partnerships with GSK and AstraZeneca to support the development of new antimicrobial drugs. Finally, because many of BARDA's partners have been small to mid-size biotechnology firms that have gaps in their product development expertise and capabilities, BARDA has established an array of core services that it can bring to bear in support of its partners' product development efforts. These core services facilitate access to subject matter experts in a variety of disciplines germane to product

development (such as clinical trial design, regulatory affairs, process engineering, etc.) as well as access to animal models and preclinical laboratories, a clinical studies network, a fill-finish manufacturing network, and BARDA's Centers for Innovation in Advanced Development and Manufacturing. These latter assets, which support BARDA's core mission of promoting biodefense product development, also enhance BARDA's response capability and collectively constitute BARDA's National Medical Countermeasures Response Infrastructure, which was mobilized for the first time during the Ebola epidemic to accelerate the development of Ebola vaccines and therapeutics and is being engaged now to expedite the development of vaccines against Zika.

ASPR has established a separate and specialized Office of Acquisitions Management, Contracts and Grants (AMCG) whose contracting authority is delegated from the HHS Senior Procurement Executive (SPE). This independent line of reporting to the ASPR and the SPE eliminates undue influence from program offices, maintains the highest standards of program integrity, and mitigates potential conflicts of interest. AMCG is an award winning and innovative contracting office, having received the HHS Secretary's 2015 Hubert H. Humphrey Award for Service to America, the 2012 HHS Small Business Award, and the 2010 HHS Project Team Award for is contribution to the H1N1 Influenza Virus response. It introduced the use of Broad Agency Announcements to ASPR which streamlined the acquisition process and initiated the use of Other Transaction Agreements to further engage industry.

AMCG has led the department in meeting contracting time lines. While the federal government and Department standard time line for awarding contracts is 180 days, AMCG awarded the

majority of its Ebola contract actions within 60 days. All Project BioShield contract actions were awarded within 128 days starting at the end of FY 2014 and with the bulk of these actions in FY 2015. In FY 2015, 90 percent of ASPR's contract actions were competed, thereby ensuring that there is opportunity for businesses capable of meeting the needs of HHS to compete on a level playing field. Exceeding targets under the President's Small Business Initiative, ASPR awarded 51 percent of eligible contract dollars to small businesses, exceeding our own 35 percent small business goal. Additionally in FY2015, ASPR awarded 91 grants totaling $212,649,385.67.

AMCG follows the acquisition processes required by the Federal Acquisition Regulation (FAR). The FAR allows for some flexibility to streamline the acquisition process, in the event of any emergency to expedite contract award by the contracting officer. This emergency authority was recently put to use by AMCG in what U.S. News and World Report on March 18, 2016 called "an unprecedented relief effort, [by] the federal government and blood banks in the United States... to provide the entire territory of Puerto Rico with safe blood to protect recipients from the Zika virus." AMCG was notified on February 24, 2016 that there was an urgent and immediate need to restock the blood supply in the Commonwealth of Puerto Rico following FDA-issued guidance effective March 1 that led to cessation of the blood collection on the island due to the need to prevent transfusion transmission of Zika virus. Working closely with BARDA to define the actual requirement, conducting market research, and seeking legal advice, and drafting the contract document; the contracting officer awarded a $4.6 million contract within six business days on March 3, 2016. On March 5, 2016, delivery of "nearly 5,000 units of blood and other products per week, enough to meet the whole territory's needs" commenced. Chris

Hrouda, Executive Vice President of Biomedical Services for the American Red Cross, commented, "I don't think this has ever been done, and I've been in this business 30 years." This herculean effort by AMCG and BARDA prevented a public health crisis from becoming a medical crisis and demonstrates the flexibility, speed, and coordination with which the two offices can operate.

ASPR strives to preserve health, mitigate suffering due to illness and injury, and expedite recovery through the development of resilient communities before, during, and after events ranging from bioterrorism attacks to natural disasters that impact public health and well-being. To achieve this goal, ASPR supports building preparedness capabilities and resiliency at the community level before disasters or public health incidents occur. ASPR's flagship program in this regard, the Hospital Preparedness Program (HPP), has provided more than $5.1 billion to state and local health departments since 2002 to better prepare the nation's health care infrastructure for man-made or natural disasters.

While hospitals remain at the center of a prepared health care system, events of the last decade, including H1N1, the Joplin, Missouri, tornado, and Superstorm Sandy, have highlighted how important it is for hospitals to work with one another and with other community health care entities to prepare and execute a health care system response. Consequently, since 2012, HPP has emphasized the importance of regional coalitions of health care entities, promoting a bottom-up approach to national resiliency that has already proven beneficial in recent responses. These Health Care Coalitions (HCCs) incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. They ensure that each

member has the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to an emergency. The health of communities is deeply intertwined with the ability of its institutions to provide care to all populations and we believe investments in HPP are critical to mitigating the cascade of negative health effects that disasters can have on a community.

ASPR has supported a number of recent initiatives to enhance the HPP program. In 2010, ASPR took the initiative to ensure that HPP funding was better aligned with CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement. This alignment reduced bureaucracy and administrative workload for grantees, and ensured the programs could leverage one another's work and avoid duplication. Alignment of the exercise requirements for both cooperative agreements and the integration of the annual grantee meetings are just two examples of efficiencies that have been achieved through this process.

Another example of program improvement was in 2012 when HPP identified eight national health care preparedness capabilities that grantees were required to support. These capabilities are sufficiently flexible to enable all-hazard planning for natural disasters, terrorist events, infectious disease outbreaks, and industrial accidents. The capabilities are designed to facilitate and guide preparedness planning and are scalable to maintain effectiveness during every day emergencies as well as disasters eliciting state and federal disaster declarations. HPP awardees use the health care preparedness capabilities to identify gaps in their preparedness efforts and better target investments to ultimately assure that their communities are safer, more resilient, and better prepared.

Lastly, to ensure that stakeholders have access to critical and up-to-date information to better support emerging needs during disaster, ASPR launched the Technical Resources Assistance Center and Information Exchange (TRACIE) in September 2015. TRACIE provides one-stop shopping for partners and stakeholders to gain access to best practices, guidance documents, and technical assistance as well as to share ideas and to collaborate with stakeholders on matters pertaining to healthcare emergency preparedness. TRACIE ensures that stakeholders at all levels of government and the private sector have access to information and resources to improve preparedness, response, recovery, and mitigation efforts. TRACIE's listserv has nearly 4000 recipients, has received over 30,000 visitors to the website, responded to more than 300 training and technical assistance requests, and signed up nearly 1200 members to the Information Exchange.

During the Zika response, ASPR has used HPP mechanisms to share information with state and local health care partners. For example, HPP's weekly update to awardees includes all of CDC's Health Alert Network advisories as well as links to other CDC-produced guidance documents. HPP encourages HCC coalition leaders and awardees to share information about Zika virus with their member facilities and organizations. HPP also encourages the HCCs to identify specialized resources, such as neurology services and maternal-fetal medicine units, and share information with member facilities and organizations about how to access and utilize them as resources for preparedness, communications/messaging, and consultative purposes.

While ASPR's ultimate goal is to empower communities to respond effectively without federal assistance, ASPR is organized to deploy subject matter experts, medical personnel, and supporting medical caches of lifesaving equipment to disaster areas when called upon. The National Disaster Medical System (NDMS) within ASPR is able to assist communities with medical services after a disaster or public health emergency and to support the DoD when there is a surge of military casualties that could overwhelm the military medical system. Since its establishment, NDMS has responded to over 300 incidents to support communities both domestically and internationally. NDMS provides assistance to communities impacted by public health and medical emergencies ranging from severe weather incidents to terrorist acts by deploying deeply experienced and specially trained medical teams. In cooperation with FEMA at the Center for Domestic Preparedness in Anniston Alabama, NDMS routinely trains for mass casualty events involving terrorist attack or natural disasters. NDMS is a unique national asset positioned and authorized to deliver essential medical services when requested by a community or partner federal agency.

During the Zika crisis, ASPR operations staff worked with key partners to share information and provide detailed situational awareness reports to senior leaders within the Department as well as across the interagency. Utilizing technologies in the SOC and various Fusion tools to collect information from internal and external data sources such as GeoHEALTH and social media analytics, staff monitor media reports, various official information systems, and other data streams to ensure that leaders and decision-makers are provided up-to-the-minute situation reports.

Infectious disease threats manifest in myriad forms and present unique challenges for preparedness and response. Fortunately, many of the lessons learned in responding to emerging infectious disease threats can inform our preparedness for acts of bioterrorism, while many of the capabilities we have developed to promote preparedness for bioterrorism simultaneously enhance our preparedness for and ability to respond to natural threats.

What is required to respond effectively may differ substantially from agent to agent and over time within a given event, as recent crises demonstrate. To meet such threats, our nation requires an array of response capabilities, the ability to adapt in real time to changing circumstances, and robust mechanisms for coordination and communication. In less than ten years, ASPR and its component programs have made contributions in each of these areas and today play a critical role in preparing for public health and medical emergencies, whether natural or deliberate in origin. Through a concerted effort over many years, ASPR has brought us closer to realizing the goals articulated in the NHSS: "National health security [as] a state in which the nation and its people are prepared for, protected from, and resilient in the face of incidents with health consequences." Thank you again and I look forward to your questions.

Written Testimony
Senate Homeland Security and Government Affairs Committee

The Federal Perspective on the State of Our Nation's Biodefense

Statement of

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Centers for Disease Control and Prevention
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For Release upon Delivery
Expected at 10:00a.m.
Thursday, April 14, 2016

Good morning Chairman Johnson, Senator Carper, and other distinguished members of the Committee. I am Rear Admiral Stephen Redd, Director of the Centers for Disease Control and Prevention's (CDC) Office of Public Health Preparedness and Response.

I am pleased to appear before the Committee today to discuss the state of public health preparedness and health security in the United States, and CDC's current level of preparedness for biological and other natural and manmade, domestic and international threats, including recent progress made in ensuring our preparedness and response capabilities. I am also happy for this opportunity to provide an update on CDC's ongoing response to the Zika virus outbreak.

CDC advances the health security of the Nation by helping communities prepare for, respond to, and recover from all hazards, including chemical, biological, radiological, and nuclear threats; natural disasters; and epidemics. Whether the hazard is naturally occurring (Zika and Ebola viruses, and hurricanes), unintentional (the 2014 West Virginia chemical spill) or intentional (anthrax attacks), effective public health emergency management and response depends on building, maintaining and constantly improving the capability of state and local health departments to prepare for and respond to public health emergencies. We have to be ready to respond to any threat: this approach to public health preparedness and response fosters development of emergency-ready public health departments that are flexible and adaptable to the needs of responding to a particular incident.

Role of State and Local Public Health Agencies

State and local public health agencies are the front lines of public health preparedness and response. CDC provides ongoing technical assistance and, where requested, on-the-ground personnel and materials to assist with response efforts. For example, CDC personnel are providing laboratory testing surge capacity and training, vector control, and surveillance support to Puerto Rico in response to the current Zika virus outbreak.

Investments in preparedness since 2001 have greatly increased the Nation`s public health preparedness for any threat. One of the lessons learned as a result of responding to the 9/11 and anthrax attacks was that state and local health departments lacked critical capabilities needed to mount an emergency response, and the Nation`s public health system also was not consistently able to provide essential public health services during an emergency. Health departments lacked laboratory networks, electronic disease surveillance systems, expertise in risk communication, and emergency operations centers.

Successful state and local response to public health emergencies depends upon many factors, including a capable state and local public health and healthcare system. To support our state, local, and territorial partners, CDC established the Public Health Emergency Preparedness (PHEP) cooperative agreement program. In the I4 ½ years since 9/11 CDC has awarded an average of $766 million dollars per year to improve preparedness at the state, local, and territorial levels. However, current funding for the PHEP cooperative agreement program is approximately $300 million dollars lower than funding amounts from 2001-2003.

The PHEP cooperative agreement program currently funds 62 awardees -- including all 50 states, eight territories and freely-associated states, and four directly-funded localities (New York City; Washington, D.C.; Chicago; and Los Angeles County) -- according to a base-plus population formula prescribed by statute, which ensures a minimum amount of funding to each awardee.

These funds support staff, pay for equipment, provide for training, enable exercises, and provide other services essential to maintaining preparedness. In addition, CDC personnel help PHEP awardees improve their performance by sharing knowledge, useful practices and lessons learned along with the tools and resources needed to identify and address gaps in preparedness capabilities.

Cooperative agreements under CDC`s PHEP program and the Hospital Preparedness Program (HPP), overseen by the Assistant Secretary for Preparedness and Response (ASPR), are aligned and managed jointly with a single funding opportunity announcement, funding application, and grant award. This

collaboration reduces the administrative burden on the awardees through a single application process for both cooperative agreements. PHEP and HPP also aligned the program capabilities, framework, and reporting requirements to streamline operations and strengthen public health and healthcare preparedness synergies.

State and local health departments have greatly increased their capacity to respond to an array of hazards, which is evidenced through states' proven success in responding to critical events without requesting direct federal support (such as a 2015 oil spill in Montana).

Lessons learned from exercises and real-life incidents

While training and skill development are important, exercises and real-life events provide opportunities to put those skills to work. PHEP awardees are required to demonstrate their capabilities at least once a year by conducting an exercise and evaluating their performance through an after-action review process. Oftentimes, jurisdictions are able to use real incidents in their communities to test operational readiness to respond to public health emergencies.

After-action reviews collect data about successes and areas for improvement identified during unexpected incidents, exercises, and real events such as festivals or concerts that draw large crowds. Data from these reviews are used to identify strengths for sustainment and gaps for future capability development. Use of this information is key to improving performance for the next incident or event. For example, the after-action review of the 2010 cholera outbreak response in Haiti recommended that CDC institutionalize the use of permanently assigned in-country CDC staff to act as Incident Managers, to better prepare staff to lead emergency response operations within the country. As a result, additional in-country staff around the world have observed and been trained on managing emergency operations in the event the country activates its Emergency Operations Center. More effective in-country response operations will reduce the geographic spread of an outbreak and help protect the U.S. against domestic cases.

CDC recently concluded emergency response operations for the 2014 Ebola outbreak in West Africa (Guinea, Liberia, and Sierra Leone) and will be identifying and addressing lessons learned in the coming months. To date, CDC has already recognized three key lessons learned:

- The need for every country to have systems in place to prevent, detect, and respond to health threats;
- The need for other countries and international support groups to be prepared to respond swiftly and effectively in a coordinated fashion when a country is overwhelmed by an incident; and
- The need to improve infection control practices with respect to health care facilities.

In response to these lessons learned, CDC is working with certain countries in Africa to help build their capacity to respond to health threats. Domestically, to improve infection control CDC is partnering with state and local public health preparedness and healthcare-associated infection control programs to develop common processes for management of persons under investigation for potential diseases. Through these partnerships CDC is also developing and sharing protocols for notification of and response to cases of emerging or re-emerging, highly contagious diseases in healthcare facilities.

A strong laboratory response network

Rapid identification of disease is critical to addressing public health threats before they become a crisis. CDC's Laboratory Response Network (LRN) maintains an integrated system of state and local public health, Federal, and international laboratories that can respond to biological, chemical, and other public health threats. The linking of state and local public health laboratories, veterinary, agriculture, and water- and food- testing laboratories over the last 15 years the LRN represents a significant advance in our preparedness capabilities and provides for rapid testing, timely notification and secure communication of laboratory results.

The LRN is a scalable and flexible asset to address public health threats. In response to the Zika virus outbreak, CDC collaborated with the Food and Drug Administration (FDA) to quickly equip LRN

laboratories around the United States with the ability to quickly test specimens for the outbreak strain of Zika virus. In recent weeks, the FDA has issued two Emergency Use Authorizations (EUA) for CDC-developed diagnostic tools. One, the CDC Trioplex Real-time (RT)-PCR Assay, allows doctors to tell which, if any, of three similar viruses (chikungunya, dengue, or Zika) has infected an individual, instead of having to perform three separate tests to determine which infection one might have. Fifty states and Washington, D.C. have been provided with materials to conduct the RT-PCR test. The second test called the CDC Zika IgM Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA), can detect antibodies that the body makes to fight a Zika virus infection; presence of such antibodies indicates that there was a recent infection. Results of this test will help patients (particularly pregnant women) and physicians determine the best approach to monitoring patient health. Both the RT-PCR and Zika MAC-ELISA tests require specialized equipment and skills and can only be done by qualified laboratories capable of performing "high-complexity tests," as that phrase is used in the Clinical Laboratory Improvement Act. As of April 5, 2016, 14 labs in 11 states were verified to conduct the RT-PCR test and 16 labs across 15 states have the capability to perform the Zika MAC-ELISA test. We expect more labs to come on line in the near future.

Medical countermeasures for public health responses

CDC's Strategic National Stockpile (SNS) manages and delivers life-saving medical countermeasures during a public health emergency. In addition to stocked products, SNS has many capabilities that can be rapidly brought to bear to respond to threats to public health and thus the nation's health security.

Holding more than $7 billion in assets, SNS is authorized to maintain a stockpile of drugs, vaccines, and medical equipment to provide for the emergency health security of the United States. These supplies and SNS capabilities are designed to support response to public health emergencies of all types. If a chemical, biological, radiological, or nuclear incident occurred anywhere in the United States or its territories tomorrow, SNS capabilities and supplies are available to respond immediately. SNS also is positioned to

support response to emerging infectious disease threats such as Ebola and Zika viruses, through personal protective equipment and other supplies to prevent infection.

CDC works with HHS's ASPR and with other Federal agencies, through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to prioritize Federal investments in medical countermeasures based on analysis of risk and support of critical markets. SNS procurements and the advanced development and procurement mechanisms managed through ASPR are critical to assuring the United States' health security with a ready stock of medicine and medical supplies to respond. The continued purchase of products which are vital for response and have no regular commercial market assures that manufacturer capabilities are maintained and product continues to be produced. And, sustained purchasing of commercially available medical supplies assures there is a ready stock for a response that might exceed normal market operations and potentially assures a more robust supply chain capability.

Just as important as having the right medical countermeasure on the shelf in the SNS is knowing our public health partners at the state and local levels will be able to effectively and efficiently receive those assets from the SNS and get them in time to the end users, individuals in need of treatment or protection.

For this reason, CDC offers training programs to ensure that our partners have the knowledge and skills they need to distribute and dispense SNS assets in a timely manner, and CDC supports exercises to test the skills of trained responders and evaluate plans for possible improvements. These trainings and exercises help our partners improve their preparedness and establish confidence in their ability to respond. In FY 2015, CDC trained 1,661 individuals at the federal, state, and local level through 66 training opportunities. Additionally, expanded offerings of three self-paced online courses provided training to another 1,776 federal, state, and local planning and response personnel. CDC also supported and participated in 20 realistic objective-based exercise events at CDC and around the country, to assess the readiness of CDC and its state, local and territorial partners.

Jurisdictions face ongoing challenges when planning to dispense medical countermeasures to large populations. Decreased funding availability impacts both staffing and infrastructure. Fewer state and local public health staff are available to protect or treat large populations of affected individuals and the infrastructure (i.e., warehouses, transportation, systems) critical to the management of a public health response requiring medical material is increasingly unfunded. These two gaps challenge state and local capacity to maintain and advance public health preparedness. CDC constantly works to develop and improve partnerships that can help support responses to health threats by filling these gaps.

These partners—who range from healthcare material trade associations to nationwide retail, pharmacy and hospital chains to faith based and community organizations—all help expand capability for delivery and dispensing of countermeasures in the communities and business sectors they serve. These partnerships improve response efficiency, provide additional means to deliver medical countermeasures to healthcare providers and populations within the community, and reduce the burden on local public health responders during times of urgent need.

CDC is currently working with Costco and Walgreens to develop medical countermeasure dispensing capabilities. Costco successfully conducted a dispensing exercise in a Virginia retail store last year to test these capabilities. As a direct result of this exercise and the planning that led up to it, Costco expressed willingness to consider requests from any local health jurisdiction to allow any of their retail stores in the United States to serve as public points of dispensing during a public health emergency. CDC has partnered with Walgreens for almost two years to develop dispensing capability, and Walgreens supports numerous local jurisdictions throughout the U.S. in their dispensing capability. This partnership continues to explore the potential use of Walgreens retail stores to not only support dispensing, but also use of trucks and drivers to support distribution, and Walgreens clinical staff to support public health operated dispensing sites.

Zika Virus Update

As of April 5, 2016, 41 countries and U.S. territories, including Puerto Rico, the U.S. Virgin Islands, and American Samoa, have reported local transmission of the Zika virus. CDC's key priority at this point is to reduce the risk of Zika virus infection to pregnant women. The virus can be transmitted through infected mosquitoes and infected sexual partners. Given the risks associated with maternal Zika virus infection, prevention is key. Therefore, CDC is taking action based on what we know now, and seeking to learn more so that we can better prevent adverse health outcomes in the future. For example, during the same week we identified Zika in brain tissue specimens from affected infants, we issued a warning to advise pregnant women not to travel to affected areas. We are working intensively with Puerto Rico and other areas to offer prevention tools to women who are or who may become pregnant. We also are engaging in studies with international partners so that we can more fully understand the magnitude of risk and the range of outcomes associated with Zika virus infection during pregnancy.

While we are working to better understand these health outcomes and the risk of transmission of Zika virus, we have developed diagnostic tests and are working to implement mosquito control measures. CDC has also been responding quickly. On January 22, 2016, we activated our Emergency Operations Center and on February 8, 2016, we elevated our Emergency Operations Center response efforts to the highest level to further enhance our activities in areas with current local transmission and to accelerate preparedness efforts in anticipation of local transmission in the continental United States and Hawaii.

For Puerto Rico, the U.S. Virgin Islands, and American Samoa, a surge in resources is urgently needed. The population of *Aedes aegypti* mosquitoes (key Zika virus transmitters) is widespread on these islands, protective environmental factors such as window screens are not in wide use, and high population density puts people there at greater risk for transmission. All three areas have already reported local Zika virus transmission, with Puerto Rico alone reporting over 300 hundred cases. Furthermore, recent outbreaks of dengue and chikungunya viruses, which are spread by the same mosquito species, suggest that Zika virus may spread extensively and rapidly in these areas. CDC has deployed staff to the U.S. Virgin Islands, American Samoa, and Puerto Rico to support response activities and provide technical assistance to

health departments there. CDC and the CDC Foundation are also partnering to create and distribute Zika Prevention Kits. Containing educational materials and initial supplies of prevention tools such as insect repellant and treated bed nets, the purpose of these kits is to help pregnant women in areas with local Zika transmission protect themselves from infection. Five thousand of these kits have been dispatched to Puerto Rico, the U.S. Virgin Islands, and American Samoa; and CDC plans to distribute approximately 50,000 kits to these areas in the future.

We have not yet seen transmission of the Zika virus by mosquitoes within the continental United States or Hawaii, but we know we are not doing enough to prepare the state public health system. More than 320 returning travelers have already been diagnosed with Zika infection. As a potential benchmark, we received reports of 3,270 travelers from 49 states with laboratory confirmed cases of chikungunya infection in 2014 and 2015. There are about 40 million people travelling between the continental U.S. and Zika-affected areas each year. Therefore, all U.S. jurisdictions must be prepared to evaluate, test, and manage patients potentially infected with Zika virus, particularly pregnant women. Furthermore, *Aedes aegypti* mosquitos are found in many areas of the United States, raising the risk of local transmission. The most recent data available suggest that *Aedes aegypti* are found in 30 states and *Aedes albopictus* (mosquitoes also known to transmit Zika virus) are found in 40 states and the District of Columbia. Recent experience with chikungunya and dengue virus infections in the United States were relatively small outbreaks localized to the southernmost locations. Zika virus may follow this pattern as well. However, any local cases or clusters of cases will be of deep concern to the people living in areas with the *Aedes aegypti* and *albopictus* mosquitoes, and we must be prepared for different scenarios including more extensive transmission risk.

CDC is working with health departments across the country to ensure coordination and to expand capacity for detecting and responding to Zika virus. Surveillance is essential to monitor and quickly identify areas with local transmission. We conduct multi-faceted surveillance for arboviruses, including Zika, through ArboNET, an integrated network which, through our Epidemiology and Laboratory

Capacity cooperative agreements, funds staff in 49 states, Puerto Rico, and six large municipalities to conduct human case investigations, collect and test mosquitoes, and perform laboratory analysis on arboviruses including Zika. Zika virus is now a nationally notifiable disease, meaning states voluntarily report instances of the virus to CDC, a critical step in Zika surveillance. CDC also is working with several states and Puerto Rico to determine a baseline prevalence of microcephaly so that any increase, should it occur, can be quickly and accurately identified. Finally, on April 1, CDC hosted a Zika Action Plan Summit focused on ensuring that states, territories, and localities coordinate planning and apply best practices – from federal and other state and local subject matter experts -- to strengthen Zika Action Plans and identify gaps in readiness or resource needs.

CDC is also collaborating in its Zika response efforts with other components of HHS, including ASPR and its Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health, and the FDA. We are also working with partners across the U.S. Government to communicate with travelers and health care providers, update travel alerts and clinical guidance, and develop improved mosquito-control methods.

Conclusion

Public health threats are everywhere. From imported measles cases, which have led to large outbreaks in the United States where it had been eliminated for years, to the Ebola virus, a threat from the other side of the world, to an earthquake that can strike without warning, the public health system must remain vigilant to protect U.S. residents.

Preparedness is not a destination. It is a process of skill development, and honing our abilities to adapt to the current environment and better prepare us to address future threats. CDC will continue to work with Federal, international, state, tribal, territorial, and local partners to ensure necessary capabilities are maintained to keep the public safe. I look forward to our continued partnership with the Congress and would be glad to answer any questions you may have.

Statement of Kevin Shea
Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Before the Senate Committee on Homeland Security and Governmental Affairs

April 14, 2016

Chairman Johnson, Ranking Member Carper, and Members of the Committee, I appreciate the opportunity to appear before you today to discuss the importance of ensuring that the United States is prepared to prevent, detect, and respond to both natural and intentional biological threats.

Safeguarding against significant plant and animal pests and diseases—ranging from avian influenza to the European grapevine moth—is vital to protecting industry, producers, export markets, and consumers, and ensuring that we have a safe and secure food supply. It remains a top priority for the U.S. Department of Agriculture (USDA), and is something we at the Animal and Plant Health Inspection Service (APHIS) are committed to every day.

Pests and diseases highlight the importance of our "One Health" approach to coordinating efforts across the government to protect human and animal health. According to the Centers for Disease Control and Prevention (CDC), about 75 percent of recently emerging infectious diseases affecting humans originate in animals. And approximately 60 percent of all human pathogens are zoonotic. The work that APHIS and its partners undertake to protect U.S. agricultural health provides benefits far beyond the fields and farms.

The impact of pests and diseases on the U.S. economy can be staggering. The outbreak of highly pathogenic avian influenza (HPAI) last year—which was the largest animal disease outbreak in U.S. history—cost U.S. taxpayers nearly $1 billion just in response, clean up, and indemnity costs. That didn't include lost export markets, temporary shortages, or price increases for certain poultry and their products.

Threats to U.S. agricultural health can come from a number of places—hitchhiking pests imported on cargo or ships, a traveler bringing food from overseas, a sick animal or pet being brought from overseas, or even nefarious attempts at agro terrorism. In addition, pests and diseases that enter the country can spread either by people, on commodities and other products, or on modes of transportation, such as automobiles or campers. Regardless of the intent or mode of entry, APHIS' focus is on putting in place preventive measures to keep pests and diseases out of the country, finding them if they do enter, as well as preparing for these threats, detecting them, and taking emergency action if necessary.

APHIS has a wide breadth of expertise and experience in protecting U.S. agriculture from plant and animal pests and diseases. From our cadre of veterinarians to our plant pathologists, wildlife biologists, entomologists, epidemiologists, and microbiologists, we have a strong scientific infrastructure that informs our decision making and actions. The relationships we have built

with our partners in this effort also serve to strengthen our protections against pests and diseases. We work closely with state departments of agriculture and natural resources, local governments, tribal partners, stakeholder groups, and federal agencies including the Centers for Disease Control and Prevention, Food and Drug Administration, and Department of Homeland Security.

To protect America's agriculture, environment, and food security, APHIS and its partners maintain a comprehensive system of overlapping safeguards that operate overseas, at U.S. ports of entry, and within the United States to prevent foreign pests and diseases from gaining a foothold in our country. While this system supports efforts to protect against both plant and animal pests and diseases, today, I will focus on our animal health protection efforts in each of these areas.

Overseas and Risk Mitigation Activities

APHIS' work to safeguard the health and value of American agriculture begins by preventing harmful pests and diseases from entering the United States. This work starts overseas, in some cases in the field or on the farm. APHIS works with foreign governments, agricultural producers, and shippers to exclude pests at their origin and treat at-risk commodities in the country of origin or on the high seas before shipments get near our shores.

APHIS, with employees stationed in more than 30 countries, collects and analyzes data on foreign pests and diseases from around the world to detect potential trade pathways for accidentally transporting foreign invasive pests. This information helps us make better policy decisions, such as where to focus risk assessments, when to modify port-of-entry inspections, and what pests we should be surveying for at home.

Our work to help our foreign counterparts build their own infrastructures and capacity to respond to emerging pest and disease conditions is another essential component of our safeguarding activities. Through our capacity building programs, we train animal health officials from other countries in developing effective systems to identify and control pests and diseases locally. This serves as an additional safeguard against the transport of pests and diseases.

We also work closely with multilateral organizations throughout the world to promote effective disease surveillance overseas and gain access to information on agriculture health issues worldwide. These include international and regional groups such as the World Organization for Animal Health and the Codex Alimentarius Commission.

Combined with our overseas efforts, APHIS' import regulations work to mitigate the risk posed by agricultural products long before they reach U.S. ports of entry. Before we will allow imports of a specific product from a specific region of the world, our scientists conduct a risk assessment that enables us to make informed decisions about the potential pest or disease risks associated with that specific commodity. Based on these assessments, and based upon public input and additional scientific perspectives we receive through the rulemaking process, APHIS will only allow imports if they can occur in a safe manner.

APHIS also maintains strict, science-based import regulations for foreign agricultural products. We require import permits for a variety of imported agricultural commodities. As appropriate based on pest and/or disease risk, we also require imports to be accompanied by official sanitary or phytosanitary certification indicating that any associated risk has been sufficiently mitigated. USDA may also require that commodities undergo treatment—such as dipping for cattle fever ticks—and/or mandatory quarantine prior to being allowed entry into the United States. As you can see, USDA's overseas and risk reduction activities play a critical role in helping to mitigate foreign pest and disease risks in the country of origin rather than in the United States.

At Ports of Entry

Through its Agricultural Quarantine Inspection (AQI) program, APHIS works in tandem with U.S. Customs and Border Protection (CBP) to address the risk of foreign pests and diseases entering the country at ports of entry, either through the movement of people or commodities. Under the Homeland Security Act of 2002, USDA maintained responsibility for establishing the regulations, policies, and procedures that govern the import of agricultural products, and CBP became responsible for conducting the actual inspections at ports. APHIS directs CBP on what pests and diseases to look for and which pathways pose the highest risk, shares information on new and emerging pests and diseases, and trains CBP agricultural specialists in how to enforce our agricultural import regulations. CBP inspections target the highest-risk cargo, as well as travelers most likely to be carrying agricultural products. APHIS also stations veterinarians at ports of entry to provide guidance on inspecting animal products to allow for safe entry.

APHIS also operates Animal Import Centers for importations of animals and animal-derived materials to ensure that exotic animal diseases are not introduced into the United States. Animals that are susceptible to or are capable of carrying diseases or pests that could seriously endanger U.S. domestic livestock or poultry must be imported through a U.S. animal import center and are inspected, tested, and quarantined depending on the species and origin. APHIS also has border inspection facilities along the southern and northern U.S. borders for inspecting cattle and other livestock transiting from Mexico and Canada.

Inside the United States

Expanding international trade is good for our farmers, our consumers, our economy, and the world. However, the increasing movement of people and goods means that foreign pest and disease introductions are a very real threat. Outbreaks can halt the movement of agricultural products, having serious economic impacts on farmers, growers, and exporters, and in the case of zoonotic disease, may affect humans.

To counter this threat, APHIS' efforts to safeguard America's agriculture and environment continue inside the United States, so that we can quickly detect any foreign pests and diseases that may have evaded our other safeguarding measures. Critical to this effort is the surveillance we and our state partners conduct throughout the country. Early pest and disease detection is important to avert economic and environmental damage; once a pest or disease becomes

established or spreads significantly, the mitigation costs can reach millions of dollars. This is in addition to lost farm revenues, damage to ecosystems, and loss of foreign markets.

Our Veterinary Services (VS) program conducts routine surveillance for foreign, emerging, and endemic animal diseases, including bovine tuberculosis, foot and mouth disease, avian influenza, and scrapie, as well as for disease vectors such as the cattle fever tick. This surveillance is done through a number of surveillance streams, including testing at slaughter facilities, livestock markets, shows, sales, buying stations, on-farm, and at rendering facilities. As an example, in FY 2015, VS tested over 2 million cattle for brucellosis, over 40,000 sheep and goats for scrapie, and over 190,000 swine for pseudorabies.

Consistent with our One Health approach to animal diseases, our Wildlife Services (WS) program also monitors wildlife for diseases that could potentially spread to livestock or impact humans. Their longstanding efforts monitoring for highly pathogenic avian influenza (HPAI) in wild birds were highlighted during the disease outbreak in poultry farms last year. Since last July, they have sampled over 43,000 wild birds in an enhanced surveillance effort, which can serve as an early warning system for HPAI in commercial poultry. This effort was coordinated with the U.S. Geological Survey, U.S. Fish and Wildlife Service and National Flyway Council. Another important effort they undertake is disease testing of feral swine that they remove through the National Feral Swine Damage Management Program. In FY 2015, WS tested over 2,800 feral swine samples for five diseases of national concern, finding, for example, that 18% were positive for pseudorabies, a disease that APHIS and U.S. industry eradicated from the domestic swine population in 2004.

Additionally, although systems of zoonotic and infectious disease surveillance in humans traditionally operate separately from those for animals, we routinely share data during ongoing cluster or outbreak investigations and on an ad hoc basis as the need is identified. For example, CDC and USDA collaborate directly on a number of well-established zoonotic disease surveillance programs including rabies, bovine spongiform encephalopathy, Trichinellosis, swine and avian influenzas, and foodborne diseases.

Laboratory and diagnostic services are another essential components of the U.S. animal health surveillance infrastructure. Our National Veterinary Services Laboratories (NVSL) serves as the only national reference and confirmatory laboratory for APHIS animal health programs, and participated in over 1,000 foreign animal disease investigations last year. To expand our capacity to detect and diagnose pests and diseases and ramp up during emergency situations, we also support the National Animal Health Laboratory Network (NAHLN) of 62 laboratories. The NAHLN is a national network of laboratories managed by State governments and universities, and is a cooperative effort between two USDA agencies—APHIS and the National Institute of Food and Agriculture (NIFA)—and the American Association of Veterinary Laboratory Diagnosticians. It provides animal disease surveillance and testing services, both daily and in the event of a large-scale animal disease outbreak. In FY 2015, NAHLN laboratories performed over 500,000 diagnostic tests in support of APHIS routine surveillance and outbreak testing needs.

We also recognize the risk posed by smuggled or improperly imported agricultural products and address this vulnerability through our smuggling interdiction and trade compliance (SITC) program. Our SITC program is responsible for intelligence gathering and other anti-smuggling activities, such as secondary market and warehouse inspections, that help prevent animal and plant pests and diseases from entering the United States. When SITC personnel identify smuggled product, they not only remove it from the market but also conduct a full investigation to identify and eliminate any illegal pathways. SITC also conducts market surveys and trend analysis and uses various intelligence tools and data systems to track products that have entered through our borders. In FY 2015, APHIS seized over 230,000 pounds of prohibited and/or restricted plants and plant products and meat and meat products and an additional 65,000 pounds of recalled product.

Emergency Response

In conjunction with our prevention and surveillance efforts, we acknowledge the absolute necessity of being able to respond swiftly and in a coordinated manner should a serious pest or disease be detected. APHIS has the authority and the ability to respond quickly and effectively to the identification of new pests and diseases. In addition, APHIS has specific emergency response guidelines for many of the pests and diseases that pose a significant threat to the United States. We've developed these response plans in conjunction with our Federal, State, tribal, and local partners, with whom we conduct exercises to test our preparedness. To ensure maximum speed and effectiveness, we have rapid response teams stationed around the country ready to travel to detection sites to coordinate Federal containment and eradication efforts. In such situations, our goal is to minimize impacts to U.S. producers and disruptions to trade.

We have in place an incident command approach to emergency response. Incident command places teams of emergency personnel and managers directly in the field to coordinate response efforts. By virtue of their placement and size, the teams and their commanders have a high level of autonomy, are able to respond quickly to new or evolving situations, and can provide extremely timely information to decision makers. In addition, teams from various local, State, and Federal agencies all speak the same language -- using standard terminology for positions and having common structures -- when working an emergency and can tap into a wider network of resources. We saw this in January, when APHIS was able to quickly deploy an incident management team to Indiana at the first sign of disease, enabling the Agency and the State to swiftly eradicate an outbreak of HPAI.

Responding to HPAI in 2015 put to test all of our emergency preparedness and response infrastructure and plans. Through our successful efforts in eradicating the disease in 2015, we learned a lot about our disease response plans that will help us be even more successful in the future. Chief among those is the need for rapid depopulation of affected animals so as to reduce the spread of the virus, and the need for all of us to improve our levels of biosecurity.

However, our HPAI response was just a piece of what we do. Of the more than 1,000 foreign animal disease investigations in which we participated last year, the vast majority turned out to be minor illnesses. This shows the vigilance of APHIS and our partners in the states and industry, to quickly respond when there may be a potential threat to U.S. livestock health.

Expanding our Ability to Protect the United States

Safeguarding U.S. agriculture and ensuring that we are prepared for any sanitary or phytosanitary threats against it is a huge undertaking, but it is one to which APHIS and our partners in the federal, state, and local governments, industry, and stakeholders are fully committed. I would like to mention two other initiatives aimed at expanding our ability to be successful.

One of the biggest lessons we learned in responding to last year's HPAI outbreak was that we could build on the Agency's existing capacity to effectively address large animal health events. Unfortunately, our current funding level for animal health activities is below levels that were available to us 10 years ago, and APHIS has seen a reduction of more than 200 animal health professionals since then. The need to rebuild our capacity is critical, and we have requested an additional $30 million in the FY 2017 President's budget request to address this need. If provided by Congress, we will use most of the funds to hire veterinarians and animal health technicians to rebuild our field force and strengthen our ability to respond to animal health emergencies. To paraphrase a proverb, this request illustrates that an ounce of prevention may well be worth a pound of cure.

Second, to further enhance our ability to respond to emerging disease threats, our Veterinary Services program published a *Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States* in July 2014. The final Framework, which we are working to complete later this year, will describe the activities to be undertaken under the framework, and will outline roles and responsibilities, possible triggers for action, and potential responses to emerging animal diseases, as well as public outreach. Due to the novelty of emerging diseases – either within a geographic area or species –detection and response will depend on close cooperation with producers. For this reason, flexibility is essential, and the framework implementation plan will outline the processes APHIS will use to develop science- and risk-based approaches and systems to respond to emerging animal diseases.

A National Blueprint for Biodefense

We appreciate the effort undertaken by the Blue Ribbon Panel on Biodefense to make recommendations to strengthen the United States' biodefense, and the recognition of the role animal health plays in this effort. I am pleased to say that APHIS is already taking a number of actions related to recommendations made in the Panel's report. I will mention several of them today.

Our Veterinary Services program has a One Health Coordination Center (OHCC) that facilitates the integration of One Health approaches throughout our animal health programs. It is our standard practice to approach our work from a One Health state of mind, and OHCC works to inform and educate USDA employees about this need. OHCC staff also leverage their knowledge and relationships to build better alliances, coordinate between government and industry partners, and network to ensure that animal agriculture is considered when One Health

issues are being addressed. OHCC also identifies unmet needs and opportunities to promote the potential contributions that APHIS can make to One Health activities.

APHIS has also undertaken several efforts around animal health data collection and sharing to help improve collaboration and coordination. We have a data management roadmap initiative to identify strengths and gaps in current data management systems for our animal health surveillance data, with the end goal of finding ways to link the systems to each other and to provide a framework for data sharing between government agencies, universities, and private organizations while maintaining appropriate security of confidential data. We also have tools such as interactive dashboards that allow self-exploration of surveillance information by our federal, state, and industry partners.

In addition, we have a comprehensive and integrated animal disease surveillance approach that includes a variety of surveillance sources of information including wildlife and other vectors. Interagency collaborations are part of this approach, which is particularly important as we address diseases of economic and public health concern. For example, we have a cooperative initiative for Influenza A virus in swine (IAV-S) with the swine industry and NAHLN laboratories to identify unique strains of IAV-S that may be of significance to animal or public health. The CDC is regularly updated on IAV-S surveillance in the U.S. and works closely with APHIS to stay apprised of current influenza issues from a veterinary perspective, linking the human and animal health perspectives into a One Health approach.

APHIS is also developing a U.S. National List of Reportable Animal Diseases (NLRAD) to complement State reportable disease lists. The NLRAD will be a single uniform, science- and policy-based, nationally supported standardized list of animal diseases/agents. The NLRAD will focus on livestock, poultry and aquaculture species. In July 2014, APHIS published the *Proposal for a U.S. National List of Reportable Animal Diseases (NLRAD) Concept Paper*. The NLRAD list was developed in direct collaboration with numerous stakeholders including the United States Animal Health Association (USAHA), American Association of Veterinary Laboratory Diagnosticians and National Assembly of State Animal Health Officials. We are currently looking at issues around laboratory implementation, data management, and confidentiality, as we work towards releasing a draft guidance document this fall. The NLRAD will be implemented through Federal-State cooperation, and will contribute to the assessment and reporting of the listed zoonotic and endemic animal diseases and facilitate response to an emerging disease or issue in the United States, as well as support trade.

In conclusion, APHIS' core mission is to protect the health of U.S. agriculture, which in turn supports public health and food security in the United States. I assure you that my Agency, and USDA, are committed to doing all we can to protect U.S. plant, animal, and human health from the threats posed by pests and diseases. I would be happy to answer any questions.

Testimony of

Aaron Firoved
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U.S. Department of Homeland Security

Before the U.S. Senate Committee on Homeland Security and Governmental Affairs

April 14, 2016

Chairman Johnson, Ranking Member Carper, and distinguished members of the Committee, thank you for inviting me to speak with you today. I appreciate the opportunity to testify on the Department of Homeland Security's role in biodefense.

The Changing Biological Threat
In the fifteen years since the U.S. anthrax attacks, we have continued to face not only the threat of biological attacks, but also naturally occurring disease outbreaks (e.g., avian influenza, Ebola virus, Zika virus), global pandemics (e.g., H1N1 influenza), and criminal acts using biological agents (e.g., ricin). The threats and risks posed by emerging and re-emerging infectious diseases and the potential research, development, acquisition, and use of biological agents by international terrorist organizations, homegrown violent extremists, and rogue states will continue to challenge our ability to warn, prepare, and protect the Homeland.

The Blue Ribbon Study Panel on Biodefense's recent *National Blueprint for Biodefense* made it abundantly clear that the threat of both manmade and natural biological disasters has not waned and, in fact, continues to grow and evolve. The effects of climate change, global connectivity, advances in biotechnology, and increased instability in the Middle East, Africa, and parts of Asia increase the likelihood of a biological event in the Homeland. Synthetic biology and gene editing offer the promise of great medical breakthroughs; however, they also offer international terrorist organizations, homegrown violent extremists, and rogue states similar potential to modify organisms for malicious purposes. In the same vein, naturally-emerging avian influenza outbreaks and antibiotic resistant bacteria reflect increasing risk to the United States. Within 24 hours, an individual infected with a virulent, contagious, potentially-manmade pathogen can land on our shores and spark an outbreak with far reaching national or global consequences. These risks and threats have also been highlighted previously in congressional testimony from Director of National Intelligence James Clapper.

In the wake of these growing threats, the Department of Homeland Security (DHS) remains fully engaged and proactive in attempting to characterize the threat, providing warning of emerging and imminent threats, and coordinating whole of government response. During the most recent Ebola Virus Disease outbreak in West Africa, DHS provided intelligence analysis to the interagency, state and local governments, and first responders, and it directed research to better characterize the threat and fill gaps in public health and operational responses. Additionally, DHS coordinated and implemented enhanced screening for more than 42,000 international passengers at five airports. The Department continues to work with state and local governments,

Intelligence Community partners, and federal partners to provide predictive analysis and early warning in addition to longer-term research and development (R&D) that strengthens preparedness and response capabilities and fosters resilient communities. We must remain vigilant and innovative as biological threats continue to evolve and new threats emerge.

Department of Homeland Security's role in Biodefense
The DHS Office of Health Affairs (OHA), along with the Science and Technology Directorate (S&T), continues to lead the Department's work with all biodefense stakeholders, from local to federal partners, to understand and meet these threats today and to be ready for the threats that will emerge tomorrow. With in-house experts including physicians, scientists, toxicologists, veterinarians, intelligence and data analysts, and first responders, the Department is positioned to address natural and manmade biological threats in our population as well as in our agriculture and wildlife through biosurveillance, biological detection, and expertise to DHS leaders.

Detection and defense against biological threats, be they acts of terrorism or naturally occurring, remain important mission areas for DHS. For large scale biological events, knowledge as early as possible allows informed decisions that can save American lives. To this end, the Department's operational biodetection and biosurveillance programs, the BioWatch Program and the National Biosurveillance Integration Center, are critical to our nation's biodefense. The capabilities are mutually reinforcing – one provides detection of selected threats at their onset in high risk areas, while the other provides public health surveillance at a broader level at later stages. Each capability is supported by a biodefense R&D portfolio in the Department dedicated to creating technology options that address identified and validated capability gaps. R&D helps the Department maintain a longer-range view and ensures operational elements are not caught off guard by emerging or new trends and threats.

The Nation's biodefense integrates numerous agencies and levels of government, and S&T's biodefense R&D portfolio serves the full range of interagency, intergovernmental stakeholders. In addition to ongoing R&D programs with OHA, S&T's portfolio extends to stakeholders outside the Department including protection of livestock from foreign animal diseases, support for acquisition of medical countermeasures, bioassay and diagnostic development, biological forensics programs, and biological event remediation. S&T's biodefense R&D portfolio is grounded in coordination and close working relationships both within DHS and with external partners.

National Biosurveillance Integration Center (NBIC)
Established in 2004 and transitioned to OHA in 2007, NBIC's mission is to enable early warning and shared situational awareness of acute biological events and support better decisions through rapid identification, characterization, localization, and tracking for biological events of national significance. Given the evolving biodefense threats that our Nation faces, both manmade and natural, greater coordination among federal, state, local, tribal, and territorial partners is required. NBIC is uniquely situated within DHS to provide a fusion of human health, animal health, and environmental data to develop a comprehensive understanding of the biological threat landscape and emerging incidents to ensure our Nation's decision-makers have timely, accurate, and actionable information.

To aecomplish this, NBIC monitors thousands of data sources and leverages the expertise of fourteen federal departments and agencies, then intcgrates this array of information into reports on global and national biological incidents that could potentially cause economic damage, social disruption, or loss of life. Over 900 federal and 1,500 state, local, tribal, and territorial offices across this spectrum of human, animal, and environmental health and response have access to NBIC's reports and analysis.

We are cognizant that reports by the Government Accountability Office (GAO) and the Blue Ribbon Panel on Biodefense have acknowledged the progress that NBIC has made delivering daily situational awareness to our partners, but have pointed out that we still have work to do to fully realize the vision of comprehensive biosurveillance integration. Towards this end, NBIC is working with the Department of Veterans Affairs on a proof of concept for a data initiative that will help to create an aggregated national view of disease trends, while also supporting VA to leverage its Electronic Health Reeord system. Similarly, NBIC is working with the Department of Defense's Defense Threat Reduction Agency to deploy new collaboration and analytic tools that will enable biosurveillance analysts from across the government to collaboratively examine and report on emerging biological threats. NBIC's efforts are also focused on biosurveillance tools and reporting for local officials so that they can address the biological incidents emerging in their own communities, while strengthening national surveillance as a whole. NBIC will continue to advance its capacity to conduct biosurveillance reporting and analysis by developing new collaboration tools, pursuing innovative data sources and methods, and fostering greater stakeholder engagement.

Public Health Emergency Medical Countermeasures Enterprise
Though the stockpiling of medical countermeasures (MCM) for the general public is the responsibility of the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response, DHS does have a role in the process. Federal procurement of MCM is governed by the interagency Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), for which the Chief Medical Officer of DHS serves as the Department's voting representative.

DHS participates as a voting member of both of the governing bodies of the PHEMCE– the Enterprise Senior Council and Enterprise Executive Committee – which are comprised of Assistant and Deputy Assistant Secretary level department and agency representatives. Additionally, DHS has voting representatives on Interagency Policy Teams covering the breadth of MCM disciplines that perform in-depth analyses of MCM related issues and report back to the governing bodies with recommendations. The structure is designed to leverage government subject matter expertise to produce a threat based, risk informed, prioritized list of MCM needs across the interagency. This prioritized list is balanced with resources, both current and projected, to develop an MCM acquisition and stockpile maintenance plan, which is then thoroughly reviewed before being approved and put into action. This process reassesses the MCM enterprise on an annual basis, and updates recommendations, informed by the most recent information available, risk assessments, and resource constraints.

BioWatch Program

The BioWatch Program is the Nation's only civilian program that provides early warning in the event of an aerosolized biological attack. The program consists of planning, preparedness, exercising, training, and early detection capabilities. Deployed at more than 30 major metropolitan areas throughout the country, the system is a collaborative effort of health professionals at all levels of government. The program is operated by a team comprised of field operators, laboratory technicians, and public health officials from city, county, state, and federal organizations. Each hour gained through early detection of a biological attack and before the onset of medical symptoms, improves the chances that response efforts will be successful. The BioWatch Program has succeeded in bringing together state and local public health, first responders, and law enforcement personnel, along with locally-deployed federal officials, resulting in communities that are better prepared not only for a biological attack, but also for an all-hazards response.

The current BioWatch system has been, and will continue to be, extensively tested, and the program is advancing plans and building capabilities in early detection and situational awareness. BioWatch builds the collective capabilities across all levels of government to effectively and rapidly mobilize in response to an attack, mitigating the impacts of a potential catastrophic bioterrorism event. The BioWatch Program is a critical component of our Nation's response to minimize the impacts of a biological attack.

The Department appreciates the GAO report and recommendations on the path forward for the BioWatch Program. GAO clearly recognizes the unique challenges for this system which was rolled out with the best available technology in 2003 to respond to an urgent threat. The relevant technical capabilities available to adversaries have only increased since then, as biotechnologies have continued their global development and dissemination. So the need for BioWatch persists. In the past two years, the capabilities of the system have been independently tested and validated. Four independent tests have been conducted over the last six years that have tested all components of the BioWatch system. This has included extensive testing of our identification assays (laboratory tests that detect selected biological agents), subsystem and system level testing in test chambers using actual threat agents, and open-air testing of simulated agents in as near an operational environment as possible. In addition, the BioWatch Quality Assurance Program has analyzed over 30,400 samples to monitor operations against performance benchmarks and requirements. The results of these tests reinforce confidence in the system's ability to achieve its mission: detecting a large-scale aerosol release of specific threat agents in our Nation's most populated areas.

The system's capability to detect biological agents was further affirmed last year when BioWatch detected the subtype of *Francisella tularensis* that is pathogenic to humans during confirmed occurrences of that strain of Tularemia in Denver, Colorado. Though the agent was not disseminated by an adversary, these detections took place during a documented uptick in naturally occurring disease. By analyzing available medical surveillance data and discussing the BioWatch detections through the BioWatch National Conference Call, local, state, and federal officials were provided with additional data for decision support in responding to this occurrence of Tularemia. This shows that the BioWatch Program is able to detect an airborne biological agent in the environment.

The BioWatch Program is more than just an environmental detection system. BioWatch also helps strengthen jurisdictional preparedness in the event of a bioterrorism event through coordinating exercises and drills; providing training, guidance and assessments, and standardized methodologies for response; and by enabling a forum for all levels of government to share data and information. Over 500 state and local partners and stakeholders representing a broad cross section of government agencies have participated in BioWatch preparedness activities in the last year. BioWatch has also coordinated environmental assessment activities, including developing initial environmental sampling plans for jurisdictions to help characterize an attack. All of the program's key elements – including response – are supported by a number of federal departments and agencies, such as HHS including the Centers for Disease Control and Prevention (CDC), the Department of Defense (DOD), the Environmental Protection Agency, and the Federal Bureau of Investigation. BioWatch also supports major events such as Super Bowls and National Special Security Events (e.g., 2015 papal visit to three U.S. cities).

Since 2014, BioWatch has been working with DHS S&T, DOD, and other federal partners to identify technologies that would substantially improve BioWatch operations. These improvements are intended to advance the current "detect to treat" capability. Additionally, BioWatch and the National Biosurveillance Integration Center are working together to improve situational awareness at all levels of government in the event of a biological attack.

State, Local, and First Responder Engagement
Key stakeholders in all our programs are state and local partners. OHA engages with the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, and the Institute of Medicine, to leverage established working groups and information sharing mechanisms for direct engagement with state and local public health officials. This engagement allows for state and local health officials to maintain awareness of, and provide expertise, feedback, and support to, OHA activities, including the BioWatch and NBIC programs.

OHA continues to seek ways to support the first responder community in its preparation and response to biological events. One initiative we are developing is the First Responder Vaccine Initiative (FRVI), which is developing the infrastructure for an anthrax vaccination pilot to evaluate the feasibility of a voluntary pre-event anthrax vaccination program among first responders using anthrax vaccine scheduled to rotate out of the CDC's Strategic National Stockpile in at least two states. DHS is facilitating transfer of the vaccine from CDC to the states. I thank this Committee for moving S. 1915, Sen. Ayotte's legislation authorizing the pilot program.

Conclusion
Since the startup of the Department, we have worked hard to strengthen our Nation's biodefense. We acknowledge and appreciate GAO's efforts to highlight areas for improvement in the Department's biodefense programs. We are committed to continued work with our partners and look forward to the Committee continuing to help build and refine these robust programs. We appreciate the Subcommittee for keeping this issue at the forefront and for your continued support to biodefense and homeland security.

United States Government Accountability Office

GAO

Testimony
Before the Committee on Homeland Security and Governmental Affairs
U.S. Senate

For Release on Delivery
Expected at 10 a.m. ET
Thursday, April 14, 2016

BIODEFENSE

The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance

Statement of Chris Currie, Director, Homeland Security and Justice

Chairman Johnson, Ranking Member Carper, and Members of the Committee:

I am pleased to be here today to discuss our work on defending the nation against biological threats. Biodefense includes measures to prevent, detect, respond to, and recover from harm or damage caused by microorganisms or biological toxins to humans, animals, or the food supply. According to Homeland Security Presidential Directive 10 (HSPD-10), published in April 2004, successful implementation of the nation's biodefense enterprise requires optimizing critical cross-cutting functions such as information management and communications, research and development, and acquisition.[1] Within biodefense, biosurveillance, as defined by the July 2012 National Strategy for Biosurveillance, is the ongoing process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health, for the purpose of (1) achieving early detection and warning, (2) contributing to overall situational awareness of the health aspects of the incident, and (3) enabling better decision making at all levels.

Threats of bioterrorism, such as anthrax attacks, and high-profile disease outbreaks, such as Ebola in West Africa and emerging arboviruses like chikungunya and Zika in the Americas, highlight the continued need for systems that provide early detection and warning about biological threats to humans. Additionally, recent outbreaks of highly pathogenic avian influenza in domestic poultry and wild birds in 21 Midwestern and Western states in 2014, 2015, and 2016 underscore the importance of maintaining effective surveillance systems within the broader context of biosurveillance (to include plant and animal). The disruption of the agriculture or food production systems can present a serious threat to the national economy, trade, and human health. Numerous federal agencies, encompassing much of the federal government, have mission responsibilities for supporting biodefense and biosurveillance activities.

Over the past 15 years, we have reported that complex interagency and intergovernmental efforts can benefit from developing a national strategy, and that interagency and intergovernmental activities can benefit from the leadership of a single entity with sufficient time, responsibility, authority,

[1]*Homeland Security Presidential Directive 10: Biodefense for the 21st Century (2004).*

and resources needed to provide assurance that the federal programs are well coordinated, and that gaps and duplication in capabilities are avoided.[2] We also have an ongoing body of biosurveillance work spanning more than a decade in which we have examined specific surveillance programs and activities carried out by the Department of Homeland Security (DHS); the Departments of Health and Human Services (HHS); and Agriculture (USDA); and several other federal departments and agencies.[3] We have identified broad, cross-cutting issues in leadership, coordination, and collaboration that arise from working across the complex interagency, intergovernmental, and intersectoral biosurveillance enterprise.

This statement describes a range of historical and present challenges to building and maintaining the nation's biodefense and biosurveillance. This statement is based on our prior work issued from December 2009 through March 2016 on various biodefense and biosurveillance efforts. We also reviewed the 2015 report of the Blue Ribbon Study Panel on Biodefense

[2]See GAO, *Combating Terrorism: Selected Challenges and Related Recommendations*, GAO-01-822 (Washington, D.C: Sept. 20, 2001), and *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

[3]See, for example, GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts*, GAO-04-877 (Washington, D.C.: Sept. 30, 2004), which discusses select federal and nonfederal human disease surveillance in humans; GAO, *Global Health: U.S. Agencies Support Programs to Build Overseas Capacity for Infectious Disease Surveillance*, GAO-07-1186 (Washington, D.C.: Sept. 28, 2007), which discusses four key programs aimed at building overseas surveillance capacity for infectious diseases in humans; GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, D.C.: Dec. 18, 2009); GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010); GAO, *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*, GAO-12-55 (Washington, D.C.: Oct. 31, 2011); GAO, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 (Washington, D.C.: Sept. 10, 2012); GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry*, GAO-13-424 (Washington, D.C.: May 21, 2013), which discusses the Department of Agriculture's efforts to better detect and control new or reemerging diseases in animals; GAO, *Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center*, GAO-15-793 (Washington, D.C.: Sept. 24, 2015); GAO, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established*, GAO-16-99 (Washington, D.C.: Oct. 23, 2015).GAO, *Emerging Infectious Diseases: Preliminary Observations on the Zika Virus Outbreak*, GAO-16-470T (Washington, D.C., Mar.2, 2016).

for selected updates.[4] The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. To conduct our prior work, we reviewed reports from the bipartisan Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Center), relevant presidential directives, laws, regulations, policies, strategic plans, and other reports; surveyed states; and interviewed federal, state, and industry officials, among others. More information on our scope and methodology can be found in each of the reports cited throughout this statement.

Background

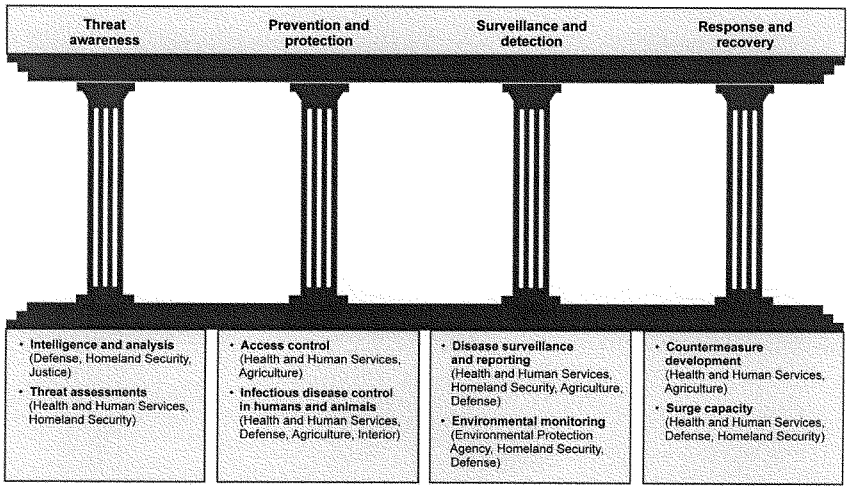
The Biodefense Enterprise

Biological threats that could result in catastrophic consequences exist in many forms and arise from multiple sources. For example, several known biological agents could be made into aerosolized weapons and intentionally released in a transportation hub or other populated urban setting, introduced into the agricultural infrastructure and food supply, or used to contaminate the water supply. Concerned with the threat of bioterrorism, in 2004, the White House released HSPD-10, which outlines the structure of the biodefense enterprise and discusses various federal efforts and responsibilities that help to support it. The biodefense enterprise is the whole combination of systems at every level of government and the private sector that can contribute to protecting the nation and its citizens from potentially catastrophic effects of a biological event. It is composed of a complex collection of federal, state, local, tribal, territorial, and private resources, programs, and initiatives, designed for different purposes and dedicated to mitigating various risks, both natural and intentional.

[4]We have not independently assessed the entirety of the Study Panel's conclusions and recommendations or the methods it used to arrive at them. However, we determined that the select members of panels related to leadership and policy issues had qualifications and subject matter expertise sufficient to provide reliable information on issues related to strategy and leadership across the biodefense enterprise.

Biodefense is organized into four pillars—threat awareness, prevention and protection, surveillance and detection, and response and recovery—and multiple federal agencies have biodefense responsibilities within the pillars. Each of these pillars comprise numerous activities—such as controlling access to dangerous biological agents used in research—that generally require coordination across federal departments as well as with state, local, and international governments, and the private sector. Protecting humans, animals, plants, air, soil, water, and critical infrastructure from potentially catastrophic effects of intentional or natural biological events entails numerous activities carried out within and among multiple federal agencies and their nonfederal partners (see fig. 1).

Figure 1: Pillars of Biodefense



Source: GAO analysis of Homeland Security Presidential Directive 10. | GAO-16-547T

Biosurveillance Threats and Responsibilities

Emerging infectious diseases represent an ongoing threat to the health and livelihoods of people and animals worldwide.[5] Many advances in medical research and treatments have been made during the last century, but infectious diseases are nevertheless a leading cause of death worldwide. In addition to causing nearly one in five human deaths worldwide, infectious diseases impose a heavy societal and economic burden on individuals, families, communities, and countries.[6] Infectious diseases are a continuous threat for reasons that include: (1) emergence—at times rapid—of new infectious diseases; (2) re-emergence of previously-known infectious diseases; and (3) persistence of intractable infectious diseases.

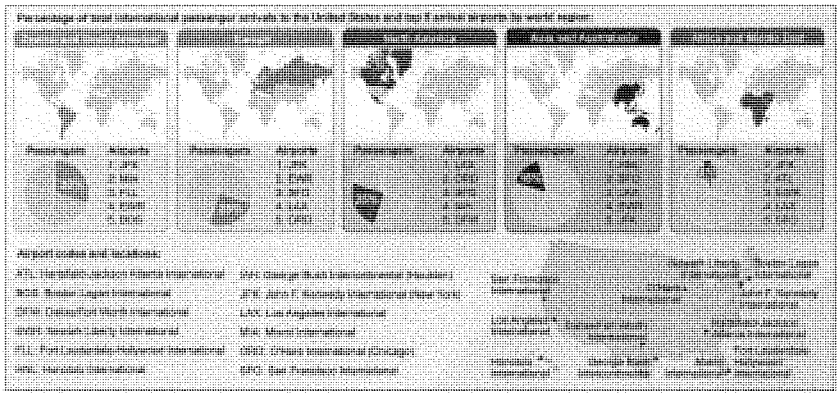
In an era of rapid transit and global trade, the public health and agricultural industries, as well as natural ecosystems including native plants and wildlife, face increased threats of naturally occurring outbreaks of infectious disease and accidental exposure to biological threats. According to the World Health Organization, infectious diseases are not only spreading faster, they also appear to be emerging more quickly than ever before. The ongoing outbreak of Zika virus in the Americas has heightened travel-related concerns regarding the spread of the virus. As of March 23, 2016, 273 cases of continental U.S. travel-associated Zika virus disease have been reported, according to Centers for Disease Control and Prevention (CDC). Figure 2 shows passenger arrivals from five regions of the world and the top five airports receiving passengers whose travel originated from each of these regions in 2014.[7]

[5]According to the Centers for Disease Control and Prevention (CDC), an emerging infectious disease is a disease whose incidence in humans has increased in the past two decades or threatens to increase in the near future.

[6]Institute of Medicine, Emerging Viral Diseases: The One Health Connection (Washington, D.C.: National Academies Press, 2015).

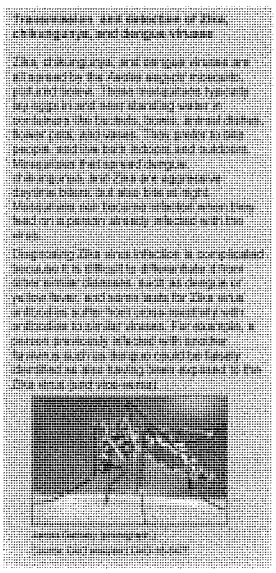
[7]See GAO, *Air Travel and Communicable Diseases: Comprehensive Federal Plan Needed for U.S. Aviation System's Preparedness.* GAO-16-127.(Washington, D.C.: December 16, 2015).

Figure 2: Top Five U.S. International Arrival Airports for Five Global Regions, 2014



Sources: GAO analysis of Department of Transportation data and Map Resources. | GAO-16-547T

According to the World Health Organization, about 75 percent of the new diseases that have affected humans in recent years are zoonotic and have been caused by pathogens originating from an animal. These emerging and reemerging diseases transmit between animals—including domestic animals and wildlife—and humans. Many of these diseases have the potential to spread through various means over long distances and to become global problems. In some cases, disease transmission is direct, in others the animals act as intermediate or accidental hosts, while in others transmission occurs, for example, via mosquitoes or ticks. Examples of emerging and zoonotic diseases include: Zika, chikungunya, and dengue viruses, West Nile virus, H1N1 (swine) influenza, severe acute respiratory syndrome (SARS), avian influenza, and rabies. Habitat loss and human encroachment on rural and wildlife environments are bringing populations of humans and animals, both farmed and wild, into closer and more-frequent contact. Increasingly, wildlife are involved in the transmission of diseases to people, pets, and livestock, and managing wildlife transmitters is an integral part of efforts to control the spread of zoonotic diseases. Diseases among wildlife can also provide early warnings of environmental damage, bioterrorism, and other risks to



human health.[8] Finally, potential bioterrorism threats also include the use of zoonotic diseases as weapons of mass destruction, such as anthrax, plague, tularemia, and brucellosis.

Numerous federal, state, local, and private sector entities have roles and responsibilities for monitoring for pathogens in human, animal, plant, food, and the environment. Federal departments, such as the HHS, USDA, DHS, and the Department of Interior, play leading biosurveillance roles for certain domains such as human and animal health, food, and air, but they also rely on support from state and local authorities or partner with other federal agencies. In other cases federal departments or agencies play supporting roles.[9] Officials at all levels of government, as well as Homeland Security Presidential Directive-21's (HSPD-21) vision of a national biosurveillance capability, acknowledge that state and local capabilities are at the heart of the biosurveillance enterprise.[10] According to federal, state, and local officials, early detection of potentially serious disease indications nearly always occurs first at the local level, making the personnel, training, systems, and equipment that support detection at the state and local level a cornerstone of our nation's biodefense posture. While there is variation in organization and structure among public-health, animal-health, and wildlife functions at the state, tribal, local, and insular levels they all share in the nation's biosurveillance responsibility. [11] Some

[8]Department of Interior's United States Geological Survey National Wildlife Health Center, which is the only federal laboratory in the United States dedicated to wildlife disease investigation, focuses on developing methods to reduce or eliminate the transmission of diseases among wildlife, domestic animals, and humans.

[9]In particular, agencies with missions that do not entail health surveillance activities may play a supporting biosurveillance role on an ongoing or ad hoc basis. For example, as demonstrated during the 2009-2010 H1N1 influenza pandemic, the Department of Education provided information on school closings, which enhanced situational awareness. In another example, although the National Weather Service does not have health surveillance responsibilities, the National Biosurveillance Integration Center (NBIC) may at times coordinate with this agency because understanding weather patterns helps predict the course of some outbreaks.

[10]HSPD-21, *Public Health and Medical Preparedness*, was issued in October 2007 to establish a National Strategy for Public Health and Medical Preparedness, which builds upon principles set forth in HSPD-10 with the goal of transforming the national approach to protecting the health of the American people against all disasters.

[11]According to the Department of the Interior's definition, an insular area is a jurisdiction that is neither a part of one of the several states nor a federal district. This is the current term to refer to any U.S. commonwealth, freely associated state, possession, or territory.

of the nonfederal partners with key responsibilities in the biosurveillance enterprise are presented in table 1.

Table 1: Selected Biosurveillance Roles and Responsibilities

Nonfederal partner	Description
Skilled Personnel	
Epidemiologists	Epidemiologists are specialists who study how diseases are distributed and transmitted in populations and the factors that influence or determine this distribution and transmission.
Informaticians	Public-health informaticians use systematic application of information, computer science, and technology to support public health.
State public-health veterinarians	State public health veterinarians typically work for the state health department and generally work in zoonotic disease control and prevention with a focus on protecting public health.
State wildlife professionals	State wildlife professionals are veterinarians, epidemiologists, biologists, or management personnel who work for state departments of wildlife, parks and recreation, or natural resources and environment.
Clinicians and diagnosticians	Early detection of a bioterrorism event or the emergence of a naturally occurring infectious disease threat may depend on an astute clinician diagnosing the first few cases, or recognizing suspicious clinical signs that require further investigation by experts in infectious diseases.
Organizations	
State and local health departments	States, through the use of their state and local health departments, have principal responsibility for protecting the public's health and therefore take the lead in conducting disease surveillance. They verify cases of notifiable diseases, monitor disease incidence, and identify possible outbreaks within their states. Generally, local health departments are responsible for conducting initial investigations into reports of infectious diseases. Local health departments are also responsible for sharing information they obtain from providers or other sources with their state department of health.
State departments of agriculture	State departments of agriculture provide services and regulations regarding the health of agricultural animals. States maintain a list of reportable diseases and require accredited veterinarians to report disease occurrences. State veterinarians coordinate the efforts of state animal-health officials who have authority for disease reporting, detection, and often, diagnosis.
Laboratories	Public-health and animal-health laboratories serve a critical role in both initial detection and ongoing situational awareness of biological events.

Source: GAO | GAO-16-547T

Independent Reports on Issues Facing the Biodefense Enterprise

Bipartisan and independent commissions have identified a range of issues facing the biodefense enterprise, many of which mirror our findings. In October 2011, the WMD Center reported its assessment of various capabilities within the U.S. biodefense enterprise in which a team of leading biodefense experts assigned letter grades to each of the capabilities for different types of outbreak. The report assigned low marks to nearly all the capabilities for address large-scale and global disease outbreaks. For example, the team assigned the grade of D (meets few

expectations) to the capability for detecting large-scale infectious outbreaks and the grade of F (fails to meet expectations) to the capability for detecting global contagious outbreaks.[12]

In 2014, a Blue Ribbon Study Panel on Biodefense (Study Panel) was established to assess gaps and provide recommendations to improve U.S. biodefense.[13] The panel's October 2015 final report identified 33 recommendations to execute over the short, medium, and long term. The Study Panel report echoed many of the same challenges highlighted in the WMD Center's report, and highlighted a sense of urgency to address the ongoing and persistent biological threats—both naturally occurring, like Ebola and Zika, and from enemies, like The Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) who have advocated for the use of biological weapons. The panel's report identified several themes we have also highlighted in our biosurveillance work, including the lack of a centralized leader, no comprehensive national strategic plan, and no all-inclusive dedicated budget for biodefense.

The Biodefense Enterprise Is Fragmented and Does Not Have Strategic Oversight to Promote Efficiency and Accountability

[12]The WMD Center, *Bio-Response Report Card: 21st Century Biological Threats*, Washington, D.C. (Oct 2011).

[13]*A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*. Bipartisan Report of the Blue Ribbon Study Panel on Biodefense (October 2015).

The Biodefense Enterprise Does Not Have Enterprise-Wide Institutionalized Leadership to Provide Strategic Oversight and Coordination

In 2011, we reported that reducing fragmentation in the biodefense enterprise could enhance assurance that the nation is prepared to prevent, detect, and respond to biological attacks with potentially devastating consequences in terms of loss of life, economic damage, and decreased national security.[14] We reported that there are more than two dozen presidentially appointed individuals with some responsibility for biodefense. In addition, numerous federal agencies, encompassing much of the federal government, have some mission responsibilities for supporting biodefense activities. However, there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise. Because none of the federal departments has authority over the entire biodefense enterprise, in 2011 we reported that the Homeland Security Council (HSC) should consider establishing a focal point to coordinate federal biodefense activities. In December 2014 officials from National Security Council (NSC) staff, which supports the HSC told us that two of its directorates work together as the focal point for federal biodefense efforts. According to NSC staff, these focal points provide strategic leadership on all federal biodefense efforts, with responsibilities to coordinate across domestic and global priorities to prevent, detect, and rapidly respond to biological threats. The focal points are to host ongoing meetings with the federal biodefense enterprise to ensure a comprehensive and coordinated approach to biodefense.

We recognize the policy work of the directorates as an important step in promoting a comprehensive and coordinated approach to biodefense, but strategic leadership issues persist. In October 2015, the Study Panel reported on ongoing leadership challenges for the enterprise. The report called for a focal point to provide strategic leadership by elevating authority above what any single agency has to help overcome the challenges faced by the biodefense enterprise.[15] The Study Panel report noted mixed opinions on the effectiveness of the current NSC staff model

[14]See, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*. GAO-11-318SP. Washington, D.C.: March 1, 2011.

[15]The Study Panel evaluated various organizational models to provide leadership, and ultimately recommended that leadership for the biodefense enterprise be institutionalized in the Office of the Vice President and that the Vice President be given budget authority to review and advise, in collaboration with the Office of Management and Budget, all biodefense budgets. Although our prior work called for an entity with sufficient time, resources, and authority to provide strategic oversight across the enterprise, we have not independently evaluated any specific leadership models.

for coordinating biodefense. Some have asserted that efforts remain fragmented under this system, but others pointed to the benefit of having a wider variety of staff involved across the spectrum of biodefense activities. However, the Study Panel found that White House councils and offices generally only become involved when a specific biodefense issue affects a prominent ongoing responsibility—a method which is not consistent with our call for a strategic approach.

The Enterprise Does Not Have an Integrated National Strategy to Guide Priorities and Investments

In 2011, we reported that while some high-level biodefense strategies have been developed, there is no broad, integrated national strategy that encompasses all stakeholders with biodefense responsibilities that can be used to guide the systematic identification of risk; assess resources needed to address those risks; and prioritize and allocate investment across the entire biodefense enterprise.[16] We have also previously reported that choices must be made about protection priorities given the risk and how to best allocate available resources.[17] Further, neither the Office of Management and Budget nor the federal agencies account for biodefense spending across the entire federal government. As a result, the federal government does not know how much is being spent on this critical national security priority. We reported that the overarching biodefense enterprise would benefit from strategic oversight mechanisms, including a national strategy, to ensure efficient, effective, and accountable results, and suggested the HSC take action.

As of February 2016, NSC staff had not developed such a strategy. Rather, they assert that the *National Strategy for Countering Biological Threats*, the *National Biosurveillance Strategy, and Presidential Policy Directive-8* work in concert to provide comprehensive strategic guidance to stakeholders with biodefense responsibilities. Although these documents demonstrate clear commitment to coordinating interagency biodefense efforts, they do not provide the strategic approach that we suggested in March 2011. For example, the *National Biosurveillance Strategy*, released by the White House in July 2012, does not provide a specific framework for prioritizing and trading off among approaches to build biosurveillance capabilities with limited resources. Moreover, as

[16]GAO-11-318SP

[17]GAO, *21st Century Challenges: Reexamining the Base of the Federal Government*, GAO-05-325SP (Washington, D.C.: Feb. 1, 2005).

previously discussed, there are four pillars of the biodefense enterprise, each complex and in need of coordination: (1) threat awareness, (2) prevention and protection, (3) surveillance and detection, and (4) response and recovery. The *National Strategy for Biosurveillance* does not—alone or in combination with the *National Strategy for Countering Biological Threats and Presidential Policy Directive-8*—address all four pillars, and more specifically, it does not address the key fragmentation issues across the biodefense enterprise, such as ensuring strong linkage and identifying gaps in investments across the four pillars.

Similarly, the Study Panel's 2015 report identified the lack of a comprehensive national strategy and dedicated budget as challenges. The Study Panel noted that leadership issues were exacerbated by the lack of a comprehensive biodefense strategy and a unified approach to budgeting, which they called vital to any strategic interagency effort for the nation's biodefense capabilities. They called for a unified approach to budgeting and prioritizing biodefense efforts. The Study Panel noted that the nation lacks a comprehensive, cohesive, and regularly updated strategy resulting in disorganization and loss of institutional knowledge associated with changes in administrations.

Biosurveillance Faces Similar Challenges

Much like biodefense, biosurveillance faces key challenges that transcend what any one agency can address on its own. We have identified challenges related to the nation's ability to detect and respond to biological events.[18] Our findings have identified challenges at all levels of government, and our more recent and ongoing work continues to highlight these challenges.

Enterprise-wide Leadership and Strategy Challenges

In June 2010, we found that there was no integrated approach to help ensure an effective national biosurveillance capability and to provide a framework to help identify and prioritize investments.[19] Without a unifying framework and an entity with the authority, resources, time, and responsibility for guiding its implementation, we concluded that it would be very difficult to create an integrated approach to building and

[18]See GAO-10-645; GAO-12-55; GAO-15-793; and GAO-16-99.

[19]GAO-10-645.

sustaining a national biosurveillance capability.[20] We recommended the HSC establish a focal point to lead the development of a national biosurveillance strategy that clarifies roles and responsibilities, provides goals and performance measures, and identifies resource and investment needs, among other elements. However, the recommendations have not been fully implemented.

The NSC staff, which supports the HSC, convened an interagency policy group that guided the completion of the National Strategy for Biosurveillance in July 2012, which addresses the intent of our recommendation to establish a focal point. However, our review of the strategy determined that the strategy alone did not fully meet the intent of our recommendation because, among other things, it did not provide the mechanism we recommended to identify resource and investment needs, including investment priorities. Subsequent to the release of the strategy, the NSC staff published a companion implementation plan, but it is not yet clear the extent to which the plan has been widely shared among and adopted by interagency decision makers as a means to help identify opportunities to leverage resources and direct priorities.

The National Strategy for Biosurveillance also does not address issues we raised related to state and local biosurveillance efforts, and that we previously recommended. In October 2011, we reported that nonfederal capabilities should also be considered in creating a national biosurveillance strategy. The backbone of biosurveillance is traditional disease-surveillance systems—designed to collect information on the health of humans and animals to support a variety of public-welfare and economic goals. These systems support biosurveillance efforts by recording national health and disease trends and providing specific information about the scope and projection of outbreaks to inform response. Because the resources that constitute a national biosurveillance capability are largely owned by nonfederal entities, a national strategy that considers how to strengthen and leverage nonfederal partners could improve efforts to build and maintain a national biosurveillance capability. Moreover, efforts to build the capability would benefit from a framework that facilitates assessment of nonfederal

[20]See GAO-10-645; GAO, *Combating Terrorism: Selected Challenges and Related Recommendations*, GAO-01-822 (Washington, D.C: Sept. 20, 2001), and *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

jurisdictions' baseline capabilities and critical gaps across the entire biosurveillance enterprise. Such an assessment of capabilities that support biosurveillance is called for in HSPD-10, which notes that the United States requires a periodic assessment that identifies gaps or vulnerabilities in our biodefense capabilities—of which surveillance and detection is a key part—to guide prioritization of federal investments. However, in a 2011 report, we noted that the federal government had not conducted a comprehensive assessment of state and local jurisdictions' ability to contribute to a national biosurveillance capability.[21]

While the size, variability, and complexity of the biosurveillance enterprise makes an assessment difficult, we concluded in our October 2011 report that the federal government would lack key information about the baseline status, strengths, weaknesses, and gaps across the biosurveillance enterprise until it conducts such an assessment. To address these issues, and building on our June 2010 recommendation to develop a national biosurveillance strategy, we recommended for such a strategy to (1) incorporate a means to leverage existing efforts that support nonfederal biosurveillance capabilities, (2) consider challenges that nonfederal jurisdictions face, and (3) include a framework to develop a baseline and gap assessment of nonfederal jurisdictions' capabilities. However, the July 2012 strategy did not adequately address the issues we raised related to state and local biosurveillance and acknowledged but did not meaningfully address the need to leverage nonfederal resources.

Challenges for Biosurveillance Capabilities

Our recent work has also identified challenges with specific biosurveillance capabilities. Specifically, we have identified biosurveillance capability challenges with, among other topics, (1) state and local public heath capabilities, (2) animal health surveillance

[21]GAO-12-55. In 2011, we reported that certain aspects of public-health capabilities have been assessed by federal agencies and professional associations. For example, CDC's guidance associated with the Public Health Emergency Preparedness (PHEP) cooperative agreement began to define elements, priorities, resource considerations, and metrics for building and assessing public-health surveillance, epidemiology, and laboratory capabilities. However, in 2013, we reported on ways to better assess the effect of cooperative agreements on awardee preparedness, including that of the PHEP. We reported that creating comprehensive performance management systems with realistic targets and incremental milestones would aid in assessing performance. However, as of September 2015, HHS was still working to address our recommendations. See, *National Preparedness: Improvements Needed for Measuring Awardee Performance in Meeting Medical and Public Health Preparedness Goals*, GAO-13-278 (Washington, D.C.: March 2013).

capabilities, and (3) two DHS specific biosurveillance efforts—the National Biosurveillance Integration Center (NBIC) and the BioWatch Program.[22] In our October 2011 report on nonfederal biosurveillance efforts, we found many of the challenges that state and local officials identified were similar to issues we reported regarding biosurveillance at the federal level. We noted that many of the challenges facing the biosurveillance enterprise were complex, inherent to building capabilities that cross traditional boundaries, and not easily resolved.

State and Local Public Health Capabilities. In 2011, we found that state and local officials identified common challenges to developing and maintaining their biosurveillance capabilities such as (1) state policies in response to state budget constraints that restricted hiring, travel, and training; (2) obtaining and maintaining resources, such as adequate workforce, equipment, and systems; and (3) the lack of strategic planning and leadership to support long-term investment in crosscutting core capabilities, integrated biosurveillance, and effective partnerships.[23] For example, state and local officials we surveyed reported facing workforce shortages among skilled professionals—epidemiologists, informaticians, statisticians, laboratory staff, animal-health staff, or animal-disease specialists. We also found that although the federal government provided some resources to help control disease in humans and animals in tribal and insular areas, there were no specific efforts to ensure that their efforts can contribute to the national biosurveillance capability. Additionally, in 2011, we found that nonfederal partners relied heavily on grants and cooperative agreements to sustain their biosurveillance capabilities. For example, the Public Health Emergency Preparedness cooperative agreement (PHEP) and the Epidemiology and Laboratory Capacity for Infectious Diseases cooperative agreement (ELC) were essential for public health epidemiology and laboratory staff. We concluded that without assessing the baseline nonfederal capabilities that support biosurveillance, identification of investment needs for a national biosurveillance capability cannot be established.

Animal Surveillance Capabilities. In the area of animal surveillance, we reported in May 2013 that USDA's Animal and Plant Health Inspection

[22]DHS's BioWatch program aims to provide early indication of an aerosolized biological weapon attack.

[23]See, GAO-12-55.

Service (APHIS) had developed a new approach for its livestock and poultry surveillance activities, but had not yet integrated these efforts into an overall strategy with goals and performance measures aligned with the nation's larger biosurveillance policy.[24] Under its prior approach, APHIS focused its disease surveillance programs on preventing the introduction of certain foreign animal diseases and monitoring, detecting, and eradicating other reportable diseases already present in domestic herds. Under this previous approach, information about nonreportable diseases, including those that are new or reemerging, was not always captured by the agency's disease surveillance efforts. We also reported in 2013 that under its new approach APHIS had begun to broaden its approach by monitoring the overall health of livestock and poultry and using additional sources and types of data to better detect and control new or reemerging diseases. For example, APHIS had been monitoring for the presence of pseudorabies—a viral swine disease that may cause respiratory illness and death—at slaughter facilities, but under the new approach, it proposed monitoring these facilities for a range of other diseases as well. However, we concluded that without integrating APHIS's new approach to livestock and poultry surveillance activities into an overall strategy with goals and measures aligned with broader national homeland security efforts to detect biological threats, APHIS may not be ideally positioned to support national efforts to address the next threat to animal and human health. We recommended that APHIS integrate its new surveillance approach with an overall strategy that guides how its new approach will support national homeland security efforts to enhance the detection of biological threats. However, while the agency agreed, this recommendation has not been implemented.

DHS Biosurveillance Efforts. In 2015, we identified persistent challenges related to two of DHS's biosurveillance capabilities, NBIC and the BioWatch program.[25] We reported in 2009 that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel—from its partner agencies, which may have been at least partially the result of collaboration challenges it faced.[26] For example, some partners reported that they did not trust NBIC to use their

[24]GAO-13-424.

[25]See, GAO-15-793 and GAO-16-99.

[26]GAO-10-171.

information and resources appropriately, while others were not convinced of the value that working with NBIC provided because NBIC's mission was not clearly articulated. In the 2009 report, we recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. DHS agreed, and in August 2012, NBIC issued the NBIC Strategic Plan, which is intended to provide NBIC's strategic vision, clarify the center's mission and purpose, and articulate the value that NBIC seeks to provide to its partners, among other things. In September 2015, we reported that despite NBIC's efforts to collaborate with interagency partners to create and issue a strategic plan that would clarify its mission and efforts, a variety of challenges remained. Notably, many of its federal partners continued to express uncertainty about the value NBIC provided. We identified options for policy or structural changes that could help NBIC better fulfill its biosurveillance integration mission, such as changes to NBIC's roles, but we did not make specific recommendations.[27]

Additionally, since 2012, we have reported that DHS has faced challenges in clearly justifying the need for the BioWatch program and its ability to reliably address that need (to detect aerosolized biological attacks). In September 2012, we found that DHS approved a next-generation BioWatch acquisition in October 2009 without fully developing knowledge that would help ensure sound investment decision making and pursuit of optimal solutions.[28] We recommended that before continuing the acquisition, DHS reevaluate the mission need and possible alternatives based on cost-benefit and risk information. DHS concurred and in April 2014, canceled the acquisition because an alternatives analysis did not confirm an overwhelming benefit to justify the cost. Having canceled the next generation acquisition, DHS continues to rely on the currently-deployed BioWatch system for early detection of an aerosolized biological attack. However, in 2015, we found that DHS lacks reliable information about the current system's technical capabilities to detect a biological attack, in part because in the 12 years since BioWatch's initial deployment, DHS has not developed technical performance requirements for the system.[29] We reported in October 2015

[27]GAO-15-793.

[28]GAO-12-810.

[29]GAO-16-99.

that DHS commissioned tests of the current system's technical performance characteristics, but without performance requirements, DHS cannot interpret the test results and draw conclusions about the system's ability to detect attacks. DHS is considering upgrades to the current system, but we recommended that DHS not pursue upgrades until it establishes technical performance requirements to meet a clearly defined operational objective and assesses the system against these performance requirements. DHS concurred and is working to address the recommendation.

Chairman Johnson, Ranking Member Carper, and Members of the Committee, this concludes my prepared statement. I would be happy to respond to any questions you may have.

GAO Contact and Staff Acknowledgments

For questions about this statement, please contact Chris Currie at (404) 679-1875 or curriec@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals making key contributions to this statement include Kathryn Godfrey (Assistant Director), Susanna Kuebler (Analyst-In-Charge), Russ Burnett, Marcia Crosse, Mary Denigan-Macauley, Tracey King, Jan Montgomery, Steve Morris, and Tim Persons. Key contributors for the previous work that this testimony is based on are listed in each product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

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Washington, D.C. 20201

DEC 2 9 2016

The Honorable Ron Johnson
Chairman
Committee on Homeland Security and Government Affairs
United States Senate
Washington, D.C. 20510

Dear Chairman Johnson:

Thank you for the opportunity to testify before the Committee on Homeland Security and Government Affairs on April 14, 2016, for the hearing entitled "The Federal Perspective on the State of Our Nation's Biodefense."

Securing our nation against biological threats, such as anthrax and emerging infectious diseases like Zika, is a challenging endeavor. Improving our preparedness for and capability to respond to biological threats is a top priority for the Assistant Secretary for Preparedness and Response (ASPR). ASPR has made numerous improvements in recent years, including developing the National Health Security Strategy and successfully procuring and developing medical countermeasures, such as influenza vaccines and antiviral drugs, to protect the nation against pandemic influenza and chemical, biological, radiological, and nuclear threats.

I thank you again for your letter and the opportunity to address your questions. I look forward to continuing our work with you and the Committee. I have enclosed a detailed response to the questions presented for the record after the hearing concluded. If you have any additional questions, please do not hesitate to contact me at (202) 260-0150.

Sincerely,

for

Richard J. Hatchett, M.D.
Deputy Director, Biomedical Advanced Research
and Development Authority

Enclosure

Questions for the Record

Senate Committee on Homeland Security and Governmental Affairs

Federal Perspective on the State of Our Nation's Biodefense
Thursday, April 14, 2016

Dr. Richard Hatchett
Deputy Director, Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

Senator Kelly Ayotte

1) **On April 13, the Centers for Disease Control and Prevention (CDC) announced that there is now definitive evidence that the Zika virus causes microcephaly and other serious brain defects in infants. The CDC also estimated that up to 30 percent of women in infested areas may eventually contract Zika. Our neighbors in Puerto Rico have already been severely impacted by the virus. There have been travel-associated cases of Zika in my home state of New Hampshire.**

   a. **How is your department coordinating with other relevant federal agencies, as well as state departments of health and health departments in Puerto Rico, the U.S. Virgin Islands, and American Samoa in the fight against Zika?**

The Assistant Secretary for Preparedness and Response (ASPR) serves as the principal advisor to the Secretary of the Department of Health and Human Services (HHS) on matters relating to federal public health and medical preparedness in response to public health emergencies. In this capacity, ASPR coordinates medical preparedness and response efforts within HHS and collaborates with other interagency and external stakeholders such as state/territory and local health departments. One of ASPR's first acts in addressing the emerging Zika threat was to activate the Disaster Leadership Group (DLG). Comprised of senior leaders from across HHS, the DLG leads information sharing and coordination in areas such as communications, laboratory capacity, medical countermeasure (MCM) development, domestic preparedness, blood/tissue/organ safety, and collaboration with international partners.

ASPR also leads the HHS Sample Sharing Working Group, which has been collecting domestic and international samples from individuals with confirmed Zika virus infection to aid the development of MCMs for Zika. Likewise, ASPR's Hospital Preparedness Program has field officers in each HHS Region around the country to provide technical assistance, best practices, and grant support to regional health care coalitions. The field officers responsible for Puerto Rico, the U.S. Virgin Islands, and American Samoa are working to develop and implement strategies to prepare and coordinate care for patients with Zika virus. ASPR is also working with the Puerto Rico Department of Health to plan for any increase in the number of cases of Guillain-Barré syndrome, a condition associated with Zika virus infection. This includes

recommendations such as regionalizing specialty care, exploring ways to augment available staffing, and surveying the potential for telehealth and/or telemedicine resources.

One example of ASPR's leadership involves coordinating efforts to support Puerto Rico's blood supply. On March 5, 2016, blood collection in Puerto Rico was suspended based on guidance issued by the Food and Drug Administration (FDA) on February 16, 2016. The guidance included a recommendation that areas with active Zika virus transmission obtain whole blood and blood components from areas of the United States without active virus transmission until a blood donor screening test or pathogen reduction technology for Zika virus becomes available. ASPR, the HHS Office of the Assistant Secretary for Health, FDA, and the Centers for Disease Control and Prevention (CDC) worked quickly to establish blood supply contracts with the American Red Cross and Blood Centers of America. HHS agencies were asked to assist on February 26, 2016, and contracts were awarded five days later on March 2, 2016. This made it possible for Puerto Rico's 11 blood establishments to receive weekly shipments of blood products. The contracts initiated by ASPR ensured an adequate supply of safe blood for residents and provided additional time for the 11 blood establishments to implement testing of all donations with an investigational blood donor screening test for Zika virus, which has been in use in Puerto Rico since early April 2016.

b. Has there been a formal plan developed that is comprehensive in nature and that focuses on interagency coordination at the state and federal levels, prevention, and response?

The National Response Framework (NRF) guides the federal response effort and prioritizes close coordination among partners. ASPR coordinates preparedness, response, and recovery efforts across the Department and the interagency under that framework. Specifically, for the Zika virus response, under Emergency Support Function #8 of the NRF, ASPR serves as the primary federal lead for critical policy decisions and identifying potential barriers for an effective response.

The Department released the *United States Government Zika Virus Disease Contingency Response Plan* in September 2016, which describes the operational response activities for the United States government (USG) if confirmed local or widespread Zika transmission occurs in the United States. The plan is available on ASPR's website at: http://www.phe.gov/Preparedness/planning/Documents/zika-response-plan2016.pdf.

c. If so, could you provide details that demonstrate how these agencies are working together?

ASPR coordinates interagency efforts to address the Zika virus through the DLG. Within ASPR, the HHS Secretary's Operations Center has been activated to respond to Zika in close coordination with CDC's Emergency Operations Center. ASPR also leads the coordination and reporting of ongoing situational awareness information to senior federal officials. In addition, ASPR coordinates with other USG departments via the National Security Council's (NSC) Interagency Policy Committee (IPC) and sub-IPC on Zika. ASPR, at the approval of the NSC, has also activated the Unified Coordination Group (UGC) in Puerto Rico in August 2016. The

UCG facilitates communication and coordination between federal agencies, state and local authorities, and the private sector for the Zika response in Puerto Rico.

ASPR's Biomedical Advanced Research and Development Authority (BARDA) has been collaborating with CDC, FDA, and the National Institutes of Health (NIH) to facilitate the development of rapid point-of-care and laboratory-based serological assays to determine who has been previously infected by Zika (especially pregnant women). ASPR/BARDA has also been working with CDC, FDA, and NIH to facilitate the development of commercial assays to identify Zika infection.

Building on partnerships and lessons learned from the H1N1 and Ebola responses, ASPR is implementing a Zika MCM strategy through the advanced development and manufacturing of new Zika vaccine candidates. In collaboration with NIH, FDA, and the Walter Reed Army Institute of Research (WRAIR), ASPR is working on Zika vaccine development, preclinical and clinical testing, and commercial scale production, including vaccine manufacturing through the Centers for Innovation in Advanced Development and Manufacturing (CIADM). ASPR supports industry partners in developing new vaccine platform technologies applicable to multiple emerging infectious diseases, including new Zika vaccine candidates.

On the international front, ASPR and the HHS Office of Global Affairs re-convened the USG Americas Region Interagency Coordination Group. This group serves as a forum for USG partners to share information and coordinate Zika preparedness and response efforts among themselves and with the Pan American Health Organization. In this case, the group has a particular focus on aligning responses to Zika-related international requests for assistance. International coordination also involves outreach to various Ministries of Health to establish public health and scientific research collaboration agreements and obtain Zika samples that help isolate the virus and validate serological diagnostics assays. ASPR is also providing technical assistance to global partners in Brazil for Zika vaccine development and commercial scale manufacturing.

2) **About a month ago, Senator Burr and I wrote to FDA to urge the agency use its authority to place Zika virus on the FDA's Priority Review Voucher program list of qualifying Neglected Tropical Diseases. Such a designation would help accelerate much needed research on Zika and even potentially lead to a Zika vaccine or treatment by leveraging private investment. In 2014, I cosponsored a bill that was signed into law which placed Ebola on the same priority review list.**

   In their response to our letter, the FDA noted that it did not believe the Zika virus met the criteria for the Priority Review Voucher program because there "appears to be a significant market for Zika virus medical products in developed nations" thereby making Zika ineligible for the program. I was disappointed in this response.

   a. **Do you disagree with the FDA's finding that Zika would not be a good candidate for its Priority Review Voucher program?**
   b. **Can you put into context the threat that Zika poses versus our current ability to mitigate the spread of the virus?**

c. Shouldn't that be a key component when considering ways to expedite the ability to produce a safe and effective vaccine or an improved diagnostic test?

The Adding Zika Virus to the FDA Priority Review Voucher Program Act, Pub. L. No. 114-146 (Apr. 19, 2016), adds the Zika virus to the list of tropical diseases included under the FDA Priority Review Voucher Program. Please see the responses from Dr. Stephen Redd, who testified on behalf of CDC and is responding to these questions on behalf of HHS agencies.

3) In its response to our letter, the FDA also stated that BARDA has activated its National Medical Countermeasures Response Infrastructure in order to provide direct assistance to product developers for vaccine and diagnostic test development and manufacturing. Could you provide me with a more detailed status update on the work that BARDA is doing related to Zika, including how you are coordinating with both relevant federal and state agencies?

In response to the Zika outbreak, BARDA mobilized the National Medical Countermeasures Response Infrastructure in early 2016. The Response Infrastructure is comprised of three CIADMs, the Fill-Finish Manufacturing Network, the Nonclinical Development Network (NDN), and the Clinical Studies Network (CSN). Collectively, they provide manufacturers and Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) partners with critical support before, during, and after national health emergencies.

BARDA mobilized the CSN to assist with sample collection for the development of Zika diagnostic validation panels. Specifically, the CSN worked to secure clinical serum specimens from Zika infected individuals in both the continental U.S. and its territories, and to provide these specimens to diagnostic test developers. Four of the five CSN participants provided proposals outlining the technical details, timelines, and costs for fulfilling this requirement. Samples were collected in Puerto Rico, New York, Florida, and Texas, in conjunction with CDC and local, state, and regional public health departments.

With respect to Zika vaccines, BARDA is collaborating with the National Institute of Allergy and Infectious Diseases (NIAID) and WRAIR to develop a purified inactivated Zika virus vaccine. The candidate vaccine was chosen based on WRAIR's experience with this viral inactivation platform, which has been used to develop many other vaccines for related viruses, including a tetravalent Dengue vaccine. The inactivated Zika vaccine, developed and produced by WRAIR with support from NIAID, has shown 100 percent efficacy in mice and monkeys and has reached the final stages of manufacturing in preparation for clinical trials. Four clinical trials are being planned for the fall of 2016: one at WRAIR, one funded by WRAIR at Beth Israel Deaconess Medical Center, one through NIAID's Vaccine and Treatment Evaluation Unit network, and one in collaboration with the NIAID Vaccine Research Center. Most candidate vaccines are in early stages of development, and work is currently underway at BARDA's Nonclinical and Clinical Development Networks to generate essential reagents for vaccine and diagnostics manufacturers.

The ability to rapidly pivot from the preclinical development of a candidate vaccine or therapeutic to manufacturing for clinical evaluation is a significant accomplishment when

confronting a rapidly evolving epidemic. In early 2016, the CIADMs were activated to support the government's coordinated response to the Zika virus outbreak in South America. Specifically, one of BARDA's CIADM partners repositioned assets to help collect materials to screen potential cell-based platforms for a Zika virus vaccine candidate. Likewise, in June, BARDA awarded a task order to the Emergent BioSolutions CIADM in Baltimore, Maryland, to develop a whole virus inactivated Zika vaccine candidate.

Plans are under way to engage the NDN to develop appropriate animal models of Zika virus infection to facilitate MCM development.

Senator Thomas Carper

1) **In its 2011 report, the General Accounting Office reported that there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise and recommended that the Homeland Security Council consider establishing a focal point to oversee these efforts. The number one recommendation included in the Bipartisan Report of the Blue Ribbon Study Panel on Biodefense is to institutionalize biodefense in the Office of the Vice President of the United States to ensure that biodefense will be addressed by every Administration at the highest levels. The second recommendation is to establish a Biodefense Coordination Council at the White House, led by the Vice President.**

   a. **Do you support establishing one individual or entity to coordinate these efforts or think that the existing structure is sufficient?**

ASPR recognizes that medical and public health is one component of the broader U.S. government (USG) effort to prevent, detect, and respond to biological threats in the homeland and overseas, along with other federal agencies. Effective structures exist under the Office of the Assistant Secretary for Preparedness and Response (ASPR) to coordinate the public health and medical components of biodefense preparedness. The ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which is a medium for interagency partners to diseuss and combine resources that produce medieal countermeasures (MCM) for identified and suspected bio threats that have been determined by the Secretary of the Department of Homeland Security (DHS) or PHEMCE leadership to pose a material or potential threat to national health security. Thc ASPR also leads the Disaster Leadership Group (DLG), whieh engages with key leadership from across the Department of Health and Human Serviees (HHS) to share information and coordinate preparedness and response activities. Both the DLG and PHEMCE are working effectively to coordinate these efforts across the Department and interagency.

   b. **How else could we improve coordination across the government in biodefense activities?**

As the principal advisor to the Secretary on matters relating to federal public health and medical preparedness in response to public health emergencies, the ASPR consistently works on improving biodefense coordination through structures such as the PHEMCE and DLG.

2) **In its final report, the Blue Ribbon Study Panel issued more than 33 reecommendations for action by the Exccutive Branch. Please explain what activities your Department or Agency is taking to address the seleet recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:**

   a. **#6 – Improve management of the biological intelligence enterprise.**

HHS/ASPR is a consumer, not a producer, of intelligence products related to biodefense. This recommendation is best directed to those in the Intelligence Community.

b. #7 – Integrate animal health and One Health approaches to biodefense strategies.

This recommendation is best directed to the U.S. Department of Agriculture (USDA), and the Department of Interior (DOI). However, HHS recognizes that the concept of One Health is important to a variety of public health issues, especially the emergence or re-emergence of naturally occurring infectious diseases and in combating antimicrobial resistance (as part of the larger USG Combating Antibiotic Resistant Bacteria initiative). DOI's U.S. Geological Survey National Wildlife Health Center (NWHC), an affiliate laboratory in USDA's National Animal Health Laboratory Network, works on One Health approaches to biodefense with USDA, HHS, and the Department of Defense's (DoD) Defense Threat Reduction Agency. NWHC is also the DOI lead for animal health emergencies under Emergency Support Function #11. A variety of pathogen threats identified by DHS and detailed in the PHEMCE Strategy and Implementation Plan are also zoonotic agents. Medical or veterinary information gleaned from these specific pathogens enhances MCM assessments.

c. #8 – Prioritize and align investments in medical countermeasures among all federal stakeholders.

Prioritizing federal resources is necessary given the range of potential threats and available resources. With that in mind, the PHEMCE developed a coordinated and strategic framework in 2012 to direct MCM investments. PHEMCE agencies work together to ensure that MCM products progress as quickly and economically as possible from early to final stage development. If needed, these products are purchased for the Strategic National Stockpile (SNS) and used effectively in an emergency. For instance, the PHEMCE framework was utilized during the Ebola response when partners leveraged assets across the federal government to support the development and evaluation of Ebola candidate vaccines and treatments.

The PHEMCE prioritization framework is based on two core principles: (1) a medical and public health obligation to limit adverse health effects from a variety of threats; and, (2) a responsibility to be prudent with the financial resources while maximizing national preparedness. The PHEMCE will continue to apply this framework to inform federal resource allocations for research, development, manufacturing, procurement, and effective utilization of MCMs. The annual PHEMCE multi-year budget report prioritizes criteria to coordinate a five-year budget plan to research, develop, procure, and stockpile MCMs.

The PHEMCE works diligently to identify and prioritize investments among federal stakeholders. Examples of these processes include:

1. An annual report to Congress from the HHS Secretary prioritizing products maintained or accessed by the SNS.
2. An annual PHEMCE Strategy and Implementation Plan with anticipated completion timelines and recent accomplishments to outline priority actions and PHEMCE agencies and partners responsible for implementation.

3. An annual multi-year budget identifying how agencies manage MCM lifecycle costs to collaborate and move products from research and development into approval, acquisition, and stockpiling. It is designed to help agencies understand and forecast impacts on their anticipated budgets. This approach provides actual costs based on the current fiscal year budget, the President's approved budget estimate for the next fiscal year, and projected requirements for the following three years.
4. Ongoing portfolio reviews across all chemical, biological, radiological, nuclear (CBRN) and pandemic threat areas to review detailed priorities and identify gaps and challenges. More specifically, to identify where resources may be better arrayed to address the appropriate challenge.
5. A product tracking tool for all contracts from agencies engaged in product development. This provides a real-time assessment of candidate products from the basic science level towards final regulatory approval and completion. The product tracking tool is available now for all vaccines, therapeutics, diagnostic efforts, and other related contracts across the PHEMCE.

d. #9 – Better support and inform decisions based on biological attribution.

This recommendation relates to intelligence gathering and law enforcement activities that are beyond HHS's scope of authority and is best directed to DHS, the Department of Justice, the Federal Bureau of Investigation (FBI), and other members of the Intelligence Community.

e. #10 – Establish a national environmental decontamination and remediation capacity.

This recommendation is best directed to the Federal Emergency Management Agency (FEMA) and the Environmental Protection Agency as the agency to whom the recommendation assigns responsibility for environmental decontamination and remediation, with the coordination of HHS and other agencies. HHS, through CDC, has conducted hazardous materials response capacity building, including decontamination training, through the FEMA facility in Anniston, Alabama. The Department, through CDC, is also involved in other planning processes that include decontamination components, such as the Chemical Incident Annex Planning.

f. #11 – Implement an integrated national biosurveillance capability.

See response to question 2h.

g. #12 – Empower non-federal entities to be equal biosurveillance partners.

See response to question 2h.

h. #13 – Optimize the National Biosurveillance Integration System.

ASPR does not manage biosurveillance programs. However, as the lead for HHS's public health and health care preparedness and response activities, ASPR is a consumer of biosurveillance information which helps direct PHEMCE priorities and improve its capabilities to prepare and respond to public health emergencies. ASPR serves as a co-chair on the DHS/Office of Health Affair's National Biosurveillance Integration Center's Advisory Board, which allows for

collaboration amongst all federal partners who conduct biosurveillance activities and provides guidance for enhancing the National Biosurveillance Integration System.

i. #14 – Improve surveillance of and planning for animal and zoonotic outbreaks.

HHS works with USDA and DOI on developing MCMs for viruses circulating in animals that could impact human health, such as highly pathogenic avian influenza (HPAI) outbreaks. Specifically, HHS is responsible for sustaining a capability to produce a pandemic vaccine at any time of the year in a U.S. licensed influenza vaccine facility. With that in mind, ASPR contracted with Sanofi Pasteur, the major domestic supplier of egg-based influenza vaccine, to ensure year-round availability. This includes enough embryonated eggs to produce 10 million monovalent doses per week.

In order to maintain this investment and capability, ASPR's Biomedical Advanced Research and Development Authority (BARDA) has been working to improve planning for animal and zoonotic outbreaks. During the 2015 HPAI outbreak, BARDA communicated daily with Sanofi Pasteur for updates and information from the USDA and the Pennsylvania Department of Agriculture. In addition, BARDA participated in several HPAI roundtable exercises initiated by Sanofi Pasteur and its egg supply subcontractors. These roundtable exercises highlighted the interagency, intra-agency and private industry cooperation, communication, and clarification of issues related to the safety, supply, and transportation of embryonated eggs for vaccines during an HPAI outbreak.

j. #15 – Provide emergency responders with the resources they need to keep themselves and their families safe.

ASPR offers a number of educational resources to emergency responders, such as the ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) and the CBRN toolkit. In addition, ASPR's Office of Emergency Management (OEM) conducts training programs to improve the readiness and safety of emergency responders, including National Disaster Medical System and the Counter-Narcotics and Terrorism Operational Medical Support program training activities.

ASPR has released a funding opportunity announcement entitled "Enhance the Ability of Emergency Medical Services to transport patients with highly infectious diseases" to assist in the development of a state Emergency Medical Services High Consequence Infectious Disease Transport Plan Template. This plan will help reduce the risks for personnel required to transport patients with highly lethal or communicable infectious diseases.

k. #16 – Redouble efforts to share information with state, local, territorial, and tribal partners.

HHS's Ebola response highlighted the importance of communicating risk-related information to state and local partners during a public health emergency. To ensure that stakeholders have access to critical and up-to-date information to better support emerging needs during disaster, ASPR launched TRACIE in September 2015. TRACIE provides one-stop shopping for partners and stakeholders to gain access to best practices, guidance documents, and technical assistance

as well as to share ideas and to collaborate with stakeholders on matters pertaining to healthcare emergency preparedness. TRACIE ensures that stakeholders at all levels of government and the private sector have access to information and resources to improve preparedness, response, recovery, and mitigation efforts. TRACIE's listserv has nearly 4000 recipients, has received over 30,000 visitors to the website, responded to more than 300 training and technical assistance requests, and signed up nearly 1200 members to the Information Exchange.

In addition, the USG's U.S. International Health Regulations (2005) National Focal Point in ASPR ensures information exchange and coordination between domestic and international partners concerning potential international public health emergencies. This notification and reporting process involves federal, state, local, territorial, and tribal stakeholders.

l. #18 – Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.

Please see the responses from Dr. Stephen Redd, who testified on behalf of CDC and is responding to this question on behalf of HHS agencies.

m. #22 – Develop and implement a Medical Countermeasure Response Framework.

Please see the responses from Dr. Stephen Redd, who testified on behalf of CDC and is responding to this question on behalf of HHS agencies.

n. #23 – Allow for forward deployment of Strategic National Stockpile assets.

Please see the responses from Dr. Stephen Redd, who testified on behalf of CDC and is responding to this question on behalf of HHS agencies.

o. #24 – Harden pathogen and advanced biotechnology information from cyber attacks.

ASPR's Critical Infrastructure Protection Program works closely with the private sector to improve the cybersecurity of health care and public health sector organizations, including laboratories, pharmaceutical manufacturers, and others that might handle biotechnology information. ASPR shares information with private sector organizations on cyber threats and works in close collaboration with other federal partners such as DHS and the FBI. ASPR is also leading the Health Care Industry Cybersecurity Task Force, which was established as part of the implementation of the Cybersecurity Information Sharing Act of 2015.

p. #26 – Implement military-civilian collaboration for biodefense.

DoD and HHS collaborate and coordinate military and civilian biodefense and MCM efforts under the PHEMCE. Through the PHEMCE, DoD and HHS collaborate and share information on research, advanced research, development, procurement, stockpiling, and distribution of MCMs. DoD and HHS both have voting membership within the PHEMCE at multiple levels. Additionally, DoD participates in all In-Process Reviews conducted for ASPR/BARDA programs and PHEMCE-wide portfolio reviews led by ASPR.

The PHEMCE Integrated Portfolio for CBRN MCMs was established within the PHEMCE in 2008 to provide a framework for collaboration among the MCM-related program components of HHS and DoD. The Portfolio Advisory Committee, co-chaired by DoD and HHS, is comprised of program representatives from various organizations responsible for the CBRN MCM programs within each department. Through the Portfolio Advisory Committee, DoD and HHS coordinate efforts to promote synergy, minimize redundancy, and, to the extent feasible, harmonize requirements for MCM development. A significant example of collaboration is the development of the Portfolio Tracking Tool, developed jointly by HHS and DoD to capture contract performance information for all CBRN MCM development efforts across both agencies.

ASPR/BARDA program managers participate in a number of DoD Integrated Product Teams, including those specifically associated with CBRN MCMs. Moreover, senior level individuals participate in DoD's Joint Program Executive Office for Chemical and Biological Defense Joint Life Cycle Management Reviews, and in various In-Process Reviews (for all DoD MCM programs), as well as on the DoD Overarching Integrated Product Team. The 2014 Ebola epidemic response demonstrated the effectiveness of the DoD and HHS relationship. CDC and DoD worked together to develop and implement Ebola diagnostics in West Africa and in U.S. laboratories. DoD also successfully transitioned Ebola vaccine and therapeutic candidates from early development to ASPR/BARDA for advanced development.

Beyond information sharing, DoD and HHS also coordinate on the research, development, and procurement of safe and effective MCMs. DoD and CDC collaborate closely on the acquisition and management of MCMs for anthrax and smallpox while ASPR/BARDA and DoD collaborate on the acquisition and management of pre-pandemic influenza vaccines. HHS and DoD are jointly developing MCMs for chemical threats and to address gastrointestinal injury associated with acute radiation syndrome.

q. #27 – Prioritize innovation over incrementalism in medical countermeasure development.

The PHEMCE supports innovation broadly, both in terms of the kinds of products it supports, as well as in its processes, business practices, and partnership models. ASPR/BARDA, for example, is developing new classes of antibiotics and new approaches to burn therapy and vaccine development. ASPR/BARDA has supported the use of innovative messenger ribonucleic acid (mRNA) based vaccines for Zika and synthetic biology techniques to develop an influenza vaccine seed stock within a week of the publication of its genetic sequence. This synthesis of artificial genes (based on publicly available sequence data) obviates the need to secure viral specimens and can now be accomplished in days as opposed to standard methods for developing vaccine seed stocks that may require weeks of effort. Other innovations in how products are screened for microbial contaminants (sterility) have been recently developed under the auspices of ASPR/BARDA and the PHEMCE, and may result in changing the way the entire pharmaceutical industry conducts such screening.

In addition, the PHEMCE has invested in a variety of novel concepts and innovations such as the development of a new ventilator that is small, relatively inexpensive, and has a broad capability to assist in ventilating patients from infants to adults. The PHEMCE has enhanced the regulatory review processes by investing in regulatory research and prioritizing the review of key products

for biodefense and radiological defense. Innovations in new adjuvants have occurred that are first in use for influenza vaccines and expand the very limited number of previously acceptable vaccine adjuvants.

r. #28 – Fully prioritize, fund, and incentivize the medical countermeasure enterprise.

PHEMCE agencies contribute to the appropriations process by identifying and quantifying MCM requirements. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 requires HHS to develop a five-year budget plan for the medical countermeasure enterprise. This multiyear plan is a tool for strategic project coordination, product transitions between agencies, communication of priorities and resources to partner stakeholders, and assistance with long-term forecasting. The goal of the multiyear plan is to outline PHEMCE programmatic estimates on a five-year rolling basis and to identify the hand-offs in the development cycle in anticipatable budget terms. This forecast allows agencies to understand the dynamic effects of PHEMCE decisions on their own strategic planning and those of downstream partners. Additionally, this tool communicates PHEMCE commitments and priorities to our industry partners. By coordinating resources and priorities, we can ensure an active medical countermeasure industry that meets our essential needs for a nimble and flexible response capability.

The HHS MCM requirement process serves to improve the outcomes of public health emergencies by focusing federal investments toward an aligned research, advanced development, acquisition, deployment, and use by PHEMCE-partner agencies including the National Institutes of Health (NIH), ASPR/BARDA, the U.S. Food and Drug Administration (FDA), and CDC. The requirement process informs private industry and academia about civilian MCM needs and facilitates effective coordination of programs with PHEMCE interagency partners. From there, the desired product volume and stockpiling goals provide critical information to support the PHEMCE leadership's allocation of resources. Prior to making investment decisions and pursuing specific acquisition targets, the PHEMCE considers MCM needs across the entire threat portfolio, along with scientific opportunity, existing resources, and other factors.

s. #29 – Reform Biomedical Advanced Research and Development Authority contracting.

ASPR's current line of authority, which includes a separate and specialized Office of Acquisitions Management, Contracts, and Grants (AMCG), appropriately distinguishes the roles and responsibilities of a certified and warranted acquisition workforce from program and scientific experts. This line of authority ensures proper checks and balances for effectively managing taxpayer investments through open and fair competition and is fully consistent with comparable agencies in the federal government. This also defuses potential or perceived concerns about conflicts of interest and corresponding legal problems, and helps avoid any appearance of undue command influence by an individual, program office, or outside source on contracting.

AMCG is an award winning and innovative contracting office that has received the HHS Secretary's 2015 Hubert H. Humphrey Award for Service to America, the 2012 HHS Small Business Award, and 2010 HHS Project Team Award for its contribution to the H1N1 Influenza

Virus response. In addition, AMCG incorporated Broad Agency Announcements, which streamlined the acquisition process and initiated the use of Other Transaction Authority to further engage industry.

AMCG has also led the Department in meeting contracting deadlines. During the Ebola response, novel contracting methods were used to support the development and evaluation of Ebola candidate vaccines and trials. While the federal government and the Department standard timeline for awarding contracts is 180 days, AMCG awarded the majority of its Ebola contract actions within 60 days. All Project BioShield contract actions were awarded within 128 days starting at the end of FY 2014 and with the bulk of these actions in FY 2015. In FY 2015, 90 percent of ASPR's contract actions were completed, thereby ensuring that there is opportunity for businesses capable of meeting the needs of HHS to compete on a level playing field. Exceeding targets under the President's Small Business Initiative, ASPR awarded 51 percent of eligible contract dollars to small businesses, exceeding ASPR's 35 percent small business goal. Additionally in FY 2015, ASPR awarded 91 grants totaling $212,649,385.67.

t. #30 – Incentivize development of rapid point-of-care diagnostics.

ASPR/BARDA is funding the development of multiple rapid point-of-care diagnostics platforms; some are in the biothreat diagnostics space and some initially address other parts of ASPR/BARDA's mission. All platforms are applicable to the biothreat space with development of a threat specific assay. ASPR/BARDA's open CBRN solicitation contains "Areas of Interest" for development of rapid point-of-care diagnostics for all biothreats for which Material Threat Assessments have been issued. The PHEMCE Diagnostics Integrated Product Team is developing requirements for all of these biothreats. Some are already available and others are in process.

u. #31 – Develop a 21st Century-worthy environmental detection system.

This recommendation is best directed to DHS and DoD. HHS is not involved in the development of environmental detection systems.

v. #32 – Review and overhaul the Select Agent Program.

On October 29, 2015, the USG released two sets of recommendations, the Federal Experts Security Advisory Panel (http://www.phe.gov/s3/Documents/fesap.pdf) and the Fast Track Action Committee-Select Agent Regulations (http://www.phe.gov/s3/Documents/ftac-sar.pdf). Recommendations from both groups support efforts to enhance the Federal Select Agent Program. HHS co-chaired both these groups and is working with federal partners to improve biosafety and biosecurity practices based on these findings. The implementation plan (http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf) for these recommendations emphasizes culture of responsibility, strengthens oversight, promotes outreach and education, conducts applied biosafety research, develops an incident reporting system, enhances material accountability and inspection processes, and rulemaking to update current regulations and guidance.

3) **The Blue Ribbon Study Panel, GAO and other experts have recommended the development of a national biodefense strategy. To date, federal agencies have produced several strategic documents that address different aspects of biodefense, including the National Health Security Strategy and the National Biosurveillance Strategy. Do you believe that existing strategy and policy documents provide sufficient coordination of biodefense activities across the federal government? What elements should be included in a unified national strategy for biodefense?**

Various cross government strategies such as the National Health Security Strategy (NHSS), the National Biosurveillance Strategy, and the National Strategy for Countering Biological Threats collectively coordinate a strategic level direction for biodefense. The NHSS is a robust strategy that addresses many components of biodefense: community health resilience; biosurveillance and situational awareness; medical and non-pharmaceutical countermeasures; health and public health and emergency management systems; and global capacity. It is an all-hazards strategy that addresses all emergencies that could impact human health. Enhancing national health security is a shared responsibility of all organizations (government and non-government), communities, and individuals.

4) **The Blue Ribbon Study Panel recommended the development of a unified budget for biodefense spending, and estimated that roughly $6 billion is spent every year on biodefense and related hazards. Please detail how much your Department or Agency spent on biodefense efforts (categorized by Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery activities, as defined by Homeland Security Presidential Directive 10) from Fiscal Years 2007-2016.**

Under Homeland Security Presidential Directive-10, the development, procurement, and stockpiling of MCMs, along with associated regulatory activities, are considered part of the Response and Recovery mission. With that in mind, the PHEMCE coordinates federal efforts to enhance MCM preparedness for CBRN threats and emerging infectious diseases. The PHEMCE is led by ASPR and includes primary HHS agency partners (CDC, FDA, and NIH), as well as, several interagency partners (DoD, the U.S. Department of Veterans Affairs, DHS, and USDA).

Within ASPR, BARDA is responsible for the advanced research and development and procurement of MCMs. BARDA's appropriations are included in the table below for FY 2007 to FY 2016. The table does not include spending from the following three sources: 1) pandemic influenza supplemental funding bills passed in 2006, 2009, and 2010; 2) Special Reserve Fund appropriations in FY 2004 that supported Project BioShield through FY 2013; and 3) Ebola funding provided in either the FY 2015 continuing resolution or supplemental emergency funding provided in the FY 2015 omnibus appropriation. All BARDA funding included in the table would be categorized as Response and Recovery.

Activity	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011*	FY 2012*	FY 2013*	FY 2014	FY 2015	FY 2016
	Enacted	Enacted	Enacted	Enacted	Enacted	Enacted	Enacted	Enacted	Enacted	Enacted
BARDA.....	119.741	131.419	306.052	340.531	340.531	340.531	415.000	778.165	734.906	1,086.691
Advanced Research and Development (ARD) (non-add).....	*119.741*	*131.419*	*306.052*	*340.531*	*340.531*	*340.531*	*415.000*	*413.494*	*415.000*	*511.700*
*Pandemic Influenza (non-add)***.....	---	---	---	---	---	---	---	*110.597*	*64.906*	*64.991*
X-Year (non-add)	---	---	---	---	---	---	---	*82.597*	*39.906*	*40.000*
Annual (non-add)	---	---	---	---	---	---	---	*28.000*	*25.000*	*24.991*
Project BioShield (non-add)	---	---	---	---				*254.074*	*255.00*	*510.00*

*BARDA ARD was funded from a transfer from the Special Reserve Fund (SRF). The SRF is based on the initial appropriation of $5.6 billion for a ten-year period (FY 2004 to FY 2013) to support procurements under Project BioShield.
**Pandemic Influenza activities prior to FY 2014 were supported from supplemental balances provided to the Department in 2006, 2009, and 2010.

5) Upon the release of the National Biosurveillance Strategy in July 2012, a strategic implementation plan for the strategy was slated for completion within 120 days. What is the status of the implementation plan? Please describe how the Office of the Assistant Secretary for Preparedness and Response coordinates biosurveillance programs and policy with other federal agencies, per the National Biosurveillance Strategy. If the implementation plan has been completed, please provide it to this Committee.

ASPR serves on the National Security Council's (NSC) Biosurveillance Sub-Interagency Policy Committee that coordinated development of the National Biosurveillance Strategy in July 2012. The White House Office of Science and Technology Policy issued the National Biosurveillance Science and Technology Roadmap in 2013 to prioritize research and development needs to improve the national biosurveillance enterprise. While the NSC led the development of a draft Implementation Plan for the National Strategy for Biosurveillance in 2013, it was not finalized or released.

Senator Ron Johnson

1) **In a letter from the Assistant Secretary for Preparedness and Response (ASPR) provided to me on June 12, 2015, the ASPR said that the Biological Incident Annex would be completed and approved in the Fall of 2015. Is that annex complete? If so, please provide a copy to the committee. If not, when will it be approved?**

The Federal Interagency Operational Plan Biological Incident Annex has been drafted. The Federal Emergency Management Agency is responsible for the report.

2) **In a letter from the ASPR provided to me on June 12, 2015, the ASPR said that HHS was developing a formal report on its preparedness and response to the Ebola outbreak. Has this formal report been completed? If not, when will it be complete? If complete, please provide a copy to the Committee.**

The Department of Health and Human Services (HHS) released its formal report, *Report of the Independent Panel on the U.S. Department of Health and Human Services Ebola Response,* in June 2016. The report is available on the Office of the Assistant Secretary for Preparedness and Response's (ASPR) website at: http://www.phe.gov/Preparedness/responders/ebola/EbolaResponseReport/Pages/default.aspx.

3) **In a letter from the ASPR provided to me on June 12, 2015, the ASPR said that the HHS had not yet identified lessons related to the U.S.'s domestic preparedness and international response to the Ebola outbreak in 2014-2015. Has HHS identified any lessons learned and resulting corrective actions taken for its preparedness and response to the Ebola outbreak? If so, please identify such lessons learned and corrective actions.**

An independent panel of experts reviewed the Department's domestic and international response to the Ebola outbreak. The *Report of the Independent Panel on the U.S. Department of Health and Human Services Ebola Response* was released in June 2016. Within the report, the independent panel identified lessons learned and developed recommendations to improve HHS and United States Government (USG) leadership and coordination for future public health threats. In response to the independent panel's report, HHS released the *U.S. Department of Health and Human Services Ebola Response Improvement Plan* in June 2016, which describes the steps the Department will take to address the recommendations of the independent panel. The report is available on ASPR's website at: http://www.phe.gov/Preparedness/responders/ebola/Documents/EbolaIP.pdf.

4) **Has HHS completed an inventory of HHS' public health response capabilities and gaps in those capabilities? Please provide the comprehensive list of such capabilities and gaps. If HHS has not yet completed such an inventory, when will this process be completed?**

ASPR has the authority to deploy federal public health and medical personnel through the United States Public Health Service and the National Disaster Medical System; directs the advanced research, development, and procurement of medical countermeasures; coordinates the integration

of federal preparedness and response activities for public health emergencies; and provides logistical support for the federal component of medical and public health responses. ASPR also supports building preparedness capabilities and resiliency at the community level before disasters or public health incidents occur. ASPR's flagship program in this regard, the Hospital Preparedness Program, has provided more than $5.1 billion to state and local health departments since 2002 to better prepare the nation's health care infrastructure for man-made or natural disasters.

ASPR has made numerous improvements to ensure national health security and to protect the American people. One such improvement is the development and continued refinement of the National Health Security Strategy (NHSS), which unified a patchwork of public health and medical preparedness, response, and recovery strategies. The NHSS works to ensure that the nation is prepared for, protected from, and resilient in the face of public health threats.

The NHSS established two overarching goals for national health security: 1) Build community resilience and 2) strengthen and sustain health and emergency response systems. With the National Health Security Review, ASPR emphasized capabilities and identified challenges for strengthening national health security, which informed the development of the National Health Security Strategy and Implementation Plan 2015-2018. Since the report, improvements have been made including:1) Integrating public health, health care, and emergency management systems; 2) Planning at the federal, state, and local levels; 3) Building national health security workforce capabilities; 4) Coordinating within government and between government and the private sector; and 5) Strengthening community resilience.

As a requirement of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, HHS provided Congress with a Public Health and Medical Situational Awareness Strategy and Implementation Plan. This strategy and plan includes ways to development and expand the bio surveillance network; modernize and enhance biosurveillance activities; and improve information sharing, coordination, and communication among biosurveillance systems.

In addition, ASPR coordinates annual assessments of USG compliance with the U.S. International Health Regulations (IHR) (2005) and provides a report to the World Health Organization (WHO). In 2016, ASPR led the USG's first participation in the WHO Joint External Evaluation Process, which assessed the United States in 19 core health security capacities within the IHR framework and the Global Health Security Agenda.

5) What process is HHS utilizing, together with other Departments and agencies, to identify major gaps in federal public health response and to prioritize capability development to meet such gaps?

The Public Health and Emergency Medical Countermeasures Enterprise (PHEMCE) has two initiatives that assess federal MCM preparedness and response gaps and capabilities: 1) Preparedness Assessments; and, 2) Integrated Capability Documents (ICD).

The Preparedness Assessment for operational capacity compares the nation's current and projected five-year level of capacity against the need for new MCMs. The result is a prioritized list of initiatives to close preparedness gaps identified in the PHEMCE Strategy and

Implementation Plan. This snapshot allows senior leaders to prioritize PHEMCE resource allocations and strategically improve preparedness.

The ICDs describes core cross-threat capabilities (e.g., supplies, staff, space, and systems) for the medical and public health system. It also quantifies the current resource levels of these capabilities, lists potential non-material solutions to increase operational capacity, and projects current operational capacity based on potential constraining parameters (i.e., operational quantity).

This information allows senior leaders to consider national capabilities and better determine product-specific requirements, including the desired characteristics of each MCM class and how many MCMs should be stockpiled. This capabilities-based MCM planning delivers cost savings for certain MCM classes, makes assets available to acquire other critical MCMs, and improves confidence that stockpiled MCMs will be available for their intended use during a public health response.

Senator Claire McCaskill

1) **We had a hearing on Ebola in 2014, and I want to clear up a number of apparent discrepancies between the information my staff had received on medical countermeasures in the strategic national stockpile in response to a document request I made in November 2013 and information provided by Dr. Lurie in response to some questions for the record (QFR) that I submitted after that hearing.**

   In a document request letter that I sent to the Department of Homeland Security (DHS) in November 2013, I requested a list of all Chemical, Biological, Radiological and Nuclear-related (CBRN) countermeasures procured for the strategic national stockpile between fiscal years 2004 and 2013. The information I received back from HHS had procurements for seven CBRN-related threats: radiation and nuclear exposure, anthrax, drug-resistant anthrax, botulism, smallpox, and nerve agents. Dr. Lurie's response to my QFRs indicates that HHS also holds countermeasures in the stockpile for cyanide, tularemia, plague, and typhus, and notes that acquisitions are planned to address exposure to glanders and research and development is ongoing for viral hemorrhagic fevers like Ebola.

   Please update the attached spreadsheet to reflect the additional procurements.

The updated spreadsheet is attached:

BARDA Response 2
to QFRs to Hatchett f

The spreadsheet includes Project BioShield procurements using the Special Reserve Fund and does not include CDC procurements. Based on the Strategic National Stockpile (SNS) Annual Review Process and recommendations by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the additional assets referenced by the Assistant Secretary for Preparedness and Response (ASPR) were acquired directly by the Centers for Disease Control and Prevention (CDC). The most recent inventory of SNS assets is available in the SNS Annual Review Report which was delivered to Congress in September 2015. The Department of Health and Human Services (HHS) is currently developing the 2015 SNS Annual Review Report FY 2018 Plan) which is anticipated by fall of 2016.

2) **When did the acquisition process begin for glanders, and where are you in that process?**

Product acquisition for glanders was initiated by the 2013 SNS Review process. As a result, the PHEMCE decided to procure meropenem IV for treatment, trimethoprim-sulfamethoxazole tablets for the longer term eradication phase, and a larger amount of trimethoprim-sulfamethoxazole tablets for post-exposure prophylaxis.

CDC is planning to procure meropenem and co-trimoxazole stockpiles for the treatment and post-exposure prophylaxis of glanders and melioidosis. Procurements that began in FY 2016 will be phased in through FY 2018.

3) **The information my staff received from HHS on countermeasure procurements listed 18 procurements that totaled over $3.3 billion. Yet in response to a question about the amount HHS was spending on medical countermeasures, Dr. Lurie stated that only 12 countermeasures had been procured under Project BioShield, plus an additional two procurements for so-called risk-mitigation products. Please explain the discrepancy between Dr. Lurie's statement and the 18 listed procurements on the attached spreadsheet?**

Procurements are broken out by contract. Notably, the VaxGen recombinant protective antigen anthrax vaccine procurement was terminated in December 2006 when VaxGen failed to meet a critical contractual milestone without delivering any doses to the SNS. In addition, because they represent different contracts, Cangene Anthrax Immune Globulin procurements of Raxibacumab (2005 and 2013) have been counted twice as separate procurements. Please note that Raxibacumab was initially a Human Genome Sciences contract in 2005, but was procured under a new contract with GlaxoSmithKline in 2013. As a risk mitigation strategy, HHS also procured the cell lines required to manufacture two other anthrax antitoxins (i.e., Valortim and AVP21D9) but has not procured these products. Finally, Emergent's BioThrax Anthrax vaccine has been procured twice under separate contracts (2005 and 2007).

4) **Dr. Lurie's QFR response also noted that generic antibiotics have been purchased for the Strategic National Stockpile to fulfil requirements for countermeasures against exposure to tularemia and plague. But those purchases weren't included in the information my staff received either. Did HHS negotiate lower prices for these generic antibiotics since they were bought in such high quantities?**

Please see the responses from Dr. Stephen Redd, who testified on behalf of CDC and is responding to this question on behalf of HHS agencies.

5) **Can you add those purchases to the enclosed spreadsheet?**

The attached spreadsheet only includes Project BioShield procurements using the Special Reserve Fund and does not include CDC procurements. However, the Pandemic and all-Hazards Preparedness Reauthorization Act of 2013 requires HHS to develop a five-year budget plan for the medical countermeasure enterprise, including CDC procurements and those made under the Special Reserve Fund. This multiyear plan is provided to the House and Senate Appropriations Committees each year and is used for strategic project coordination, product transitions between agencies, communication of priorities and resources to partner stakeholders, and assistance with long-term forecasting. The goal of the multiyear plan is to outline PHEMCE programmatic estimates on a five-year rolling basis and to identify the hand-offs in the development cycle in anticipatable budget terms. The current report covers PHEMCE spending estimates for FY 2015 through FY 2019.

6) In the same response, Dr. Lurie noted that DHS has issued 13 Material Threat Determinations (MTDs) that are currently active. Yet the chart he provided shows 15 active MTDs. Can you explain this discrepancy?

The chart depicted in Dr. Lurie's November 19, 2014 questions for the record lists each material threat assessment (MTA) individually. Four MTAs were combined into two Material Threat Determinations (MTD). Specifically, volatile and low volatile nerve agents have independent MTAs and both were included in a single MTD issued in September 2011. Additionally, radiological materials and nuclear detonations have independent MTAs but are included as a single MTD issued in September 2004.

7) I understand that we get non-exclusive licensing rights for patentable inventions that result from the development of medical countermeasures supported by the U.S. Government. Can you explain what this means, exactly?

Under the Bayh-Dole Act (or Patent and Trademark Law Amendments Act) and its implementation, small businesses and nonprofit organizations that retain titles to inventions made and put into practice with federal support must grant the United States Government (USG) a nonexclusive, nontransferable, and irrevocable license. In other words, when the USG awards a grant, contract, or cooperative agreement to a small business or nonprofit organization for research and development of a MCM, the USG may use or license the invention to carry out USG purposes without paying a royalty to the small business or nonprofit organization.

8) What is the federal government's threshold investment for obtaining licensing rights for a product that we've invested taxpayer dollars in?

The licensing rights are determined in accordance with the Bayh-Dole Act and its implementation, which make no reference to a threshold investment.

9) Have we retained licensing rights for any of the medical countermeasures in the strategic national stockpile, and, if so, which ones?

The USG would retain a government use license for any invention initiated through federal investment, including products purchased for the SNS. Products purchased for the SNS might also be covered by privately owned inventions in which the government would have no rights.

10) Have we used these rights and sold the license for any of these, and if so, how much have we made by licensing them? If not, why not?

The Bayh-Dole Act government use license is a nontransferable license that cannot be sold or licensed to commercial parties to develop the invention. On the other hand, government-owned inventions are commonly licensed to commercial parties for commercialization under royalty bearing licenses by the agencies that developed the inventions.

11) The strategic national stockpile has a large, but not unlimited, budget to purchase countermeasures in case of an attack or an outbreak of some kind. Yet we've spent $1.4 billion on anthrax countermeasures alone. Two of the investments were for anthrax antitoxins that cost $3,100 and $8,200 per dose. We also bought 10 million doses of Biothrax, an anthrax vaccine with a four-year shelf life, in 2005, and then we bought another 18.75 million doses two years later, which is two years before the shelf life of the first round of procurements. Can you explain the reasoning for the second round of purchasing?

Anthrax is one of the more significant bioterrorism threats relative to other potential pathogens. Preparing for and responding to anthrax is a complicated process, which requires an array of medical products to:

1. Provide post-exposure antibiotic prophylaxis to individuals who may not be symptomatic, but have a likelihood of having been exposed. This ranges in the millions of possible doses for a 60-day course of treatment.
2. Provide vaccine for long-term protection to individuals who will be exposed to potentially contaminated environments and to augment protective coverage from antibiotics.
3. Provide antibiotics for treatment of actual anthrax disease.
4. Provide antitoxins for the treatment of anthrax toxemia (lethal toxin), a highly specific aspect of anthrax infection that is not addressed by administration of antibiotics.
5. Provide potential ventilatory support for patient management.

With that in mind and considering limited funding, the PHEMCE developed a strategy to target potential products based on greatest necessity. The idea was that once the nation's ability to counter anthrax improved, the PHEMCE would then address other areas of preparedness.

ASPR's Biomedical Advanced Research and Development Authority (BARDA) and the PHEMCE have made significant progress in preparing for the threat of an anthrax attack/release. BARDA has invested approximately $1.4 billion on anthrax antitoxins and anthrax vaccines. Current requirements for anthrax antitoxin include 288,000 treatment courses for anthrax and 526,000 treatment courses for multi-drug resistant anthrax. The current requirement for anthrax is enough vaccine to protect 25 million individuals. Considering that the current licensed regimen requires three doses, this equates to 75 million doses of anthrax vaccine.

12) I understand that there are planned reductions in holdings of a number of products in the strategic national stockpile in order to meet projected budget appropriations and medical countermeasure preparedness will be affected for a more high-priority threats if current budgetary constraints continue. How are your funding priorities established, and how much is the anthrax investment crowding out other needed countermeasures?

Annual review of the SNS (known as the SNS formulary) is mandated by Homeland Security Presidential Directive-21, Public Health and Medical Preparedness and Section 319F-2(a) of the Public Health Service Act. Through this review, the PHEMCE examines all SNS content, identifies and prioritizes formulary gaps, and recommends corrective actions to close those gaps.

The ultimate goal is to minimize the public health impact of events caused by high priority threats through the effective delivery of MCMs.

Recommendations are based on stockpiling goals established by the PHEMCE. The PHEMCE also considers various formulary options and recommends stockpile reductions in areas with minimal impact as possible impact on national MCM preparedness. In recent years, the amount of anthrax vaccine in the SNS has been reduced to allow for other critical acquisitions against anthrax and other high priority threats.

13) I asked Dr. Lurie about how anthrax ended up in the strategic national stockpile because my staff received documents showing that this was not originally a priority for the strategic national stockpile, and in response, she stated that "It is a therapeutic that potentially could be effective against an antibiotic resistant anthrax infection and when present antibiotic therapy is not working." This answer sounds very theoretical to me. It "potentially could" be effective in the very specific situation where we have an antibiotic resistant anthrax infection AND when present antibiotic therapy isn't working.

During the 2001 anthrax attacks, five of the 11 individuals who contracted inhalational anthrax died, even when treated with antibiotics. Antibiotics are only considered effective if initiated early in the course of disease. Anthrax antitoxins offer an improved treatment option to decrease overall mortality. If a drug resistant form of anthrax were used in an attack, the antibiotics would not be effective. However, the antitoxins, which were not available in 2001, would remain applicable. As mentioned previously, the PHEMCE strategy is to have antibiotics, antitoxins, and vaccines available to mitigate the negative health impacts of exposure or potential anthrax exposure.

Do we know how or if anthrax works, and, if not, what is the reasoning behind using our limited funding on it for the strategic national stockpile when several other priorities have yet to be funded?

The U.S. Food and Drug Administration (FDA) has licensed/approved three anthrax antitoxin products (two monoclonal antibodies and one polyclonal serum) that have demonstrated efficacy under the FDA animal rule, both when administered alone and when administered with antibiotics. When the antitoxins were evaluated in conjunction with an antibiotic in the animal models, they provided additional survival benefits compared to animals who received only antibiotics.

The mechanism of action of the antitoxins is well understood. Inhalation anthrax is an infectious and highly lethal disease that occurs when an infectious dose of *Bacillus anthracis* reaches sites deep within the lung, the spores germinate, and the bacteria begin to multiply. Once in the blood stream, the bacilli release two toxins (lethal toxin and edema toxin), which allow the bacteria to evade the immune system, proliferate, and ultimately kill the infected host. Antibiotics are known to be highly effective if administered very early after exposure, but are often ineffective once anthrax disease has become clinically detectable. Anthrax antitoxins can be used to treat symptomatic anthrax disease. The antitoxins bind to a component of the toxins known as the

protective antigen, neutralizing the toxins and thereby preventing massive tissue injury and death.

14) Has there even been a Material Threat Assessment issued specifically for antibiotic resistant anthrax?

A specific MTA for multidrug resistant anthrax does not exist. The multidrug resistant anthrax planning scenario and consequence modeling are a result of the broader April 2005 anthrax MTA.

15) Imvamune hasn't been approved by the FDA, and Phase III trials aren't supposed to start until 2017. Yet we started adding it to the stockpile way back in 2007. The World Health Organization's Scientific Advisory Group of Experts noted in 2014 that Imvamune is not recommended for emergency use until more information is available regarding its efficacy and safety. In fact, one paper in the scientific journal Biosecurity and Bioterrorism stated unequivocally, "There is no apparent programmatic use for the vaccine at this time." What is the rationale for stockpiling something that the World Health Organization says should not be stockpiled?

As you may know, ASPR was authorized by the Pandemic and All-Hazards Preparedness Act in December 2006. Within that authorizing language, ASPR was instructed to develop MCMs for the entire population, including at-risk populations. Imvamune was stockpiled in 2007 after the FDA determined that sufficient safety, efficacy, and manufacturing data existed to potentially use the vaccine under an Emergency Use Authorization (EUA) for individuals at risk for a serious adverse reaction to the licensed smallpox vaccine, ACAM2000, in the event that a public health emergency is declared. In particular, this pre-EUA includes individuals of all age groups with HIV and atopic dermatitis.

In June 2007, BARDA awarded a contract to Bavarian Nordic to manufacture Imvamune, a Modified Vaccinia Ankara (MVA) smallpox vaccine. The Imvamune vaccine was first delivered to the SNS in 2010 and was developed to augment, not replace, ACAM2000. Bavarian Nordic initiated its pivotal, Phase III safety and immunogenicity study in March 2015, which is designed to show non-inferiority to ACAM2000.

The World Health Organization's (WHO) Scientific Advisory Group provided recommendations, but the WHO actually requested that a portion of the smallpox vaccine stockpile include Imvamune.

Senator Rob Portman

1) **In your testimony you mention the coordinating bodies at work during crises—specifically the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and the Disaster Leadership Group (DLG)—whose role it is to coordinate and collaborate with a broad range of stakeholders and agencies during emergencies. While you mention the PHEMCE initiated an early response to Ebola, I think many of us also remember the many systematic problems that led to an uncoordinated and slow response to Ebola.**

   Based on your role as Acting BARDA Director and Acting Deputy Assistant Secretary at ASPR and the involvement in the Ebola response, what were the major lessons learned for your agency? How have you worked to address any lack of coordination and improve on the agency's response for the future?

In June 2016, the Department of Health and Human Services (HHS) released a formal report titled *Report of the Independent Panel on the U.S. Department of Health and Human Services Ebola Response*. Within the report, an independent panel identified lessons learned and developed recommendations to improve HHS and United States Government (USG) leadership and coordination for future public health threats. The report can be found at: http://www.phe.gov/Preparedness/responders/ebola/EbolaResponseReport/Pages/default.aspx.

In response to the independent panel's report, HHS released the *U.S. Department of Health and Human Services Ebola Response Improvement Plan* in June 2016, which describes the steps the Department will take to address the recommendations of the independent panel. The report is available on ASPR's website at: http://www.phe.gov/Preparedness/responders/ebola/Documents/EbolaIP.pdf.

2) **While I understand Zika is different from the Ebola epidemic we faced in 2014, I think we would benefit from applying lessons learned during the rapid spread of Ebola in 2014. In 2014, Congress appropriated $5.4 billion in emergency funding to combat Ebola, specifically by providing funding to the FDA and the Biomedical Advanced Research Development Authority to support the development of rapid diagnostics and treatments. I think Zika provides us with an opportunity to test these new mechanisms and utilize this new infrastructure to address Zika more rapidly than Ebola.**

   GAO has previously recommended that since the mission responsibilities and resources for biosurveillance are dispersed across a number of federal agencies, efforts to develop a biosurveillance system could benefit from focused leadership for the interagency community. The Blue Ribbon Study Panel on Biodefense Report also highlighted that U.S. biodefense programs lack of clear governance structure and leadership.

   What is your agency doing to address these recommendations? How did the lack of focused leadership impact the initial Ebola response? What improvements can be made as we approach the U.S. response to Zika?

As the principal advisor to the Secretary on matters relating to federal public health and medical preparedness in response to public health emergencies, ASPR is consistently working on ways to improve biodefense coordination through structures such as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and the Disaster Leadership Group (DLG). Through the PHEMCE ASPR leads engagement with key leadership across HHS, as well as its interagency partners, to share information and coordinate preparedness and response activities. Likewise, ASPR leads the DLG, which is a medium for senior leaders from across the Department to discuss and combine resources that produce MCMs for identified and suspected bio threats. Both the DLG and PHEMCE are working effectively to coordinate efforts across the Department and interagency.

With that in mind, ASPR does not manage biosurveillance programs. However, ASPR is a consumer of biosurveillance information which helps to direct PHEMCE priorities.

Dr. Stephen Redd
Centers for Disease Control and Prevention
Responses to Questions for the Record
Senate Homeland Security and Government Affairs Committee
"Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

Senator Kelly Ayotte:

1. On April 13, the Centers for Disease Control and Prevention announced that there is now definitive evidence that the Zika virus causes microcephaly and other serious brain defects in infants. The CDC also estimated that up to 30 percent of women in infested areas may eventually contract Zika. Our neighbors in Puerto Rico have already been severely impacted by the virus. There have been travel-associated cases of Zika in my home state of New Hampshire.

a. How is the CDC coordinating with other relevant federal agencies, as well as state departments of health and health departments in Puerto Rico, the U.S. Virgin Islands, and American Samoa in the fight against Zika?

CDC's State Coordination Task Force, one of several CDC Zika response incident management teams, works very closely with state and territorial public health departments, including those in Puerto Rico, U.S. Virgin Islands, and American Samoa. CDC deployed senior epidemiologists and other subject matter experts to these territories to help manage the local response. In addition, the State Coordination Task Force established desks with dedicated staff who are in daily contact with CDC and local health department staff to provide technical assistance and to coordinate responses to requests for information and resources. CDC also works closely with the territories to help them develop Zika response plans and funded a $6.5 million contract to provide dedicated Zika response staff to the Puerto Rico Department of Health and other territories to ensure continuity of response operations. This is in addition to other awards CDC has made to Puerto Rico to support vector control efforts and other preparedness and response activities.

Many of the CDC Zika response activities currently underway support state, local, tribal, and territorial health department response activities. Examples of these activities include:

- Improving laboratory testing surge capacity
- Deploying CDC staff to affected areas
- Providing vector control guidance and services
- Conducting maternal health surveillance and outreach, including implementation of a U.S. pregnancy registry
- Providing risk communications materials
- Developing Zika prevention recommendations
- Assembling and delivering Zika Prevention Kits to Puerto Rico

CDC planning guidance for states, territories, and localities include:

- Guidance on a risk-based plan that includes actions to be considered upon laboratory confirmation of the first locally acquired case of Zika virus infection in their jurisdiction and a support tool for them to consider a phased response to Zika virus.
- Guidance for vector control that accompanies the phased risk-based plan.
- Resources for risk communication.

On April 1, 2016 CDC hosted a Zika Action Plan (ZAP) Summit to:

- Provide senior state and local officials with information and tools needed to improve Zika preparedness and response within their jurisdictions.
- Increase knowledge on the latest Zika science, including implications for pregnant women.
- Increase knowledge of crisis and risk communication principles.
- Accelerate readiness for local response to Zika transmission through training and technical assistance to help jurisdictions establish surveillance and identify best practices for vector control.

During the ZAP Summit, CDC obtained feedback from participants on challenges and issues that required follow-up. Based on that feedback, CDC initiated a series of teleconferences in 2016 to provide updates on key areas of interest. They include:

- Communications: May 6
- Pregnancy and Birth Defects: May 11
- Vector Surveillance/Control: May 17
- Sexual Transmission/Pregnancy Planning: June 2
- Epidemiology: June 8
- Diagnostics/Laboratory Capacity/Testing Interpretation: June 13

CDC announced availability of funds to accelerate state and local Zika response planning.

- Public Health Preparedness and Response (PHPR) Cooperative Agreement for All-Hazards Public Health Emergencies ($25 million):
  - 41 state, 4 locality, and 8 territorial applicants. Eligibility is based on the geographic locations of the two mosquitoes known to transmit the Zika virus (*Aedes aegypti* and *Aedes albopictus*).
  - Supports building specific capabilities such as to respond to Zika virus disease, to reduce the spread of Zika associated with *A. aegypti* and *A. albopictus* mosquitoes, and to minimize maternal-fetal transmission of Zika virus.
- Epidemiology and Laboratory Capacity for Infectious Diseases funding:
  - As of May 13, 2016, Zika epidemiology and laboratory testing ($39 million) and Zika vector control and surveillance ($15 million).
- U.S. Zika Pregnancy Registry:
  - As of May 13, 2016, total funding amount of approximately $8.5 million.

Examples of how CDC is coordinating with other federal agencies are noted in responses to sub-questions (b) and (c) below.

b. Has there been a formal plan developed that is comprehensive in nature and that focuses on interagency coordination at the state and federal levels, prevention, and response?

Yes. CDC actively participated in the development of an HHS Zika response plan (United States Department of Health and Human Services Zika Virus Disease Preparedness and Response Plan for Areas at Risk for Local Zika Virus Transmission and High-Volume of Travel Associated Cases), and response plans for Puerto Rico and other affected territories.

CDC also provided guidance for states and localities to develop plans that includes a phased response comprising four categories of risk:

1. preparation (vector present or possible in jurisdiction)
2. mosquito season (*A. aegypti* or *A. albopictus* mosquito-biting activity)
3. confirmed local transmission (single case, or cases clustered in a single household/community in a county or jurisdiction)
4. widespread local transmission (multiple locations within a county/jurisdiction).

Each risk category includes recommended response activities in the following targeted areas: response action, communication, surveillance, laboratory testing, vector control, outreach to pregnant women, and blood safety.

CDC also provided guidance to state, tribal, local and territorial jurisdictions to conduct response exercises. CDC recommends that all 50 states, Puerto Rico, the U.S. Virgin Islands, and U.S. Affiliated Pacific Islands exercise portions of their Zika Action Plans as the ongoing outbreak necessitates.

c. **If so, could you provide details that demonstrate how these agencies are working together?**

CDC is collaborating with multiple agencies on the Zika response. These activities include:

- Vector control:
  - Environmental Protection Agency (EPA) provided a public health emergency exemption for In2Care mosquito traps, which include an insecticide that attracts mosquitoes that transmit Zika virus and LifeNet bed nets. Three other emergency exemptions were also issued to CDC for other products to prevent mosquito bites (pretreated curtains, pretreated bed nets, and a dissolvable tablet product for treating other articles during community events).
  - Department of Transportation (DOT) and the EPA are collaborating on disinsection recommendations for aircraft.
  - Department of Defense (DoD) on providing training to mosquito control application teams.
  - Navy Entomology Center of Excellence to identify novel mosquito products and application technologies which could be utilized to control Zika outbreaks.
  - DoD to assess the presence of the mosquito vector in the Republic of the Marshall Islands (RMI) and the ability of RMI to control the vector.
- Blood safety:
  - CDC has been working closely with state, local, and territorial health departments, the U.S. Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), public health partners such as the Council of State and Territorial Epidemiologists, and blood collection organizations to ensure a safe and sustainable U.S. blood supply. These efforts include providing guidance on implementing FDA recommendations for donor deferral, donor screening, and product management to reduce the risk of transfusion-transmission of Zika virus.
- Research:
  - National Institutes of Health (NIH) to facilitate the transfer of research efforts into products and services that will effectively combat Zika.
- Puerto Rico collaboration:

    - CDC linked the Puerto Rico Housing Authority (part of the U.S. Department of Housing and Urban Development) to partners, including Home Depot, to explore methods and strategies to mosquito-proof homes.
- Diagnostics:
    - BARDA to expand laboratory diagnostics manufacturing in the short-term and encourage commercial production of the immunoglobulin (IgM) assay in the long-term.

2. About a month ago, Senator Burr and I wrote to FDA to urge the agency use its authority to place Zika virus on the FDA's Priority Review Voucher program list of qualifying Neglected Tropical Diseases. Such a designation would help accelerate much needed research on Zika and even potentially lead to a Zika vaccine or treatment by leveraging private investment. In 2014, I cosponsored a bill that was signed into law which placed Ebola on the same priority review list.

In their response to our letter, the FDA noted that it did not believe the Zika virus met the criteria for the Priority Review Voucher program because there "appears to be a significant market for Zika virus medical products in developed nations" thereby making Zika ineligible for the program. I was disappointed in this response.

a. Do you disagree with the FDA's finding that Zika would not be a good candidate for its Priority Review Voucher program?

The Adding Zika Virus to the FDA Priority Review Voucher Program Act, Pub. L. No. 114-146 (Apr. 19, 2016), adds the Zika Virus to the list of tropical diseases included under the FDA Priority Review Voucher Program.

b. Can you put into context the threat that Zika poses versus our current ability to mitigate the spread of the virus?

Zika virus is transmitted primarily through the bite of an infected *Aedes* species mosquito (*A. aegypti* and *A. albopictus*). These are the same mosquitoes that spread dengue and chikungunya viruses. Forty-one states have the type of mosquitoes that can become infected with and spread Zika virus.

Predicting the degree of any local transmission is difficult as many different ecological, environmental, and human factors influence the likelihood of any transmission. Some of these factors include the time of year, weather patterns, population density, type of housing, penetrance of air conditioning or screens, presence of vector breeding sites, and human behavior. These factors influence the number of mosquito vectors around an infected person and the likelihood of the vector biting another person. Experience with local transmission of dengue and chikungunya, other *Aedes*-transmitted viruses, in the continental United States in recent years might be predictive; in all cases, when local transmission occurred, it was of limited duration and affected few people. While dengue and chikungunya diseases provide a predictive model, and suggest that any outbreaks in the U.S. mainland are likely to be relatively small and localized, we cannot predict the extent of any local transmission of Zika virus with complete confidence due to the variety of factors that can influence transmission.

CDC continues to work at the highest level of response along with state, local, and territorial health officials to understand the risks Zika virus poses to people and quickly share what we learn. The agency collaborates with public health partners and with state health departments to alert healthcare providers

and the public about Zika, to provide state health laboratories with diagnostic tests, to publish guidelines for testing of people with suspected Zika, and to publish guidance documents for response planning.

c. Shouldn't that be a key component when considering ways to expedite the ability to produce a safe and effective vaccine or an improved diagnostic test?

Yes, since the beginning of the Zika response, CDC received Emergency Use Authorizations (EUAs) from FDA for two new diagnostic tests for Zika virus. The CDC Zika IgM Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) detects antibodies that the body makes to fight a Zika virus infection. The test is used on blood samples from people with a history of symptoms associated with Zika and/or people who have recently traveled to an area during a time of active Zika transmission. The Trioplex Real-time (RT)-PCR Assay allows doctors to tell if an individual is currently infected with chikungunya, dengue, or Zika using one test, instead of having to perform three separate tests. As of June 6, 2016, 38 laboratories (in 32 states including District of Columbia (DC), 3 DoD laboratories) have completed verification panels for the Zika MAC-ELISA test. Seventy-four laboratories including 15 DoD laboratories in 39 states and DC and Puerto Rico have completed verification panels for the Trioplex test. These diagnostic tools were developed by CDC and granted EUAs earlier this year.

CDC is building laboratory capacity and infrastructure to test for Zika virus and other infectious diseases across the U.S. by providing critical laboratory supplies, reagents, equipment, and training for diagnostic testing and surveillance activities in states and territories. CDC resources are supporting laboratory surge capacity, which will help meet state testing needs, especially in Puerto Rico. In addition, CDC continues to work on improving diagnostics for Zika.

In preparation for a possible increase in demand, additional CDC laboratories have been trained and equipped to accept specimens for Zika testing. CDC can respond to an increase in demand and expand capacity through training additional staff at CDC and within state and local health departments via the Laboratory Response Network (LRN). CDC also partners closely with the Association of Public Health Laboratories (APHL), which can assist with expansion of laboratory capacity. Availability of a commercial manufacturer of the diagnostic tools would also assist with capacity.

Senator Tammy Baldwin:

Dr. Redd, thank you for CDC's ongoing work to investigate and respond to the recent and concerning outbreak of Elizabethkingia anophelis in Wisconsin.

1. **How is CDC supporting the Wisconsin Department of Health Services' disease preparedness and response efforts and capabilities during this Elizabethkingia investigation?**

CDC provides support to Wisconsin through multiple funding awards to help support the state's response to infectious disease outbreaks. In Fiscal Year (FY) 2015, Wisconsin received $3,028,480 from CDC through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) cooperative agreement. This funding supports outbreak investigations through expanded epidemiology and laboratory capacity, including cross-cutting epidemiology and laboratory staff. CDC also provided Wisconsin $10,844,792 in FY 2016 through the Public Health Emergency Preparedness (PHEP) cooperative agreement. This program funds state, local, and territorial health departments to improve readiness to respond to public health emergencies.

Beyond funding, a CDC Epidemic Intelligence Officer assigned to and stationed in Wisconsin was integral to the initial *Elizabethkingia* investigation. A total of 19 CDC investigators were deployed to Wisconsin to provide onsite technical assistance to the Wisconsin Department of Public Health (WDPH) from February 14, 2016 (the date of the hearing) through April 17, 2016. More than 70 epidemiologists, laboratory staff, and leadership in CDC's Division of Healthcare Quality Promotion; Division of High-Consequence Pathogens and Pathology; and Division of Foodborne, Waterborne, and Environmental Diseases at CDC Headquarters in Atlanta are providing substantial support.

The joint CDC-WDPH investigation eventually identified 66 cases of primarily community-associated infections, all occurring in southeastern Wisconsin, northeastern Illinois, or western Michigan, with specimen collection dates from November 23, 2015 to May 30, 2016. CDC assisted in patient interviews and clinical data review to identify potential patient exposures, conducted point prevalence surveillance of patients and contacts, conducted environmental sampling, and provided laboratory testing and technical assistance for patient and environmental isolates. The patients have a variety of healthcare and community exposures and co-morbidities. Hypothesis generating interviews, structured interviews, and environmental sampling did not identify a food, water source, personal care product, healthcare product, or healthcare setting as a point source.

CDC recently deployed additional investigators to Wisconsin on July 18, 2016 in a further attempt to identify an organism source. CDC investigators will assist WDPH to identify common exposures through patient focus group interviews with small groups of patients with related isolates. CDC and WDPH will then apply the findings from the patient focus group interviews to identify prevention and control measures.

2. How is CDC assisting Wisconsin's public health laboratories in this investigation, including working to identify a source of the outbreak and the rapid testing of Elizabethkingia samples?

CDC work on the *Elizabethkinga* outbreak includes genetic and microbiological testing and analysis, determining growth characteristics, and creating specialized selection media for isolation. Informatics specialists, epidemiologists, and academic partners have tested samples for antibiotic resistance, performed genome sequencing, and conducted multiple analyses to shed light on the source of this outbreak. CDC is also developing new screening tools, such as an *Elizabethkingia* specific Real-time polymerase chain reaction (RT-PCR), which is now able to help screen samples.

CDC continues to work closely with investigators in Wisconsin and Illinois in the continuing investigation and in identifying the source of *Elizabethkingia anophelis* (*E. anophelis*) infections. Wisconsin and CDC distributed information to public health departments and clinical partners to ensure effective diagnosis, treatment, and surveillance of illnesses. CDC's laboratory continues to receive and analyze *Elizabethkingia* isolates from states across the country to help determine if they are *E. anophelis* species, and if they represent related or different clusters of cases. As of July 20, 2016, CDC has tested several hundred isolates related to the outbreak, including point prevalence surveillance swabs from case patients and contacts, suspected medical and personal care products, and environmental samples. This type of surveillance will continue as a critical component of the epidemiologic, environmental, and laboratory investigation to determine the source of infections.

3. **The Blue Ribbon Study Panel on biodefense emphasized the importance of implementing "One Health" principles in order to address the nation's biodefense needs. But the panel also recognized serious shortcomings, where agencies specialize in either human health or animal health, but where wildlife authorities are "rarely included at all." With the real and escalating risk associated with emerging diseases of wildlife origin, how does the CDC leverage the expertise of the USGS National Wildlife Health Center and academic partners such as University of Wisconsin-Madison to holster the effectiveness of the "One Health" approach to address emerging infectious disease concerns? What increases in capacity and resources at the National Wildlife Health Center are necessary to support CDC's goals under the "One Health" approach?**

CDC recognizes that the concept of One Health is important to a variety of public health issues, especially the emergence or re-emergence of naturally occurring infectious diseases and in combating antimicrobial resistance, including as part of the larger U.S. Government initiative on Combating Antibiotic Resistannt Bacteria.

The One Health concept recognizes that the health of humans is connected to the health of animals and the environment. Animals, including wildlife, share our susceptibility to some diseases and environmental hazards. Because of this, animals are not only potential vectors for human disease but can serve as early warning signs of potential human illness. For example, birds often die of West Nile virus before humans get sick with West Nile virus fever.

The USGS National Wildlife Health Center (NWHC), the only Federal high-containment biosafety level 3 facility focused on wildlife disease investigations, is therefore an essential One Health partner due to its expertise on wildlife issues. CDC and NWHC have partnered on various zoonotic research investigations (sylvatic plague, monkeypox, bat rabies, and West Nile virus). CDC is currently discussing a collaboration with the National Wildlife Health Center on a study regarding non-human reservoirs for Zika virus in vertebrate animals such as primates, reptiles, and birds. The National Wildlife Health Center's expertise in wildlife field work would be extremely valuable for the success of the study. The National Wildlife Health Center and the University of Wisconsin-Madison participate in the National Animal Health Laboratory Network (NAHLN), a network of laboratories focused on diseases of animals, such as avian influenza, which have the potential to harm humans. Diagnostic testing through laboratories in the NAHLN can provide vital information to CDC about potential reservoirs of zoonotic diseases throughout the United States. CDC defers to the National Wildlife Health Center to determine the capacity and resource increases that are necessary to monitor disease and assess the impact of disease on wildlife populations.

In addition, the USGS can provide a range of science for One Health beyond the aforementioned potential collaboration with CDC. USGS science activities work to understand the environmental transport and fate of chemicals used to control mosquitos and other disease vectors, the toxicity effects of these chemicals on non-target organisms such as pollinators, and the potential environmental exposure pathways of these chemicals to humans. The USGS also has capabilities to help understand potential environmental persistence of infectious disease agents shed from human and animal hosts, and the potential immunosuppressive effects of chemicals used for disease vector control.

Senator Thomas R. Carper:

1. **In its 2011 Report, the General Accounting Office reported that there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise and recommended that the Homeland Security Council consider establishing a focal point to oversee these efforts. The number one recommendation included in the Bipartisan Report of the Blue Ribbon Study Panel on Biodefense is to institutionalize biodefense in the Office of the Vice President of the United States to ensure that biodefense will be addressed by every Administration at the highest levels. The second recommendation is to establish a Biodefense Coordination Council at the White House, led by the Vice President.**

    a. **Do you support establishing one individual or entity to coordinate these efforts or think that the existing structure is sufficient?**
    b. **How else could we improve coordination across the government in biodefense activities?**

Please see HHS responses.

2. **In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:**

    c. **#8 – Prioritize and align investments in medical countermeasures among all federal stakeholders.**

CDC is part of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which defines and prioritizes requirements for public health emergency medical countermeasures. Created by HHS in 2006, PHEMCE is a coordinated interagency effort led by the ASPR and includes two HHS agencies in addition to CDC: FDA and NIH. PHEMCE also includes interagency partnerships with the DoD, Department of Homeland Security (DHS), Department of Veterans Affairs, and United States Department of Agriculture. PHEMCE coordinates the research, development, procurement, and preparation for the effective utilization of antiviral medical countermeasures among the civilian population.

    e. **#10 – Establish a national environmental decontamination and remediation capacity.**

This question applies largely to the Environmental Protection Agency (EPA). The response below is relevant to #10(c), regarding studies of those exposed to biologic agents.

The nation depends on emergency responders to preserve the public's safety and health when disasters strike. To successfully meet this challenge, emergency responders must be protected from the hazardous

conditions that disasters and other emergencies create, whether natural or manmade. A plan for monitoring emergency responder health and safety is an important part of protecting them.

CDC worked with the U.S. National Response Team (NRT) and a number of federal agencies, state health departments, labor unions and volunteer emergency responder groups to develop the Emergency Responder Health Monitoring and Surveillance (ERHMS) system. The ERHMS framework provides guidelines for protecting the health and safety of emergency responders before, during, and after deployments. This surveillance system was initiated in response to lessons learned from 9-11 and other emergency events, and information and actions recommended under the ERHMS framework can inform decisions regarding the need for long term monitoring of responders. CDC encourages organizations to adopt this system to help ensure the health and safety of responders before, during, and after a response. Additional information about this framework can be accessed at http://www.cdc.gov/niosh/topics/erhms/.

f. #11 – Implement an integrated national biosurveillance capability.

The Nation's biosurveillance capability is founded on public health surveillance systems developed and strengthened by state and local health departments with support from CDC. A range of surveillance systems contribute to the nation's capacity for early detection, rapid characterization, and effective response to public health threats.

CDC is implementing an overarching Surveillance Strategy comprised of the six components briefly described below. The goals of the Surveillance Strategy include improving standardization and commonality of platforms across CDC systems, reducing duplication, tackling workforce and informatics challenges at CDC and State and local public health systems, and reducing the burden of participation in surveillance for healthcare and public health. Implementation of the Surveillance Strategy will improve the agency's overall capabilities to work with other public and private health systems. The improvements will advance our data systems in a way that clinicians, state and local public health agencies, and CDC can more rapidly share information to take effective public health action to promote health security and reduce reporting burden by eliminating redundant reporting.

Several on-going initiatives support Surveillance Strategy implementation and integration. Each of these initiatives seeks to improve the quality and timeliness of surveillance data reporting to CDC while also reducing burden on, and providing additional value to, STLT health departments. Examples of on-going systems and initiatives included in CDC's overarching Surveillance Strategy include:

National Syndromic Surveillance Program: Promotes and advances a syndromic surveillance system for the timely exchange of data received through the BioSense platform primarily from emergency department visits in participating state and local jurisdictions. These data are used to improve nationwide situational awareness and to enhance responsiveness to hazardous events and disease outbreaks.

National Notifiable Diseases Surveillance System Modernization Initiative: This program is a nationwide collaboration enabling local, state, territorial, federal, and international public health agencies to share notifiable disease-related health information received from hospitals, healthcare

providers, and laboratories within participating jurisdictions. Public health uses this information to monitor, understand, control, and prevent the occurrence and spread of state-reportable and nationally notifiable infectious and noninfectious diseases, conditions , and outbreaks (e.g., measles, viral hemorrhagic fever, anthrax, Legionnaires Disease). Ongoing improvements will increase reporting standardization, timeliness, and data quality.

The Electronic Laboratory Reporting Initiative: This initiative is increasing the proportion of test results reported electronically to health departments and CDC by commercial clinical laboratories and public health laboratories. Building capacity to electronically receive reports of cases of notifiable conditions and track diseases with pandemic potential in real time will enable us to more rapidly share information and take effective public health action.

The Electronic Death Reporting Initiative: This initiative has been accelerating and enhancing the completeness of cause-of-death reporting nationwide, enabling near real-time mortality surveillance. The initiative currently funds 35 states to increase timeliness of transmission of mortality records to CDC. CDC plans to provide additional funding to states to work on timeliness and quality of the mortality records, with an emphasis on mortality records for drug-related causes of deaths. Since 2010 timely transmittal (within 10 days of death) of mortality records from states to CDC increased from 7% to 47%. Faster transmission enables CDC to transform the National Mortality System into a near, real-time public health surveillance system.

Workforce development: The CDC Surveillance Strategy includes development of a public health workforce training and support plan to improve surveillance systems and to address technological considerations practitioners face. Training and development will ensure a healthy informatics vision and governance, skilled workforce, and effective use of a well-designed system.

CDC Integrated Surveillance Platform: CDC is modernizing its systems by designing, developing, and adopting an initial set of services that will form the beginnings of a cloud and web based data collection information technology platform. When fully implemented, this platform would support public health surveillance data collection, analysis, and dissemination efforts across the agency and with public health partners. The Platform would enable public health programs to use surveillance data more quickly and efficiently.

i. #14 – Improve surveillance of and planning for animal and zoonotic outbreaks.

Although human and animal health agencies typically are in independent government departments, these agencies work collaboratively on public health issues involving the animal-human-ecosystem interface using an interdisciplinary One Health approach. Establishing and maintaining relationships between these agencies prior to outbreaks is essential to an effective response. To that end, animal health and human health programs within CDC, FDA, the United Stated Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS), USDA Food Safety and Inspection Service (FSIS), and DHS maintain liaisons embedded in each other's organizations to ensure ongoing and daily collaboration in surveillance, detection, and response. In addition, CDC, FDA and USDA have more formal institutional collaboration in certain areas. For example, the three agencies, together with state and local health departments, run the National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS), which tracks antibiotic resistance across food animals and human foodborne diseases.

Recent public health emergencies that involved One Health collaboration between CDC and USDA include a variety of foodborne outbreaks, human salmonellosis linked to backyard poultry flocks and other animals, and One Health response to Highly Pathogenic Avian Influenza H5 Outbreaks. Additionally, FDA and USDA worked very closely to investigate the initial outbreak of Porcine Endemic Diarrhea Virus in the U.S. These collaborative investigation teams allow for real-time sharing of human and animal health data to better identify the source of the outbreaks and reduce the risk of continued transmission and illness to both people and animals.

j. #15 – Provide emergency responders with the resources they need to keep themselves and their families safe.

CDC provides emergency responders with resources to keep themselves and their families safe through several programs.

- Anthrax vaccine
  - Anthrax vaccine from the Strategic National Stockpile (SNS) supports the DoD's vaccination program for active duty service members, as part of the joint stockpiling arrangement between DoD and CDC established in 2008. Through this interagency agreement, anthrax vaccine from SNS holdings is held in a reserved quantity for DoD requirements and delivered prior to expiration in order to meet the demand for anthrax vaccination of DoD personnel. DoD reimburses CDC for the vaccine received to fund replacement of the product delivered to DoD.
  - CDC and HHS support the DHS' development of an anthrax vaccination program pilot for first responders. CDC commits to providing vaccine from the SNS that is near its expiration date to support the pilot program and supports meeting the goals of implementing a safe and effective vaccination program without compromising other ongoing preparedness activities or reducing response capabilities through participation in the pilot.
- Disaster Science Responder Research (DSRR) Program
  - The goals of the DSRR are: 1) to identify critical topic areas needing further research to better protect emergency responders, and 2) to implement a framework that allows for responder research to be started quickly when a disaster or emergency occurs, without interfering with the response itself. The types of research conducted may include: the impact of a novel exposure, unexpected or severe health effects, the effectiveness of a proposed intervention, mental health/resilience issues, disease outcomes with latency periods, and take-home exposures. We believe the results of this research will lead to reduced health risks for responders, and to improvements in the effectiveness of emergency responses. Additional information can be found on our website: http://www.cdc.gov/niosh/topics/disasterscience/default.html
- National Personal Protective Technology Laboratory (NPPTL)
  - Established in 2001 with a primary focus on improving worker safety and health through better personal protective technologies.
  - Mission is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective equipment (PPE).

- One of the key goals of the NPPTL is to develop the scientific basis for PPE guidelines and requirements in advance of a biological event. Through audits and respirator certification, CDC improves the quality and inventory of respiratory protection for workers in multiple industries, including those involved in biological response. In FY 2015, CDC completed 364 certified respirator decisions, including 733 new approvals, and 173 complete respirator audits. CDC supported the use of PPE in the Ebola response by completing testing on PPE ensembles used in West Africa to provide additional heat stress mitigation guidance and improving the test methods used for assessing liquid and viral barrier performance of PPE.
- CDC also collaborated with the Occupational Safety and Health Administration (OSHA) to publish recommendations for hospital respiratory protection program managers.

- Fire Protection Research Foundation
  - Initiated in FY 2015, CDC is collaborating with the Fire Protection Research Foundation to establish cleaning procedures for firefighter PPE.
  - This research and development effort is being conducted to establish clear and definitive guidance for the fire services for applying cleaning and decontamination procedures that effectively remove both chemical and biological contaminants. Firefighter exposure to persistent harmful contaminants in PPE is an increasingly serious problem both on the fire ground to highly toxic substances including a variety of carcinogens, and more insidiously to an increasing range of infectious pathogens that are encountered in patient care and different emergency operations.
- Study to evaluate DHS' chemical, biological, radiological, and nuclear (CBRN) assessments to improve available medical countermeasures
  - Approved in FY 2016, CDC is evaluating the latest DHS hazard assessments to identify the most likely chemical and radiological agent threats that would be used in an intentional or unintentional large scale release or a natural disaster.
  - Assessment will include testing the filtration efficacy of currently fielded National Institute for Occupational Safety and Health (NIOSH) CBRN certified air purifying respiratory protective devices (APRs) against these chemical and radiological agents. It is vital to know whether the currently fielded NIOSH CBRN APRs can provide adequate respiratory protection against the most likely chemical and radiological agent threats to ensure the first responders are protected while performing mission-essential functions of Federal agencies including following a biological attack.

In addition, as discussed above in response to question #2(e) regarding recommendation #10, CDC worked with the U.S. National Response Team (NRT) and a number of federal agencies, state health departments, labor unions and volunteer emergency responder groups to develop the Emergency Responder Health Monitoring and Surveillance (ERHMS) system. The ERHMS framework provides guidelines for protecting the health and safety of emergency responders before, during, and after deployments.

l. #18 – Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.

CDC is the lead federal agency for developing infection control guidelines that U.S. health care facilities can use when implementing local protocols and procedures. Key related activities include:

- Healthcare Infection Control Practices Advisory Committee (HICPAC):
  - CDC maintains this federal advisory committee that includes experts from throughout the federal government and private sector, and representatives from professional societies, hospital associations, public health associations, healthcare accreditation organizations, and consumer groups.
  - HICPAC advises the agency on healthcare-related issues and infection control.
  - Advisory committee meetings and calls are open to the public; all draft recommendations of the advisory committee are posted in the Federal Register for public comments, which are summarized and discussed at public meetings. Once finalized, recommendations such as these sometimes are promulgated into regulations and oversight requirements by occupational safety and health regulatory authorities such as OSHA and the Centers for Medicare & Medicaid Services (CMS), as well as other non-governmental entities like The Joint Commission.
- Multidisciplinary group of CDC experts:
  - Convened during infectious disease public health emergencies, this group includes CDC experts in healthcare infection control and quality, occupational safety and health, clinical experts, and experts in particular pathogens (influenza virus, Ebola virus, Middle East Respiratory Syndrome Coronavirus) to review existing healthcare recommendations.
  - In situations where a new or emerging infection occurs and there is a lack of available data, CDC develops interim guidance based on the best information available (e.g., existing CDC guidance for similar diseases, current epidemiologic and laboratory information, peer-reviewed evidence, and expert opinion), including published literature and field experience. Interim guidance is specifically written to allow flexibility in implementation so that protocols and procedures can take facility-specific characteristics (like facility design or types of supplies available) into consideration across health care settings.
  - Draft guidance is shared with other federal health agencies as part of the formal governmental clearance, and input is incorporated before posting as interim guidance on CDC's website. During the process, CDC also gets input from clinical experts (e.g., Emory University and Nebraska Medical Center during the outbreak involving the Ebola virus).
  - CDC actively engages the healthcare, occupational safety, labor union and public health communities to disseminate the recommendations. Feedback from users about the interim guidance, along with emerging information, is used to refine recommendations in real-time throughout the emergency, with updates documented on the CDC website.

m. #22 – Develop and implement a Medical Countermeasure Response Framework.

CDC currently develops, distributes and updates guidance on medical countermeasure (MCM) planning requirements for state and local partners. In 2013, CDC released "Distributing and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness, Version 11."[1]

This guidance includes information and planning considerations on all aspects of the state and local functions necessary to request, receive, and utilize MCMs from SNS. It provides detailed information on the resources and capabilities required for all hazards preparedness, and recommends additional development of threat specific plans to address the challenges associated with differing threats to public health. For example, effective response to a large scale anthrax exposure requires different MCM dispensing mechanisms and timelines than those required during an influenza pandemic. CDC is working to develop additional threat specific operational and clinical guidance and information to support the development and improvement of these threat specific plans and capabilities at the state and local level. In addition, some medical countermeasures held in the SNS require specific guidance for clinical use in response to public health emergencies. CDC develops this guidance, based on current science and research data, and publishes it for use by planners and clinicians preparing to use medical countermeasures from the SNS.

The majority of SNS-held products are for use in an emergency in accordance with their FDA approved label instructions. Certain SNS-held products do not have FDA-approved indications for their intended use in a public health emergency, and for these products, CDC must use regulatory mechanisms such as Emergency Use Authorizations or Investigational New Drug protocols to provide appropriate frameworks for safe and effective use of these products in an emergency. CDC develops these mechanisms for each individual product, as required, in collaboration with FDA, based on current science and available research and other evidence. For certain MCM that are FDA-approved and being used for their intended indication but may have some deviations from the approved labeling, Emergency Use Instructions may be generated by CDC.

As they become available, clinical guidance documents are posted on the CDC website, and regulatory documents such as Emergency Use Instructions for SNS-held products are on the password protected CDC JOIN External Partners SharePoint site, to allow access by our state and local partners evaluating and expanding on their existing MCM response plans. As required information becomes available CDC

[1] This document is available to state and local planners through password protected resource and technical assistance websites maintained by CDC.

is prioritizing and developing additional guidance as needed for SNS-held products requiring additional guidance for clinical use.

n. **#23 – Allow for forward deployment of Strategic National Stockpile assets.**

CDC holds SNS products in centralized storage facilities across the country for rapid deployment through a tested network of transportation partners. Each state has plans to receive from CDC and distribute SNS medical countermeasures to local communities as quickly as possible. Under CDC's distribution and dispensing recommendations for oral post-exposure prophylaxis countermeasures for anthrax, CDC guidance to states emphasizes that a widespread release of aerosolized anthrax requires a jurisdiction to provide appropriate countermeasures to a community the first 48 hours following an anthrax incident to save lives. CDC currently is developing additional threat-specific operational and clinical guidance and information to support the development and improvement of state and local threat-specific plans and capabilities, and may consider recommending time-based guidelines for distributing and dispensing some of the other SNS medical countermeasures.

Product procured for the SNS is held in centralized storage under a rigorous quality control program utilizing security, environmental monitoring and routine inventory inspections to ensure that each countermeasure is in optimal condition and ready for rapid deployment. This level of quality control allows CDC to participate in the joint Food and Drug Administration and Department of Defense Shelf Life Extension Program to extend the useful life of SNS products. Extending the SNS quality control program and inventory management capacity to ensure the compliance and efficacy of product held in forward deployed storage locations creates additional costs for both CDC and participating jurisdictions. The existing SNS storage network and logistical infrastructure is optimized to leverage strategically located warehouses and tested, refined transportation capabilities and to meet delivery commitments to each jurisdiction. Expansion of this network to accommodate forward deployment must be carefully evaluated to determine whether any increased delivery speed for the requesting jurisdictions outweighs the increased costs of implementation and the opportunity cost of not being able to deploy that product to other jurisdictions in the region.

CDC reviews and evaluates requests from jurisdictions that request forward deployment of medical countermeasure resources from the SNS. Since the safety and stability of the product is one of the most critical factors to consider, removing product from SNS inventory for forward deployment into state and local custody requires extensive work by both parties. Jurisdictions requesting forward deployment must address and meet required standards for security, environmental control and accountability to ensure the availability and efficacy of the product in an emergency, including specific temperature control requirements for specific products. CDC must also evaluate whether the request for forward deployment of product to a jurisdiction reduces CDC's capability to use that product to respond to an event in another location.

o. **#24 – Harden pathogen and advanced biotechnology information from cyber-attacks.**

CDC promotes secure use of information and information technology and protects sensitive data by:

- Managing firewalls that protect CDC's network and systems.

- Scanning CDC's network and systems for vulnerabilities that can cause damage.
- Responding to incidents that have a negative impact on CDC's network and systems.
- Establishing policies and guidelines that promote a secure operating environment for CDC.
- Providing training that promotes security awareness for CDC staff.
- Approving software for safe use in the CDC work environment.

In addition, regulations issued by HHS and USDA under the Federal Select Agent Program (FSAP) (42 CFR 73.11; 9 CFR 121.11; 7 CFR 331.11), require the following security for IT systems to ensure that only those approved for access to biological select agents and toxins can gain access through the IT systems:

- Ensure that all external connections to systems which manage security for the select agent and toxin registered space are isolated or have controls that permit only authorized and authenticated users;
- Ensure that authorized and authenticated users are granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agents and toxins is suspended or revoked;
- Ensure that controls are in place that are designed to prevent malicious code (such as computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to select agent and toxin registered spaces;
- Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and
- Establish procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the select agent and toxin records maintenance requirements are rendered inoperable.

r. #28 – Fully prioritize, fund, and incentivize the medical countermeasure enterprise.

CDC is part of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which defines and prioritizes requirements for public health emergency medical countermeasures. PHEMCE, created by the Department of Health and Human Services (HHS) in 2006, is a coordinated interagency effort led by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes two HHS agencies in addition to CDC: FDA and the National Institutes of Health. PHEMCE also includes interagency partnerships with the Department of Defense, Department of Homeland Security, Department of Veterans Affairs, and the United States Department of Agriculture. PHEMCE coordinates the research, development, procurement, and preparation for the effective utilization of antiviral medical countermeasures among the civilian population. CDC collaborates with PHEMCE to prioritize and adjust the SNS formulary annually based on current threats and available funding.

PHEMCE standardizes the civilian medical countermeasure requirement development process to address the national ability to utilize medical countermeasures in a public health emergency effectively. The PHEMCE medical countermeasure requirement process leverages:

- Public health consequence modeling
- Subject matter expert evaluations
- Estimates of current national response capabilities

The medical countermeasure requirement process and subsequent stockpiling and procurement goals stem from sound scientific, medical, and epidemiological principles and result in a national stockpile of medical countermeasures CDC will deliver to state and local public health officials for use during a public health emergency. PHEMCE teams represented by intergovernmental agency experts conduct formulary reviews to develop or revise recommendations as to which specific medical countermeasures will fulfill stockpiling goals. PHEMCE and CDC use current clinical practice, market availability, and the best application of public funds to guide acquisition targets and decisions. CDC also uses PHEMCE recommendations to prepare the SNS Annual Review Report that informs HHS budget formulation for medical countermeasures held in the SNS.

v. #32 – Review and overhaul the Select Agent Program.

On October 29, 2015, the U.S. Government released two sets of recommendations, the Federal Experts Security Advisory Panel (http://www.phe.gov/s3/Documents/fesap.pdf) and the Fast Track Action Committee-Select Agent Regulations (http://www.phe.gov/s3/Documents/ftac-sar.pdtf). Recommendations from both groups support efforts to enhance the Federal Select Agent Program. HHS co-chaired both these groups and is working with the federal partners to improve biosafety and biosecurity practices based on these findings. The implementation plan (http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf) for these recommendations emphasizes culture of responsibility, strengthens oversight, promotes outreach and education, conducts applied biosafety research, develops an incident reporting system, enhances material accountability and inspection processes, and rulemaking to update current regulations and guidance.

The Federal Select Agent Program (the collaboration between CDC's Division of Select Agents and Toxins and APHIS' Agriculture Select Agent Services) underwent three reviews that were publicly released in October of 2015: (1) the CDC 90 Day Internal Review of the Division of Select Agents and Toxins, ordered by the CDC Director, (2) the Federal Experts Security Advisory Panel review, and (3) the Fast Track Action Committee review. The three review reports, each of which have been released to the public, include recommendations designed to strengthen the Federal Government's biosafety and security practices and oversight, through actions by the FESAP and more broadly by governmental and private entities. The FESAP is in the process of addressing the recommendations contained in these reports. An update on its progress towards implementation of these recommendations can be found at: http://www.cdc.gov/phpr/dsat/review_initiatives.htm. We believe CDC should continue to implement the recommendations from the three recent reviews, and further reviews should be deferred until after the current processes have run their courses.

3. The Blue Ribbon Study Panel, GAO and other experts have recommended the development of a national biodefense strategy. To date, federal agencies have produced several strategic documents that address different aspects of biodefense, including the National Health Security Strategy and the National Biosurveillance Strategy. Do you believe that existing strategy and policy documents provide sufficient coordination of biodefense activities across the federal government? What elements should be included in a unified national strategy for biodefense?

Please see HHS response.

4. The Blue Ribbon Study Panel recommended the development of a unified budget for biodefense spending, and estimated that roughly $6 billion is spent every year on biodefense and related hazards. Please detail how much your Department or Agency spent on biodefense efforts (categorized by Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery activities, as defined by Homeland Security Presidential Directive 10) from Fiscal Years 2007-2016.

CDC's Public Health Preparedness and Response activity works 24/7 to protect the safety, security, and health of the United States from public health threats, foreign and domestic, intentional and naturally occurring. CDC provides life-saving responses to chemical, biological, radiological, and nuclear threats, as well as other disasters, outbreaks, and epidemics. These activities are essential to CDC's goal to protect Americans' health and safety by:

- Supporting state and local health department preparedness activities
- Responding to public health emergencies
- Ensuring an available supply of medical countermeasures
- Overseeing and regulating laboratories that import and possess the most deadly pathogens and toxins
- Providing comprehensive situational awareness
- Working 24/7 to respond to calls from medical professionals and the general public
- Building international Emergency Operation Center capacity and enhancing global health security

The table below, based on CDC budget lines, shows historical funding levels for certain public health preparedness and response activities, as well as funding for biosurveillance, anthrax vaccine research, continuity of operations, and cyber security. Although the table captures funding for certain programs that contribute to biodefense, and funding for those programs make up a significant portion of CDC spending on biodefense, there is other work throughout the Agency that contributes to biodefense and which is not reflected in the table, such as the Electronic Laboratory Reporting Initiative and the Electronic Death Reporting Initiative.

Centers for Disease Control and Prevention
Preparedness and Response Aetivity Budget

(budget resources in millions of dollars)

	FY 07	FY 08	FY 09	FY 10	FY 11	FY 12	FY 13	FY 14	FY 15 Enacted	Emrgncy	FY 16 Enacted
CDC Preparedness and Response Capability*	157.54	147.52	163.36	131.29	126.35	117.54	111.42	133.8	133.8	---	138.8
BioSense	52.01	34.39	34.39	34.4	33.77	20.73	19.65	23.37	23.35		23.0
State and Local Preparedness**	766.66	746.04	746.60	760.99	664.29		623.21	661.04	661.05	---	668.2
Strategic National Stockpile***	496.35	551.51	570.31	595.66	591.00	533.79	477.58	549.34	534.35	---	575.00
Domestic Ebola Response	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	576.00	N/A
Total	1,472.56	1,479.46	1,514.66	1,522.34	1,415.41	1,329.48	1,231.86	1,367.55	1,352.55	576.00	1,405.00

*Includes Upgrading CDC Capacity, Botulinum Toxin Research, Quarantine, Real-Time Lab Reporting, and Anthrax Vaccine Research

** Includes Academic Centers and All Other State and Local Capacity Funding lines

***Funding in FY 2007 and FY 2008 for Strategic National Stockpile program include a comparability adjustment of -$7.4 million. In FY 2009 budget, CDC transferred the funds to support Business Services Support activities.

5. **Upon the release of the National Biosurveillance Strategy in July 2012, a strategic implementation plan for the strategy was slated for completion within 120 days. What is the status of the implementation plan?**

Please see HHS response.

Please describe how the Centers for Disease Control and Prevention coordinates biosurveillance programs and policy with other federal agencies, per the National Biosurveillance Strategy. If the implementation plan has been completed, please provide it to this Committee.

CDC coordinates across the agency and federal government in various ways, including sharing of information directly or through the National Biosurveillance Integration Center, collaborating on policy development coordinated through the Executive Branch (e.g., the Office of Science and Technology Policy's Homeland Biodefense Science and Technology Capability Review), collaborating on joint projects (e.g., Global Health Security Agenda implementation with DoD, State Department, and others), and working directly at the program level to optimize resources, especially with regard to capacity building at the domestic and foreign levels.

A precursor to the 2012 National Biosurveillance Strategy was CDC's National Biosurveillance Strategy for Human Health and accompanying Concept Plan for implementation. This document was used as an initial guide for CDC's internal and external biosurveillance coordination. After the release of the National Biosurveillance Strategy in 2012, CDC participated in the interagency effort to draft the accompanying implementation plan.

Senator Ron Johnson:

1. **What metrics has the CDC or its partners at HHS collected regarding the success of its public outreach in West Africa related to Ebola?**

CDC worked with the governments and other response partners in countries that were heavily affected by Ebola in West Africa to design and deliver evidence-based strategies for health promotion on Ebola prevention and control, and medical care. Examples of CDC-led activities include:

- Development of comprehensive messaging guides
- Design of low literacy communication materials
- Interactive radio programs such as "Ebola Big Idea of the Week"
- Training of journalists and health personnel on Ebola risk communication
- Hot spot site visits and joint outreach with surveillance teams
- Community-based ambulance exhibitions (to reduce fear of using ambulances)
- Technical guidance to local social mobilization partners including non-governmental organization (NGO) consortiums

CDC conducted or supported multiple national household surveys to assess changes in the public's knowledge, attitude, and practices (KAP) relating to Ebola prevention and medical care in the affected countries in West Africa. In addition, CDC conducted rapid qualitative assessments to generate a more in-depth understanding of cultural factors linked to Ebola transmission, and used the findings to tailor intervention strategies and advise the respective governments.

In Sierra Leone, CDC supported four national household KAP surveys with information collected from more than 10,000 cumulative respondents between August 2014 and July 2015. The results showed major improvements in the public's knowledge, attitudes, and practices related to Ebola:

- Knowledge that Ebola virus can be prevented by avoiding contact with bodily fluids increased from 87% to 94% between August 2014 and December 2014
- Knowledge that Ebola virus can be prevented by avoiding traditional burials that involve washing or touching of the corpse increased from 85% to 93% between August 2014 and July 2015
- Belief that spiritual healers can successfully treat Ebola virus decreased from 19% to 5% between August 2014 and July 2015
- Acceptance of safe burials increased from 65% to 79% between October 2014 and July 2015
- Intention to call the health facility when Ebola virus is suspected increased from 71% to 91% between August 2014 and July 2015
- Frequent handwashing increased from 66% to 87% between August 2014 and July 2015

Similarly, the Liberia KAP survey supported by CDC epidemiologists in December 2014 revealed high awareness and knowledge such that over 9 in 10 respondents knew that Ebola virus can be transmitted by washing or touching an infected corpse. The KAP survey supported by CDC in Guinea also found high knowledge of Ebola virus prevention (ranging from 73% to 83%) especially in the geographic areas where communication efforts were intensified. Additional analysis from Sierra Leone demonstrated that when people received Ebola information from multiple reinforcing sources they were more likely to have correct Ebola knowledge and able to adopt behaviors that prevent infection. CDC is now building upon these lessons learned from Ebola health promotion to strengthen the capacity of governments and partners in the affected West African countries to execute effective risk communication strategies to prevent Ebola virus and other emerging global health threats elsewhere.

2. What are the interim results regarding potential vaccines that will be effective against Ebola?

Currently, there is no FDA-approved vaccine available for Ebola virus. Experimental vaccines for Ebola virus are under development but they have not yet been fully tested for safety or effectiveness. Phase I and II/III trials are being conducted including in the U.S. and in several European and African countries. CDC, in partnership with the government of Sierra Leone, launched the Sierra Leone Trial to Introduce a Vaccine against Ebola (STRIVE) in April 2015. This trial is still underway. More than 8,000 individuals were vaccinated with the rVSV-ZEBOV vaccine through STRIVE, just one of three large rVSV-ZEBOV vaccine studies being conducted in West African Ebola-affected countries. WHO and NIH are leading the other two studies.

Because of effective control of the Ebola epidemic, cases declined dramatically during the trial. As a result, STRIVE will not be able to measure vaccine efficacy. However, STRIVE does have a sub-study in which blood samples from vaccinated participants are being tested to determine if participants' immune systems responded to the vaccine by making antibodies to protect against Ebola virus and how long these antibodies may last.

Senator Rob Portman:

As you know, in 2013 the President signed a reauthorization of the Pandemic and All-Hazards Preparedness Act. This reauthorization included funding for public health and medical preparedness program, such as the Hospital Preparedness Program. In FY 2014 over $255 million went out in grants to state and local health departments to assist the nation's healthcare system in preparing for public health emergencies.

Yet, it seems when hospitals were put to the test during the Ebola response, there were significant gaps in the ability of the hospital to adequately treat the patient and protect health care workers.

It is clear that we must do more to ensure every hospital is ready if a patient with Ebola or other highly infectious disease walks into their emergency room. More so, we must ensure that there are hospitals in regions throughout the country that are specifically designated to treat these type of patients.

[The response to this question is from HHS/ASPR, which administers the Hospital Preparedness Program]

a. **What was lacking from the Hospital Preparedness Program and other programs in PAHPA that led to hospitals not being adequately prepared for Ebola?**

Investments made through Hospital Preparedness Program (HPP) funding support preparedness efforts across the nation's health care system to better address new and emerging threats to public health when day-to-day capacities of health and emergency response systems are exceeded.

For much of its history, HPP funding has supported the purchase of critical resources needed to respond to disasters. Some resources are specific medical resources; others include communication systems, registry, patient tracking, information sharing, and credentialing systems that require sustainment. Without this funding, many states would be unable to properly respond and save lives without other federal support. Because of HPP investments, in recent years, there have been many demonstrations of communities that were able to respond with little to no federal support at the time of an event.

Regarding preparedness for Ebola, the Department of Health and Human Services (HHS), and HPP specifically, worked to enhance preparedness across the nation's health care infrastructure using existing tools and resources as well as newly appropriated funding. Utilizing emergency supplemental funding, HHS developed a regional approach to caring for future Ebola patients. Building upon the state and jurisdiction-based tiered hospital approach and meeting Congress' regional directive, HPP provided awardees with $194.5 million of Ebola supplemental funding to establish a nationwide, regional

treatment network for Ebola and other infectious diseases.[2] This approach balanced geographic need, differences in institutional capabilities, and the potential risk of needing to care for an Ebola patient. While preparedness for Ebola was the focus, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced. Furthermore, to prepare for and provide safe and successful care of patients with Ebola, HHS awarded an additional $12 million to establish a National Ebola Training and Education Center (NETEC). The NETEC will offer state health departments, regional Ebola and other special pathogen treatment centers, state and jurisdiction-based Ebola treatment centers, and assessment hospitals expertise, training, technical assistance peer review, monitoring, and recognition.

It is important to note that the supplemental funding for Ebola built upon more than a decade of HPP investments that bolstered health care system preparedness and response at hospitals and other health care providers across the nation. Beginning on April 15, 2014, and prior to the award of supplemental funding, HPP began issuing health care system guidance, checklists, and training documents, offered the flexibility and processes to use cooperative agreement funds to directly address Ebola, and convened national calls and webinars to provide updated information about Ebola to physicians, nurses, hospital executives, emergency medical service providers, and public health leaders, reaching hundreds of thousands of the nation's frontline health workforce.

b. How can we ensure that hospitals are prepared for future highly infectious diseases like Ebola or Zika in the future?

A few important lessons learned from the national health care system's response to Ebola include the need for sustained health care worker safety, from clinicians and laboratory workers to ancillary staff; recognizing that care of Ebola patients is clinically complex and demanding; and understanding that early case recognition is critical for preventing spread and improving outcomes. These lessons highlight the importance of sufficient and stable preparedness funding and the need for a national network of hospitals for treating highly pathogenic infectious diseases, such as Ebola.

HHS has taken several steps to ensure a strong and resilient national health care system. The funding provided through the HPP Ebola funding opportunity (financed from Ebola supplemental appropriations) is intended to ensure the nation's health care system is ready to safely and successfully identify, isolate, assess, transport, and treat patients with Ebola or persons under investigation for Ebola, and that it is well prepared for a future Ebola or Ebola-like outbreak. While the focus in the Ebola supplemental appropriation is on preparedness for Ebola, it is likely that preparedness for some other novel, highly pathogenic diseases will also be enhanced through these activities. Through the Ebola funding administered by HPP, the U.S. now has a network of 91 (as of August, 2016) Ebola treatment centers and 196 (as of August, 2016) assessment hospitals for their states or jurisdictions. The funding also supports health care coalitions (HCCs) to prepare frontline hospitals, emergency medical services, and the overall health care system. In addition, HPP funding established ten (as of June, 2016) regional Ebola and other special pathogen treatment centers, which can be ready within a few hours to receive a confirmed Ebola patient from their region, across the U.S., or medically evacuated from outside of the

[2]CDC, *Interim Guidance for U.S. Hospital Preparedness for Patients under Investigation (PUIs) or with Confirmed Ebola Virus Disease (EVD): A Framework for a Tiered Approach*, http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/hospitals.html.

U.S. (as necessary). These hospitals will also have enhanced capacity to care for highly infectious diseases.

Moreover, HPP has worked to foster infectious disease training and education throughout the country through a separate funding opportunity jointly established with the Centers for Disease Control and Prevention (CDC). The NETEC is comprised of staff from hospitals that have successfully evaluated and treated Ebola patients in the U.S. In collaboration with staff from CDC and ASPR, the NETEC offers expertise, education, training, technical assistance, peer review assessments, and recognition reporting to regional Ebola and other special pathogen treatment centers, state and jurisdiction-based Ebola treatment centers, and assessment hospitals.

CDC is conducting innovative research to identify new and improved ways to prevent the spread of infectious diseases like Ebola in healthcare facilities through investments in the Prevention Epicenters Program. The Prevention Epicenter program is a unique research platform through which CDC collaborates with academic investigators across 11 sites to conduct innovative infection control and prevention research, developing and testing innovative approaches to preventing infections and improving patient safety in healthcare settings. In 2015, CDC awarded a total of $11 million to six of these Prevention Epicenters to expand infectious disease research efforts. The goal is to help doctors and nurses better protect the health and safety of their patients, and each other, from high-risk disease threats through projects focused on:

- Preventing the spread of infectious agents in healthcare facilities, including Ebola virus
- Evaluating best approaches to using personal protective equipment
- Minimizing the role of the healthcare environment in infection transmission

HPP is also targeting preparedness for infectious diseases through its annual cooperative agreement program. In the continuation guidance for budget period five (July 2016 to June 2017), HPP awardees must:

- work to establish new partnerships with infection control or prevention programs in their jurisdictions that can advance the development of stronger health care system infection control and prevention programs;
- enhance partnerships to ensure cross-discipline information sharing among state, local, and territorial public health preparedness programs and HCC members, surveillance programs, communicable disease programs, and health care associated infection control programs; and
- evaluate state, HCC, and hospital needs for personal protective equipment and training resulting from lessons learned during the 2014 Ebola response.

Further, HPP awardees in jurisdictions located on the U.S.-Mexico border or the U.S.-Canada border must conduct activities that enhance border health, particularly regarding disease detection, identification, investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks (whether naturally occurring or due to bioterrorism). This focus on cross-border preparedness reinforces the U.S. public health and health system preparedness whole of

eommunity approach, which is essential for local to global threat risk management and response to actual events regardless of source or origin.

The care of patients with infectious diseases is a regular part of clinical care in every U.S. health care facility. However, the capacity of these resources is built primarily on daily and seasonal demand, not on the less frequent occurrence of highly pathogenic, frightening, or novel infectious diseases that, if not controlled, could affect large numbers of people. The recent U.S. Ebola experience highlighted that many hospitals were initially reluctant to accept a patient with Ebola and that unanticipated gaps in hospital preparedness existed. Accordingly, it is unclear if adequate capacity, capabilities, and geographic distribution of resources exist to manage serious infectious disease scenarios.

On July 1, 2016 the Office of the Assistant Secretary for Preparedness and Response awarded a contract to the MITRE Corporation and the RAND Corporation, through the Centers for Medicare and Medicaid Services' Alliance to Modernize Healthcare, to determine the feasibility of establishing a system for patient care and transportation requiring specialty capabilities, including the potential for biocontainment. This one year project will help determine whether additional steps are necessary to ensure that U.S. citizens with infectious diseases have access to safe and appropriate care. If deemed necessary, the project will develop a conceptual model and sustainability analysis for a system that bridges day-to-day and pandemic planning to help ensure that patients with emerging infectious diseases receive the care they need. Analysis will include evaluation of the financial incentives for hospitals to prepare for biological events, the need for a formalized stratified system/accreditation standards, and sustainable funding strategies.

Senator Clair McCaskill:

1. I asked Dr. Lurie about how Anthrax ended up in the strategic national stockpile because my staff received documents showing that this was not originally a priority for the strategic national stockpile, and in response, she stated that "It is a therapeutic that potentially could be effective against an antibiotic resistant anthrax infection and when present antibiotic therapy is not working." This answer sounds very theoretical to me. It "*potentially could*" be effective in the very specific situation where we have an antibiotic resistant anthrax infection AND when present antibiotic therapy isn't working.

Do we know how or if Anthrax work, and, if not, what is the reasoning behind using our limited funding on it for the strategic national stockpile when several other priorities have yet to be funded?

CDC collaborates with PHEMCE to prioritize and adjust the SNS formulary annually based on current threats and available funding. PHEMCE and CDC use current clinical practice, market availability, and the best application of public funds to guide acquisition targets and decisions.

Abthrax (raxibacumab) is an FDA-approved antitoxin for both treatment and post-exposure prophylaxis of inhalational anthrax when administered in combination with recommended antibacterial drugs. Raxibacumab increased survival in animal studies when administered by itself (44% of rabbits survived compared with no survivors in the control group, and 64% of nonhuman primates survived compared with no survivors in the control group) and in combination with antimicrobial drugs (82% of rabbits survived compared with 65% given levofloxacin alone). CDC guidance recommends that an antitoxin

should be added to combination antimicrobial drug treatment for any patient for whom there is a high level of clinical suspicion for systemic anthrax.[3]

BARDA purchased Abthrax currently in the stockpile. CDC will not purchase Abthrax for the SNS with appropriated funding until FY 2019, as outlined in the PHEMCE Multi Year Budget.

AVA (BioThrax) is FDA approved anthrax vaccine for pre-exposure prophylaxis of anthrax and post-exposure prophylaxis when administered in conjunction with recommended antibacterial drugs. The FDA approved indication for Post-exposure prophylaxis was based on the Animal Rule. The FDA approved indication for post-exposure prophylaxis (PEP) was granted under the Animal Rule Summary. The ability of BioThrax to increase the probability of survival after stopping post-exposure antibiotic treatment was assessed in rabbits. Rabbits treated with both antibiotics and BioThrax had a survival rate of 70% to 100%, depending on the vaccine dose administered. In contrast, in two studies of rabbits that received only antibiotic treatment, survival rates were 44% and 23% respectively. The U.S. Advisory Committee on Immunization Practices recommends 60 days of antimicrobial drug prophylaxis for immediate protection and a 3-dose series of BioThrax for long-term protection after exposure to anthrax. To ensure adequate and continued protection, everyone exposed to aerosolized *Bacillus anthracis* spores should receive a full 60 days of PEP antimicrobial drugs, whether they are unvaccinated, partially vaccinated, or fully vaccinated.[4, 5]

2. When did the acquisition process begin for glanders, and where are you in that process?

PHEMCE-approved procurements for antimicrobials for *Burkholderia mallei* (glanders) and *Burkholderia pseudomallei* (meliodosis) for post-exposure prophylaxis and treatment are slated to begin in FY 2016 and FY 2017. The procurements will be spread out over a number of years according to lifecycle management principles, so that all of the MCM will not expire at the same time.

3. Dr. Lurie's QFR response also noted that generic antibiotics have been purchased for the Strategic National Stockpile to fulfill requirements for countermeasures against exposure to tularemia and plague. But those purchases weren't included in the information my staff received either. Did HHS negotiate lower prices for these generic antibiotics since they were bought in such high quantities?

With the exception of gentamicin, antimicrobials used for plague and tularemia post-exposure prophylaxis and treatment are also used for anthrax; since the quantities required for anthrax generally exceed those needed for plague or tularemia, they are purchased under the anthrax umbrella of antimicrobials. Generic forms of these antimicrobials have been available and stockpiled for years. For

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[3] Hendricks KA, Wright ME, Shadomy SV, Bradley JS, Morrow MG, Pavia AT, et al. Centers for Disease Control and Prevention expert panel meetings on prevention and treatment of anthrax in adults. Emerg Infect Dis. 2014 Feb. http://wwwnc.cdc.gov/eid/article/20/2/13-0687_intro

[4] Wright JG, Quinn CP, Shadomy S, Messonnier N. Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR Recomm Rep. 2010;59 (RR-6):1–30. PubMed.

[5] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm474027.htm

many products, CDC is able to purchase required quantities for the SNS through negotiated contracts at the best price for the government, but other products, especially those that are widely available and generally low cost are subject to rapid price increases if there is a market shortage and require reconsideration. As with all procurements, CDC manages price fluctuations through collaboration with PHEMCE partners and manufacturers when price changes exceed predictable norms. In addressing challenges of this nature, CDC follows the prescribed protocol of adhering to PHEMCE's recommendations regarding prioritization of requirements and works with the manufacturers to adapt current procurement and future projections based on product availability and purchase price.

Post-Hearing Questions for the Record
Submitted to Mr. Kevin Shea
From Senator Thomas R. Carper

"The Federal Perspective on the State of Our Nation's Biodefense"

April 14, 2016

1. In 2011, the General Accounting Office reported that there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise and recommended that the Homeland Security Council consider establishing a focal point to oversee these efforts. The number one recommendation included in the Bipartisan Report of the Blue Ribbon Study Panel on Biodefense is to institutionalize biodefense in the Office of the Vice President of the United States to ensure that biodefense will be addressed by every Administration at the highest levels. The second recommendation is to establish a Biodefense Coordination Council at the White House, led by the Vice President.
    a. Do you support establishing one individual or entity to coordinate these efforts or think that the existing structure is sufficient?

       Response: It could be beneficial to have one individual or entity, not tied to a single department or agency, coordinate biodefense efforts across the federal government, depending on the details of such a proposal. If there were a single entity, it would be critical that they ensure appropriate resources and focus is paid to both the human and animal side of the issue.

    b. How else could we improve coordination across the government in biodefense activities?

       Response: It is important to ensure that the appropriate people are engaged in a coordinated effort. In some instances, animal agriculture has not been included as a major constituent in this type of initiative, so an improved evaluation upfront of the government entities and stakeholders that should be included would be beneficial. Additionally, the disparity between biodefense funding for human and animal health must be addressed to ensure the whole health community (animal, human, and environmental) makes progress; otherwise, the biosurveillance needed to protect and promote health will not be realized.

2. In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note

recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

Response: APHIS has addressed those recommendations directed at the Agency, as well as provided input on several that, while not directed at the Agency, we are contributing to.

a. #6 – Improve management of the biological intelligence enterprise.

   Response: APHIS will continue to support veterinary liaisons within the Centers for Disease Control and Prevention, National Biosurveillance Integration Center and the National Center for Medical Intelligence. This ensures animal health remains included in discussions.

b. #7 – Integrate animal health and One Health approaches to biodefense strategies.

   Response: APHIS' Veterinary Services program has a One Health Coordination Center (OHCC) that facilitates the integration of One Health approaches throughout our animal health programs. It is our standard practice to approach our work from a One Health state of mind, and OHCC works to inform and educate USDA employees about this need. OHCC staff also leverage their knowledge and relationships to build better alliances, coordinate between government and industry partners, and network to ensure that animal agriculture is considered when One Health issues are being addressed. OHCC also identifies unmet needs and opportunities to promote the potential contributions that APHIS can make to One Health activities.

   In July 2014, APHIS published the *Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States.* The Framework describes four goals for addressing emerging diseases:

   - Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern, or have trade implications;
   - Detect, identify, and characterize disease events;
   - Communicate findings and inform stakeholders; and
   - Respond quickly to minimize the impact of disease events.

   It also is necessary to incorporate lessons learned into our and our partners' future planning.

   As part of that process, APHIS also released a concept paper for a U.S. National List of Reportable Animal Diseases (NLRAD), which it developed in cooperation with the USAHA and others. The goal of the concept paper is to create a uniform,

science- and policy-based, nationally supported standardized list of animal diseases. It will provide the basis for consistent reporting with uniform case findings and reporting criteria. This will facilitate national, interstate, and international commerce; assist in meeting international reporting obligations to the World Organization for Animal Health (OIE) and trading partners; support the generation of export certifications; contribute to the assessment and reporting of listed zoonotic and endemic animal diseases; and facilitate response to an emerging disease or issue in the United States.

APHIS is also developing implementation guidance for the emerging disease framework that will outline roles and responsibilities, possible triggers for action, and potential responses and is developing guidance for the NLRAD to address issues such as laboratory implementation, confidentiality, and reporting and data management.

c. #8 – Prioritize and align investments in medical countermeasures among all federal stakeholders.

Response: APHIS will continue to work with both public and private researchers and private companies to look for new platforms that would allow for foreign animal disease countermeasures to be produced safely in the U.S. and provide safe and efficient protection as well as have the ability to identify vaccinated from infected animals. Additionally, APHIS will continue to work with other Federal agencies, academia, and industry to adapt diagnostic tests, and pathogen detection and characterization strategies that were developed for human testing, to allow for use in animal testing for relevant zoonotic disease agents. Likewise, continued development in animal disease countermeasures, where appropriate, will be shared with other entities concerned with human diagnostics.

d. #9 – Better support and inform decisions based on biological attribution.

Response: With the support of the Department of Homeland Security, APHIS, in close collaboration with the Department of Justice, National Biodefense Analysis & Countermeasures Center, and other National Laboratories, will continue recent efforts to sequence and characterize historical and newly obtained animal disease agents to facilitate future trace-back analyses for the purpose of molecular epidemiology and attribution. APHIS will also continue to collaborate with the Department of Justice on concepts of operations for joint animal disease and attribution/forensic investigations as recently described in World Organization for Animal Health (OIE) Bulletin 2015; 3:62-65.

e. #10 – Establish a national environmental decontamination and remediation capacity.

Response: APHIS will continue to work with interagency partners to develop decontamination and remediation capacity to support response to animal health incidents. Ongoing collaborations include partnerships with the Department of Homeland Security and the Environmental Protection Agency as well as several states to develop decontamination and disposal tools for use during an animal health emergency response.

f. #11 – Implement an integrated national biosurveillance capability.

Response: While this recommendation is not directed at APHIS, our Agency is committed to collaborating in an integrated system. APHIS has a liaison embedded at the National Biosurveillance Integration Center to help with this collaboration.

g. #12 – Empower non-federal entities to be equal biosurveillance partners.

Response: APHIS will continue to work with State, Private, and Federal partners to develop strategies that the animal health community can implement. For example, the National Animal Health Laboratory Network (NAHLN) works with 58 State and university veterinary diagnostic laboratories around the country that routinely implement APHIS' animal health national surveillance programs and ensure the laboratories stand prepared to diagnose and respond to high consequence livestock, poultry, aquaculture and zoonotic diseases of concern. Additionally, the NAHLN program collaborates with non-federal partners on development and validation of new diagnostic assays; planning for emergency preparedness exercises and drills; and advancements in data collection via secure electronic messaging of diagnostic test results.

h. #13 – Optimize the National Biosurveillance Integration System.

i. Response: APHIS continues to participate in the National Biosurveillance Integration System, and has a liaison embedded at the National Biosurveillance Integration Center (NBIC). The work of the APHIS liaison ensures daily interactions between APHIS and partner agencies, and contributes to coordinated national biosurveillance. For example the APHIS liaison contributes to daily information assessments in NBIC, providing input from global sources, as well as insights and perspectives on diseases of concern for U.S. livestock and associated zoonotic risks to public health. In addition, the APHIS liaison tests/uses biosurveillance and analytical tools under development by NBIC. In addition to these efforts, APHIS will continue to participate in the Biological Indications and Warning Analytic Community.

j. #14 – Improve surveillance of and planning for animal and zoonotic outbreaks.

Response: APHIS works every day in a wide range of areas to continually improve its surveillance and planning for animal and zoonotic disease outbreaks. We have a comprehensive and integrated animal disease surveillance approach that includes a variety of surveillance sources of information including wildlife and other vectors. Interagency collaborations are part of this approach, which is particularly important as we address diseases of economic and public health concern. We continue to work with state, tribal, industry, academic, and laboratory partners to develop Comprehensive Integrated Surveillance (CIS) systems that improve our ability to detect and respond to animal and zoonotic disease outbreaks. Specific examples of our work to improve CIS include:

- APHIS works in close collaboration with public health officials in the response and communication during zoonotic disease outbreaks through our One Health Coordination Center. These efforts include developing strategies, policies, and training to help animal health stakeholders to effectively engage with public health counterparts, provide guidance, facilitate information exchange, and enhance responses to One Health issues.
- APHIS works with the Centers for Disease Control and Prevention (CDC), and other agencies to evaluate genotyping technologies for zoonotic pathogens; and we support the testing and development of new technologies to address zoonotic pathogens during outbreaks and investigations. These activities help us protect public health and benefit animal health and marketability.
- APHIS is a member of the Federal interagency biosurveillance community, and participates on the Biosurveillance Indications and Warning Analytic Community steering committee to promote greater understanding of agricultural for threats that may also impact human health, and/or the U.S. economy. Through this interaction, APHIS leverages tools employed by all partners to augment other APHIS global biosurveillance initiatives.
- APHIS is implementing the National List of Reportable Animal Diseases (NLRAD) concept paper and the Framework for Response to Emerging Animal Diseases. The NLRAD and Emerging Disease Framework will facilitate early detection, reporting, and response to emerging disease outbreaks in animal populations, including zoonotic diseases.
- We are continually evaluating and refining diagnostic methods and testing algorithms for accurate and rapid detection of important zoonotic diseases such as brucellosis, influenza, and tuberculosis across several domestic livestock species.

- We have a cooperative initiative for Influenza A virus in swine (IAV-S) with the swine industry and NAHLN laboratories to identify unique strains of IAV-S that may be of significance to animal or public health. The CDC is regularly updated on IAV-S surveillance in the U.S. and works closely with APHIS to stay apprised of current influenza issues from a veterinary perspective.

APHIS has also undertaken several efforts around animal health data collection and sharing to help improve collaboration and coordination. We have a data management roadmap initiative to identify strengths and gaps in current data management systems for our animal health surveillance data. The end goal is to find ways to link the systems to each other and to provide a framework for data sharing between government agencies, universities, and private organizations while maintaining appropriate security of confidential data. We also have tools such as interactive dashboards that allow self-exploration of surveillance information by our federal, state, and industry partners.

k. #15 – Provide emergency responders with the resources they need to keep themselves and their families safe.

Response: Not applicable.

l. #16 – Redouble efforts to share information with state, local, territorial, and tribal partners.

Response: Not applicable.

m. #18 – Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.

Response: Not applicable.

n. #22 – Develop and implement a Medical Countermeasure Response Framework.

Response: Not applicable.

o. #23 – Allow for forward deployment of Strategic National Stockpile assets.

Response: Not applicable.

p. #24 – Harden pathogen and advanced biotechnology information from cyber-attacks.

Response: Not applicable.

q. #26 – Implement military-civilian collaboration for biodefense.

Response: Not applicable.

r. #27 – Prioritize innovation over incrementalism in medical countermeasure development.

Response: Not applicable.

s. #28 – Fully prioritize, fund, and incentivize the medical countermeasure enterprise.

Response: Not applicable.

t. #29 – Reform Biomedical Advanced Research and Development Authority contracting.

Response: Not applicable.

u. #30 – Incentivize development of rapid point-of-care diagnostics.

Response: APHIS will continue to look for ways to utilize point-of-care or point-of-need type diagnostic technologies that are being developed for the human health community. By utilizing existing technology, APHIS will take advantage of the concept of 'build it once use it many'. The animal and environmental health community is not always apparent to rapid-point-of-care diagnostic developers; they're focused on the human health community. USDA will continue to look for ways to better communicate our needs to these developers. As an example, we are planning a meeting with the Department of Homeland Security and the Defense Advanced Research Project Agency that will look at potential tools being developed for human and environmental diagnostics to see if they would be applicable to the animal health community. Additional examples include the development of an isothermal point of care assay for the detection of Capripoxviruses (Das, et al., Clin. Micro. 2013), and ongoing supported projects within APHIS to develop a field deployable microfluidics platform for the pen-side detection of foot-and-mouth disease virus and parapoxvirus.

v. #31 – Develop a 21st Century-worthy environmental detection system.

Response: Not applicable.

w. #32 – Review and overhaul the Select Agent Program.

Response: The Federal Select Agent Program has been the subject of several recent, extensive, external and internal reviews and is currently working to address and implement the recommendations of these reviews. Many of the recommendations in these reviews address concerns expressed in the Blueprint. In addition, APHIS has requested a nearly $5 million increase in the FY 2017 President's budget to strengthen our Select Agent program. The Select Agents program needs to be able to address the increasing scientific complexity of the regulatory issues related to research with select agents and toxins. This funding would allow us to hire personnel with strong scientific, standard-setting, security and policy backgrounds to handle evolving demands and fully carry out the inspection program, as well as increased support for needed IT infrastructure.

3. The Blue Ribbon Study Panel, GAO and other experts have recommended the development of a national biodefense strategy. To date, federal agencies have produced several strategic documents that address different aspects of biodefense, including the National Health Security Strategy and the National Biosurveillance Strategy. Do you believe that existing strategy and policy documents provide sufficient coordination of biodefense activities across the federal government? What elements should be included in a unified national strategy for biodefense?

Response: The existing strategy and policy documents are adequate and sufficiently address biodefense and biosurveillance issues that should be coordinated across the biosurveillance enterprise. The documents may need to be reviewed again in the near future to understand what has been accomplished and then reframed based on any new resources. However, the biodefense and biosurveillance communities cannot implement the strategy if all sectors of the health community (animal, human, and environmental) are not appropriately and proportionately invested in. Currently, the existing funds are spread disparately across the various elements of the biosurveillance enterprise. The funding for each area needs to be examined and adjusted to ensure all interdependent areas are funded adequately so they can move forward at the same time.

4. The Blue Ribbon Study Panel recommended the development of a unified budget for biodefense spending, and estimated that roughly $6 billion is spent every year on biodefense and related hazards. Please detail how much your Department or Agency spent on biodefense efforts (categorized by Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery activities, as defined by Homeland Security Presidential Directive 10) from Fiscal Years 2007-2016.

Response: The information follows.

	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Surveillance and Detection ($ millions)	$423.282	$426.138	$362.936	$396.794	$417.935
Prevention and Protection –*Critical Infrastructure Protection* ($ millions)	8.659	8.597	10.169	10.178	10.158
Response and Recovery ($ millions)	9.346	10.942	10.061	10.181	10.161
Total, APHIS ($ millions)	$441.287	$445.677	$383.166	$417.153	$438.254

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Surveillance and Detection ($ millions)	$226.500	$225.959	$295.254	$193.391	$234.689
Prevention and Protection –*Critical Infrastructure Protection* ($ millions)	55.404	58.774	62.560	59.750	62.560
Response and Recovery ($ millions)	21.709	20.041	21.759	21.081	27.009
Total, APHIS ($ millions)	$303.613	$304.774	$379.573	$274.222	$324.258

*Funding amounts vary between fiscal year 2011 and 2012, due to the change in budgetary structure and the ability to track and report on certain activities.

The following activities are included in this accounting:

APHIS conducts activities targeted at excluding and reducing potential threats entering our borders through the Agency's Agricultural Quarantine Inspection (AQI) program and analyzing data streams regarding agricultural imports. The AQI program encompasses various activities to address agricultural pest and disease risks posed by international travel and trade. These activities include developing regulatory import policies to protect the health of U.S. agriculture and ecosystems; conducting off-shore risk reduction activities, such as foreign commodity preclearance programs for specific products; and, treating arriving containers and cargo, among others. The AQI program is funded by user fees and appropriations for certain activities.

The Agency has programs that protect critical infrastructure, including agriculture and food, and government facilities. Activities include gathering and analyzing plant and animal health information, including zoonotic disease information, and assessing potential agricultural threats. APHIS monitors select agents and toxins, and regulates registered entities that possess, use, or transfer them, to ensure the safe and secure importation and interstate transport of animal pathogens. APHIS also ensures continued mission operations and protection for employees. Funding for these activities is provided for in the appropriation.

Lastly, APHIS maintains a cadre of trained professionals prepared to respond immediately to animal and plant health emergencies. Personnel investigate reports of suspected exotic pests and diseases and take emergency action if necessary. APHIS also actively engages State, Tribal, and local governments, and industries to advance their emergency preparedness and response capabilities. Funding for these activities is also provided for in the appropriation.

5. Upon the release of the National Biosurveillance Strategy in July 2012, a strategic implementation plan for the strategy was slated for completion within 120 days. What is the status of the implementation plan? Please describe how the Animal and Plant Health Inspection Service coordinates biosurveillance programs and policy with other federal agencies, per the National Biosurveillance Strategy. If the implementation plan has been completed, please provide it to this Committee.

   Response: APHIS defers to the National Security Council regarding the status of the implementation plan.

   APHIS continues to work with our interagency and other partners to forward the goals of the National Biosurveillance Strategy. For example:

   - To maintain a global health perspective, APHIS is currently working with the Department of Health and Human Services, Centers for Disease Control and Presentation, on the Global Health Security Agenda (GHSA).
   - We are active in the National Biosurveillance Integration Center (NBIC), contributing to coordinated national Biosurveillance with our liaison embedded in NBIC.
   - To address the research coordination part of the Strategy, APHIS works with the Agricultural Research Service, the National Institute for Food and Agriculture, the Department of Homeland Security's Science and Technology, the Foreign Animal Disease Threats Working Group, and academia to coordinate the research & design efforts that enable biosurveillance.
   - APHIS is coordinating with DHS on an Enhanced Passive Surveillance (EPS) project to link veterinarians with state diagnostics laboratories to track lab results arising from disease syndromes reported in livestock herds. These

data can be used to assess animal health trends. We have also worked with the Department of Health and Human Services, Department of State, and the University of Minnesota to develop a set of core competencies for One Health practitioners that focus on the multi-disciplinary approach to disease monitoring.

- USDA has a memorandum of agreement with the National Center for Medical Intelligence (NCMI) to embed two USDA full time equivalents (FTEs) to support product development (adding agriculture subject matter expertise) and liaise within the community. Appropriate information developed here is shared with need to know and cleared experts within USDA.
- USDA has a memorandum of understanding that establishes the procedures that APHIS, USDA Office of Inspector General (OIG), and the Federal Bureau of Investigation (FBI), Laboratory Division have mutually agreed to use to support specific tasks to be performed by each agency in support of joint USDA and FBI missions involving Agroterrorism.

Post-Hearing Questions for the Record
Submitted to Mr. Kevin Shea

"The Federal Perspective on the State of Our Nation's Biodefense"

April 14, 2016

From Senator Joni K. Ernst

1. **Since highly pathogenic avian influenza ("HPAI") struck Iowa's turkey and egg laying industry, the Animal and Plant Health Inspection Service ("APHIS") has amended the indemnification formula by increasing the life cycle of a laying hen from 80 to 90 weeks, which was a great benefit to producers. I understand that, in an effort to seek a formula that properly reflects the value of the birds lost last year, producers have requested additional updates, specifically:**

    a) Updating the Bureau of Economic Analysis ("BEA") 10 year average data to the latest available (2003-2012) for calculating last year's indemnity, and

    b) Eliminating the additional 6% deduction for assumed debt retirement, capital improvements, research and development and asset valuation.

    Has APHIS considered these updates to the formula? If not, why not? If so, please describe APHIS's conclusions with respect to these potential updates. If APHIS intends to make these or any other updates to the indemnity formula, would they be applied retroactively for the producers impacted in last year's outbreak?

    Yes, APHIS has considered these updates. The updated 2012 Bureau of Economic Analysis (BEA) data, which is updated once a year, came out after the outbreak had started. APHIS used the most recent data available at the beginning of the outbreak.

    Additionally, the 6% deduction for assumed debt retirement, capital improvements, research and development, and asset valuation is included because in cases of egg-laying hens, we are trying to determine the amount of net income that ultimately would be used to improve the asset (or bird) value. In doing so, historical information from the BEA shows that one-fifth of net income becomes retained earnings, and the Agency believes that about half of retained earnings would be used to increase bird asset value.

APHIS is also looking to adjust the calculator to make it more transparent and based on data that is updated more promptly than the BEA data. We have also examined the calculator several times and updated it mid-outbreak based upon input received from industry. For example, APHIS increased the number of weeks' worth of eggs for which it would provide compensation based upon updated data it received from the poultry industry. In that case, for the sake of uniformity, APHIS provided corrective indemnity payments to producers who had been affected during the outbreak. APHIS will continue to consider new data and respond appropriately moving forward. As USDA considers additional changes to how it determines values for indemnity payments, the Department will make a decision on when these changes become effective. The level of data currently available and how the changes can be made in a uniform manner are some of the considerations that factor into this decision.

From Senator Ron Johnson

1. **Has the USDA completed an inventory of its animal health response capabilities and identified gaps in those capabilities? Please provide the comprehensive list of such capabilities and gaps. If USDA has not yet completed such an inventory, will USDA complete such an inventory, and if so, when?**

A critical part of APHIS' mission is to prevent, prepare for, respond to, and recover from animal and plant health emergencies. To achieve this, we constantly look for new or better ways to improve how we manage emergency situations. To prepare for animal health emergencies, APHIS finalized an Emergency Preparedness and Response Training/Exercise Strategy and Plan (TEP) in October 2014, for fiscal years 2015-2017. Comprehensive training and exercises provide vital practice before an actual animal disease incident occurs. The TEP is designed to enhance the preparedness of APHIS and its Federal, State, and tribal partners to respond to livestock and poultry health incidents and other hazards. At the beginning of each fiscal year, APHIS hosts a training and exercise workshop with its partners to update the TEP by translating the Agency's preparedness strategic goals and priorities into specific activities, and to coordinate training and exercise activities. In FY 2015, there were 53 events (40 trainings and 13 exercises) aligned with APHIS' training and exercise priorities and objectives. Following the 2015 highly pathogenic avian influenza (HPAI) outbreak, APHIS developed the 2016 HPAI Preparedness and Response Plan (attached). This comprehensive plan aims to improve APHIS' response capabilities and processes ensuring the most effective services during an HPAI outbreak. To develop the plan, we collaborated

with the industry and State partners and listened to producers, academia, our responders, and other stakeholders to identify improvements and to be better prepared should HPAI return in the future. The plan incorporates the capabilities needed to prepare for and respond to an HPAI outbreak, and focuses on the following areas: preventing or reducing future outbreaks, enhancing preparedness, improved and streamlined response capabilities, and preparing for the potential use of AI vaccines. APHIS has also looked at preparedness and response for other diseases such as foot-and-mouth. In addition, APHIS recently launched the Volunteer Emergency Ready Response Corps (VERRC). The VERRC is a way to quickly bring in resources on the ground as we need them to respond to emergencies, especially in the early stages of an emergency. The VERRC is a list of volunteers who are available to help APHIS respond to emergencies. These APHIS employees, from across the Agency, volunteer to be trained and ready to deploy to support any emergency, no matter the program.

Last year's massive HPAI response tested our abilities and emphasized the need of enhanced preparedness. Our stakeholders and government partners expect APHIS to continue leading emergency preparedness and response for foreign and emerging disease incidents, and providing support for other animal health events. Effective response to foreign and emerging animal health events requires advance and continuous preparation. To that end, the President's Budget for FY 2017 includes a request for additional $30 million in preparedness funding to address these identified gaps:

Staffing and support: We need to hire additional personnel who are prepared to respond to animal health events and to increase their level of training. When an animal disease of national concern is detected, the Agency needs to quickly conduct epidemiologic investigations to minimize the potential for continued spread of animal pathogens. The Agency has seen a reduction of more than 200 animal health professionals in the Veterinary Services organizational unit over the last decade. APHIS responders need thorough training and appropriate equipment to effectively exercise their response roles and responsibilities and reduce startup time for operations during an animal health event.

- Tools and tactics: More funding is needed to develop response tools and tactics for use in animal disease events, for activities such as depopulation, disposal, and decontamination and technologies for early detection of emerging and foreign animal diseases, both in livestock and wildlife. Currently, no APHIS laboratory has the capacity to screen large numbers of wildlife samples.

- Data Management: A robust animal health information collection, integration, and computing platform is needed to allow the integration of internal and external data streams to enable national disease detection and reporting, decision-making for action, response and recovery capacity and to support laboratory scientific computing. Note:

This is included in the tools and tactics component of our preparedness request as part of the 2017 budget.

- Vaccine stockpile: The national stockpile of foot-and-mouth disease vaccine is in need of modernization. With the increase requested in the 2017 President's Budget, APHIS will move forward with approaches that begin to include manufacturer-held vaccine stocks to supplement the traditional antigen stockpile.

From Sen. Tammy Baldwin

1. **The Blue Ribbon Study Panel on biodefense emphasized the importance of implementing "One Health" principles in order to address the nation's biodefense needs. But the panel also recognized serious shortcomings, where agencies specialize in either human health or animal health, but where wildlife authorities are "rarely included at all." With the real and escalating risk associated with emerging diseases of wildlife origin, how does APHIS leverage the expertise of the USGS National Wildlife Health Center and academic partners such as University of Wisconsin-Madison to bolster the effectiveness of the "One Health" approach to address emerging infectious disease concerns? What increases in capacity and resources at the National Wildlife Health Center are necessary to support USDA's goals under the "One Health" approach?**

APHIS Wildlife Services (WS) National Wildlife Research Center (NWRC) is the research arm of WS dedicated to developing methods to resolve conflicts at the wildlife-human-agricultural interface (i.e., One Health). NWRC conducts a number of collaborative disease surveillance projects with the National Wildlife Health Center (NWHC) on issues ranging from plague to avian influenza. For example, NWRC, U.S. Geological Survey, Centers for Disease Control and Prevention, and State natural resources agencies form the Interagency Steering Committee for Avian Influenza in Wild Birds. This committee uses a One Health approach to detect and respond to avian influenzas of concern to wildlife, agriculture, and public health. WS also serves on the Interagency Black-footed Ferret Recovery Team with the NWHC to develop, register, and assist in technology transfer for the implementation of a plague vaccine to protect ferrets and prairie dogs from the lethal plague virus. Control of plague in these species will also help reduce the risk of exposure to people. WS also works collaboratively with the NWHC to support a One Health approach on diseases that affect animals and people through the detection and testing of mortality events. WS' National Wildlife Disease Program has wildlife disease biologists located throughout the country, conducting wildlife surveillance and management activities. When they detect sick and dying wildlife, they work in cooperation with the NWHC in Madison to submit biological samples for testing. Once a disease of concern is detected, WS and the NWHC work

collaboratively with agricultural and public health agencies to develop surveillance and response plans.

In addition to its collaborations with NWHC, our NWRC also works jointly with over 40 universities domestically and abroad on One Health issues. This research involves issues such as avian influence, Zika virus, feral swine diseases, chikungunya, plague, tularemia, Japanese encephalitis virus, encephalitis viruses, rabies, West Nile virus, chronic wasting disease, and numerous other pathogens. Most recently, NWRC has been working with the University of Wisconsin-Madison on research related to avian influenza viruses in wild birds, and on using serological studies in wildlife to better understand the epidemiology of pathogens in the environment.

The NWHC is the only national diagnostic laboratory dedicated to diagnosing diseases in wildlife. While domestic animal and public health laboratories can do some testing for diseases in wildlife, their primary missions are not wild animals. Maintaining and improving the diagnostic capabilities at the NWHC are important to APHIS' One Health strategy of rapidly detecting diseases of concern and implementing control strategies to prevent entry of such pathogens into domestic animals and people.

Post-Hearing Questions for the Record
Submitted to Dr. Aaron Firoved
From Senator Thomas R. Carper

"Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

Question#:	1
Topic:	Biodefense Oversight
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its 2011, the General Accounting Office reported that there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise and recommended that the Homeland Security Council consider establishing a focal point to oversee these efforts. The number one recommendation included in the Bipartisan Report of the Blue Ribbon Study Panel on Biodefense is to institutionalize biodefense in the Office of the Vice President of the United States to ensure that biodefense will be addressed by every Administration at the highest levels. The second recommendation is to establish a Biodefense Coordination Council at the White House, led by the Vice President.

Do you support establishing one individual or entity to coordinate these efforts or think that the existing structure is sufficient?

How else could we improve coordination across the government in biodefense activities?

Response: As the Blue Ribbon Study Panel on Biodefense noted, clear leadership and accountability across the federal biodefense enterprise are critical in the response to a biological incident. Given the diverse range of departments and agencies involved in countering biodefense, each with its own statutory obligations and responsibilities, providing unity of federal effort is a challenge that requires continual engagement and collaboration.

Under Homeland Security Presidential Directive 10, "Biodefense in the 21st Century" (HSPD-10, 2004), the Secretary of Homeland Security is responsible for coordinating domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks, while the Department of Health and Human Services is responsible for coordinating all Federal-level assets supporting the state and local medical and public health response and USDA is responsible for leading the plant and animal health

Question#:	1
Topic:	Biodefense Oversight
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

response. DHS would be better positioned to fulfill its HSPD-10 responsibilities if there were a mechanism for the Department to assess biodefense capabilities across the interagency to identify and bolster weak links in the overarching homeland biodefense and crisis response enterprise.

Additionally, the National Security Council could establish an interagency biodefense policy panel to review and assess the status of HSPD-10 implementation to improve unity of effort and prioritize joint goals.

Question#:	2
Topic:	Blue Ribbon Study Panel Recommendation #6
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#6 - Improve management of the biological intelligence enterprise.

Answer: DHS defers to the Office of the Director of National Intelligence on the status of action items for Recommendation 6.

DHS components, including the Office of Intelligence and Analysis (I&A), Office of Health Affairs (OHA), and the Science and Technology Directorate (S&T), coordinate closely with the broader U.S. intelligence community (IC) to understand and assess biological threats that could impact the homeland.

DHS S&T incorporates information from across the IC into the Bioterrorism Risk Assessments and Material Threat Assessments that are used to prioritize biodefense activities across the interagency. The Material Threat Assessments support Material Threat Determinations by the DHS Secretary. Additionally, the National Biosurveillance Integration Center (NBIC) is coordinating closely with the IC in the production of their new classified product, *Biosurveillance Intelligence Highlights*, which is disseminated monthly to National Biosurveillance Integration System partners as of April 2016.

Question#:	3
Topic:	Blue Ribbon Study Panel Recommendation #7
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#7 - Integrate animal health and One Heath approaches to biodefense strategies.

Response: In 2007, Congress authorized the National Biosurveillance Integration Center (NBIC) to integrate and analyze data related to human health, animal, plant, food, and environmental monitoring systems, through Public Law 110-53. As a part of this mission, NBIC actively collects and integrates animal health and disease data into its daily biosurveillance activities. Animal health and disease data is obtained from open source media reports, Federal agency reports, and scientific and academic publications. Specific analysis and insight into animal health and disease data is also obtained from our interagency liaison staff who represent the National Wildlife Health Center (NWHC) and U.S. Department of Agriculture (USDA). In addition, NBIC analysts and subject matter experts represent the diverse field of veterinary health and medicine.

Within DHS Office of Health Affairs, the Food, Agriculture and Veterinary Defense (FAVD) Branch is responsible for oversight and management of the department's implementation of HSPD-9: Defense of the United States Agriculture and Food. In addition, FAVD collaborates with state and local emergency planners, state agriculture boards, and farm industry stakeholders to build food and agriculture preparedness tools.

Question#:	4
Topic:	Blue Ribbon Study Panel Recommendation #8
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#8 - Prioritize and align investments in medical countermeasures among all federal stakeholders.

Response: The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is an interagency coordinating body led by the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR). The PHEMCE coordinates Federal efforts for the development, procurement, and use of medical countermeasures across HHS, DHS, DoD, VA, and USDA. This coordination enhances our collective preparedness for biological and emerging infectious diseases.

DHS actively participates in the PHEMCE and related efforts to prioritize and align MCM investments, but defers to HHS for additional information.

Question#:	5
Topic:	Blue Ribbon Study Panel Recommendation #9
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#9 - Better support and inform decisions based on biological attribution.

Response: The DHS Science and Technology Directorate's (S&T) Chemical-Biological Defense Division has a strong partnership with the Federal Bureau of Investigation (FBI) on both biological and chemical forensics. Forensics is the technology route via which attribution would be made if a biological event were to occur. Jointly funded (DHS/FBI) S&T programs are conducted at the National Biological Forensic Analysis Center (NBFAC), located within the National Biodefense Analysis & Countermeasures Center (NBACC) and several Department of Energy National Labs. There is mutual benefit in these programs as much of the technology developed for forensics applications are of value in developing techniques to detect emerging threat agents, which could be used in acts of bioterrorism against the civilian population.

Question#:	6
Topic:	Blue Ribbon Study Panel Recommendation #10
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#10 - Establish a national environmental decontamination and remediation capacity.

Response: The Environmental Protection Agency (EPA) is the lead Federal agency for environmental decontamination and remediation. Even in areas of immediate relevance to DHS, such as how to decontaminate DHS assets (e.g. boats, planes, ports of entry) after a biological attack, DHS would rely on EPA for guidance.

The Federal Emergency Management Agency provides Federal support in response to the release of hazardous materials through the National Response Framework and the National Disaster Recovery Framework and, if activated, through Emergency Support Function (ESF) #10.

Question#:	7
Topic:	Blue Ribbon Study Panel Recommendation #11
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#11 - Implement an integrated national biosurveillance capability.

Response: The National Strategy for Biosurveillance, released in July 2012, and the corresponding implementation plan were the products of an extensive interagency process reflecting the expertise of Federal departments and agencies including DHS. It represents a whole-of-government effort designed to facilitate early detection and enable ongoing situational awareness of the potential human, animal, or plant health impacts from chemical, biological, radiological, nuclear, or environmental incidents. The scope of this effort covers a range of threats, including a weapon of mass destruction or other deliberate attack, an emerging infectious disease, a pandemic, an environmental disaster, or a widespread food-borne illness. Biosurveillance capabilities provide essential information that contributes to broaden situational awareness. The Strategy's goal is to achieve a well-integrated nationwide biosurveillance capability that provides essential information quickly to inform decision-making at all levels. The implementation plan was completed on February 15, 2013, as required in the Strategy.

Question#:	8
Topic:	Blue Ribbon Study Panel Recommendation #12
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#12 - Empower non-federal entities to be equal biosurveillance partners.

Response: Partnerships with non-federal stakeholders are critical for achieving a timely response to a biological event. The National Biosurveillance Integration Center (NBIC) is charged with disseminating key biosurveillance information to State, Local, Tribal, and Territorial (SLTT) communities. The Center currently produces products specifically for our SLTT partners and distributes them in a variety of mechanisms including direct email, via fusion centers, and through information portals.

NBIC is also exploring opportunities for enhanced collaboration and feedback from SLTT and private sector partners. NBIC is working with the University of North Carolina-Chapel Hill on the National Collaborative for Bio-Preparedness (NCBP), an initiative that integrates and analyzes state and local data sets, like Emergency Medical Services, 911, and poison control center data, for possible early indicators of disease trends and biological incidents.

In addition, NBIC is leading the coordination of an inaugural OneHealth workshop, in partnership with the Association of State and Territorial Health Officials (ASTHO), to build engaged partner capacity regarding biosurveillance activities throughout the SLTT community. This workshop will address community challenges through dialogue within the vast SLTT community.

Question#:	9
Topic:	Blue Ribbon Study Panel Recommendations #13
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#13 - Optimize the National Biosurveillance Integration System.

Response: In 2007, Congress authorized the National Biosurveillance Integration Center (NBIC) to integrate and analyze data related to human health, animal, plant, food, and environmental monitoring systems, through Public Law 110-53. The Government Accountability Office (GAO-16-413T), the White House (*National Strategy for Biosurveillance, 2012*), the Blue Ribbon Study Panel on Biodefense *(A National Blueprint for Biodefense, 2015)*, and Homeland Security Presidential Directive 21 have also consistently recognized the importance of achieving integrated biosurveillance. Furthermore, integrated biosurveillance activities serve as a crucial homeland security imperative. NBIC provides situational awareness on emerging infectious diseases and biological events through collaboration with Federal partners in the interagency community, including key public health agencies. NBIC reports, and its responses to requests for information provide valuable insight into key biological events, particularly for stakeholders who do not have a biodefense-centric mission, but whose operations may be impacted by biological incidents.

While Federal partners are often willing to share information with NBIC, agencies have also noted that sharing raw data presents a number of challenges including the need for personnel to interpret data, a lack of resources and the IT infrastructure, and restrictions to sharing data such as privacy concerns. NBIC is working with its partners to address these issues and facilitate information sharing to support national biosurveillance.

For instance, NBIC is working with the Department of Veterans Affairs (VA) on a data sharing initiative that will help to create a de-identified, aggregated national view of disease trends for the Center, while also facilitating the understanding of those trends in our veteran population for the VA. NBIC plans to replicate this shared value model with other interagency partners to increase the integration of information across the interagency. This shared value model was presented to the NBIC Advisory Board

Question#:	9
Topic:	Blue Ribbon Study Panel Recommendations #13
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

members at the 5 May meeting to facilitate dialogue about applying this model to their departments and agencies.

Similarly, NBIC is working with the Department of Defense's Defense Threat Reduction Agency to deploy new collaboration and analytic tools with the Biosurveillance Ecosystem platform that will enable biosurveillance analysts from across the government, including DoD Armed Forces Health Surveillance Branch and HHS Assistant Secretary for Preparedness and Response, to collaboratively report on emerging biological threats identified through examination of open source and agency specific data sets.

While these efforts will greatly improve the Center's ability to integrate and analyze interagency data, progress towards achieving the mission of integrated biosurveillance will be difficult to achieve without additional funding. In a recent report on NBIC, the Government Accountability Office also noted concerns about the imbalance between the size and nature of NBIC's mission and the resources that it had available to achieve it.

Question#:	10
Topic:	Blue Ribbon Study Panel Recommendation #14
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#14 - Improve surveillance of and planning for animal and zoonotic outbreaks.

Response: Although DHS does not have the primary role for establishing animal health data collection systems, information regarding animal and zoonotic outbreaks is important to the mission of the Office of Health Affairs (OHA) and the National Biosurveillance Integration Center (NBIC). It is NBIC's mission to enable early warning and shared situational awareness of acute biological events, including animal and zoonotic threats, and support better decisions through rapid identification, characterization, localization, and tracking. NBIC's liaisons with the National Wildlife Health Center (NWHC) and U.S. Department of Agriculture (USDA) and its on-staff veterinarian and public health experts are using animal health data to create an integrated and comprehensive picture of animal and zoonotic threats.

In addition, OHA helps to plan and prepare for animal and zoonotic outbreaks. For example, in 2014, OHA deployed personnel to Texas to educate and assess Customs and Border Protection's (CBP) Border Patrol canine handlers currently in field, their canine care processes, and provide recommendations for DHS workforce health and protection against Chagas disease. Additionally, OHA's Food, Agriculture, and Veterinary Defense Branch has collaborated with DHS's Science and Technology Directorate's Center of Excellence to conduct a Chagas study within CBP's canine population through Texas A&M University. DHS's "One Health" unity of effort in coordination with Texas A&M University's Chagas study will provide valuable information to protect the DHS workforce and advance the knowledge of the disease.

Recently, the oversight for the Integrated Consortium of Laboratory Networks (ICLN) transitioned to OHA. The goal of the ICLN is to create the basis for a system of laboratory networks capable of integrated and coordinated response to, and consequence management of, acts of terrorism and other major incidents requiring laboratory response capabilities such as animal and zoonotic outbreaks. Establishing a laboratory network

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Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

system to strengthen early detection and consequence management is consistent with Homeland Security Presidential Directives 9, 10, 21 and 22.

Question#:	11
Topic:	Blue Ribbon Study Panel Recommendation #15
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#15 - Provide emergency responders with the resources they need to keep themselves and their families safe.

Response: In 2015 the Department of Homeland Security (DHS) Office of Health Affairs (OHA) established the First Responder Vaccine Initiative (FRVI) to continue to oversee activities related to the development of the Anthrax Preparedness and Protection Pilot (Anthrax Vaccine Pilot).

The FVRI continues to pursue the implementation of a comprehensive Anthrax Vaccine Pilot in jurisdictions in two to five states to provide anthrax vaccine that is cycling out of the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS). The Pilot will allow participating jurisdictions to offer voluntary anthrax vaccinations to first responders and provide FRVI the opportunity to evaluate the feasibility and acceptance of pre-event anthrax vaccinations within the first responder community.

The FRVI manager is working with partners within and outside of DHS to develop a website, training and education materials, logistical platforms, and administrative processes to ship and track vaccine. In collaboration with the Department of Health and Human Services, DHS will facilitate the shipment of anthrax vaccine in support of the Anthrax Vaccine Pilot from the SNS to participating sites.

The First Responder Vaccine Initiative supports first responders and strengthens their personal protection through vaccination.

Question#:	12
Topic:	Blue Ribbon Study Panel Recommendation #16
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#16 - Redouble efforts to share information with state, local, territorial, and tribal partners.

Response: The Department of Homeland Security (DHS) recognizes that state, local, territorial and tribal partners are key stakeholders in the homeland security enterprise. Further, these entities are on the front lines of response and often operate without federal assistance in the first critical moments and hours of an incident. Effective and meaningful information sharing by and between federal agencies and the state, local, territorial and tribal partners is essential for coordinated and appropriate responses to any hazard. The Office of Health Affairs (OHA) is involved in several initiatives aimed at enhancing this critical area.

The National Biosurveillance Integration Center (NBIC) is charged with disseminating key biosurveillance information to State, Local, Tribal, and Territorial (SLTT) communities. The Center currently produces products specifically for our SLTT partners and distributes them in a variety of mechanisms including direct email, via fusion centers, and through information portals.

NBIC is also exploring opportunities for enhanced collaboration and feedback from SLTT and private sector partners. NBIC is working with the University of North Carolina-Chapel Hill on the National Collaborative for Bio-Preparedness (NCBP), an initiative that integrates and analyzes state and local data sets, like Emergency Medical Services, 911, and poison control center data, for possible early indicators of disease trends and biological incidents.

In addition, NBIC is leading the coordination of an inaugural OneHealth workshop, in partnership with the Association of State and Territorial Health Officials (ASTHO), to build engaged partner capacity regarding biosurveillance activities throughout the SLTT community. This workshop will address community challenges through dialogue within the vast SLTT community.

Question#:	12
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Committee:	HOMELAND SECURITY (SENATE)

OHA is also a strong advocate and partner with the DHS Office of Intelligence and Analysis (I&A) in its work with fusion centers. Primarily centered around sharing best practices and improving engagement of the public health and medical community in a predominately law enforcement construct, the initiative works with fusion centers to engage other local partners as well as to connect fusion centers with sources of critical information, including products and analytic services of OHA's own NBIC. Our state and local outreach provides technical assistance on the ground and facilitates classified threat briefings for state and local audiences. OHA continues to sponsor security clearances to select SLTT partners as part of our ongoing efforts to enhance information exchange with our critical state, local, territorial, and tribal partners.

Question#:	13
Topic:	Blue Ribbon Study Panel Recommendation #18
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#18 - Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.

Response: DHS defers the answer to this question to the Department of Health and Human Services (HHS). Section 2801 of the Public Health Service Act, 42 U.S.C. 300hh, as well as a number of National Strategies and Presidential Directives[1] establish the Secretary of HHS as the Federal lead responsible for the protection of the health of the civilian population against both intentional and accidental or naturally occurring threats. One part of this responsibility includes establishing and utilizing a standard process to develop and issue clinical infection control guidance for biological events. DHS's primary responsibility with respect to infection control during a biological event or pandemic is to ensure that DHS personnel have sufficient supplies and training to allow them to perform their critical missions throughout the event.

[1] These include but are not limited to the National Strategy for Public Health and Medical Preparedness (Homeland Security Presidential Directive-21, October 2007); the National Response Framework (January 2008); the National Health Security Strategy (December 2009); and the National Preparedness Goal (Presidential Policy Directive – 8, March 2011).

Question#:	14
Topic:	Blue Ribbon Study Panel Recommendations #22
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#22 - Develop and implement a Medical Countermeasure Response Framework.

Response: DHS collaborates with military and civilian agencies on the development of medical countermeasures through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), chaired by the Department of Health and Human Services (HHS), with an Executive Steering Committee on which the DHS Office of Health Affairs is a voting member.

The Strategic National Stockpile is managed by the Centers for Disease Control and Prevention (CDC) within HHS. State and local authorities are in charge of dispensing the SNS assets to the nation's civilian population in a crisis, although doing so in an effective time frame is challenging. DHS has engaged in a dedicated effort to fulfill the mandates of Presidential Executive Order 13527 to develop a Federal capability for the timely provision of medical countermeasures (MCMs) after a biological attack. DHS, under FEMA's lead, has been working with the Department of Defense and other partners to craft solutions to the critical challenges of dispensing medical countermeasures (MCMs) at the necessary scale and speed to save lives. DHS components continue to work with interagency and intergovernmental partners to advocate for and help implement recommendations that would improve provision of MCMs after a biological attack.

DHS is one of the few civilian federal agencies to acquire antiviral MCMs and develop a Points of Dispensing model, thus positioning it at the forefront of Federal agencies in terms of biological preparedness. The DHS MCM Program maintains its own stockpile of medical countermeasures to ensure that DHS personnel have sufficient supplies and training to allow them to perform their critical missions during a biological event.

Question#:	15
Topic:	Blue Ribbon Study Panel Recommendation #23
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#23 - Allow for forward deployment of Strategic National Stockpile assets.

Response: The Strategic National Stockpile is managed by the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS). DHS defers the answer to this question to HHS, the Federal agency charged with ensuring general public health preparedness for the United States.

Question#:	16
Topic:	Blue Ribbon Study Panel Recommendation #24
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#24 - Harden pathogen and advanced biotechnology information from cyber attacks.

Response: Under the new Federal Information Security Management Act, the Department's National Protection and Programs Directorate (NPPD) authority extends to anything that protects federal Executive Branch civilian information or information systems, and NPPD's technology deployments are similarly authorized. Thus perimeter defense issues that cover protection of pathogen and advanced biotechnology information used and stored on civilian, federal systems are generally a matter of policy. To help protect this type of information in the private sector, the Department routinely shares best practices, responds to incidents, and generally provided resources the private sector can use to improve their cybersecurity. Additionally, DHS disseminates information to the public and private sectors regarding general cyber hygiene through its Stop.Think.Connect.™ Campaign, a public awareness campaign that promotes safer online behavior and effective cyber hygiene resources and information for all Americans. This information can often serve as a foundational resource in cybersecurity awareness for a variety of sectors and system owners.

Question#:	17
Topic:	Blue Ribbon Study Panel Recommendation #26
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#26 - Implement military-civilian collaboration for biodefense.

Response: The Office of Health Affairs (OHA) agrees that DHS can utilize the experience and knowledge of the Department of Defense (DoD) in the biodefense space. While OHA and DoD serve different mission spaces, our collaboration continues to be critical for mutually advancing our Nation's biodefense capabilities.

Specifically, the OHA BioWatch program has collaborated at multiple levels with the DoD since the inception of the BioWatch program in 2003. This collaboration is apparent in both BioWatch day-to-day operations as well as ongoing efforts to enhance the Program's capabilities through various technology enhancements.

DoD and DHS share common technologies and methods. BioWatch technology has similar underlying technology as DoD's detection equipment, but BioWatch is more portable and quieter to better suit our mission need of operating in visible areas within major cities. BioWatch utilized several DoD institutions to conduct multiple, independent tests of its technology, including Dugway Proving Ground (DPG), Edgewood Chemical and Biological Center (ECBC), and the Naval Surface Warfare Center Dahlgren Division (NSWC-DD).

Since 2011, BioWatch has been using DoD reagents for screening, while retaining Centers for Disease Control and Prevention (CDC) verification testing, to enhance overall confidence in testing results. Both DoD and CDC use Polymerase Chain Reaction (PCR), which experts widely consider to be the most appropriate and sensitive method to screen aerosol samples.

BioWatch and DoD have an agreement in place for the emergency transport of the Rapidly Deployable Laboratory (RDL) that is housed, maintained and deployed from a DoD installation. In addition, for mail and parcel screening and some special event samples, BioWatch uses the DoD Enzyme-linked immunosorbent assays (ELISA).

Question#:	17
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Committee:	HOMELAND SECURITY (SENATE)

DoD and BioWatch have a joint contract vehicle to acquire quality assurance (QA) and statistical analyses support for CBRNE detection systems. The NSWC-DD serves as the BioWatch QA Program's Sample Standards Laboratory (SSL) to create QA and proficiency test samples and to archive operational samples. In response to the 2015 DoD incident involving the shipment of inactivated agents from DPG, the BioWatch QA program participates in committees and workgroups with DoD to provide recommendations for alternative materials and QA measures for production from a customer perspective.

DoD is an active participant in the DHS BioWatch Program of Record. BioWatch has worked to establish close relationships with military installations that are located in BioWatch Jurisdictions. BioWatch is deployed on eight military installations and collaborates with the DoD through the BioWatch Military-Civilian Working Group. The group has conducted six joint military-civilian exercises, and developed guidance for establishing memoranda of understanding (MOU) with local military installations to operate BioWatch monitoring on base. BioWatch provides guidance materials, and conducts exercises and training with DoD partners involved in responding to a BioWatch Actionable Result (BAR).

BioWatch and DoD are collaborating on enhancing BioWatch capabilities through various working groups and initiatives, including the Technical Coordination Working Group (TCWG), the BioAlliance, Homeland Information Biological Response Incident Demonstration (HIBRID), Joint United Forces Korea Portal and Integrated Threat Recognition (JUPTR) demonstration, and the BioWatch Laboratory Technology Refresh. The BioAlliance, a subgroup of TCWG, focuses on collaborative opportunities for biosurveillence technologies. The alliance has resulted in the identification of multiple, potential technology capability areas that could fill current BioWatch gaps. HIBRID is a joint DHS/DoD surveillance demonstration, with BioWatch as a key participant that will develop improved information sharing processes/decision support and capabilities.

In addition, BioWatch and DoD have been partnering to provide a critical layer of biodefense at special events and National Special Security Events (NSSEs), including the 2015 Papal visits, the Super Bowl, the Boston Marathon and the Republican and Democratic National Conventions. (Supported 124 events in 2014-2015).

Finally, NBIC works daily with elements of DoD such as the Armed Forces Health Surveillance Branch to examine emerging disease threats and is working with the Defense Threat Reduction Agency to deploy new collaboration and analytic tools within the Biosurveillance Ecosystem platform that will enable biosurveillance analysts from

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across the government, including DoD Armed Forces Health Surveillance Branch and HHS Assistant Secretary for Preparedness and Response, to collaboratively report on emerging biological threats identified through examination of open source and agency-specific data sets.

Question#:	18
Topic:	Blue Ribbon Study Panel Recommendation #27
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#27 - Prioritize innovation over incrementalism in medical countermeasure development.

Answer: Medical countermeasure (MCM) development has been and continues to be important for the security of our nation. The Department of Homeland Security (DHS) agrees with the Blue Ribbon Panel and supports a comprehensive national strategy that optimizes our capability in this area.

DHS is an active member of the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Led by the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR), membership is comprised of interagency partners including HHS, DHS, DoD, VA, and USDA. DHS is the lead agency responsible for conducting threat and risk assessments that are leveraged in PHEMCE requirements setting. DHS is also a key partner in PHEMCE response planning, policy, guidance, and communication. Working together, the PHEMCE partners develop overarching strategy, guidance and priorities for the enterprise.

Innovation is recognized as an important element for success in MCM development. A stated priority for the PHEMCE has been investing in basic research, discovery, early advanced development, and acquisition of current and novel MCMs. DHS supports this and will continue to work with partner agencies to ensure that the homeland security perspective, as well as the unique tools and assessments the Department provides, are leveraged to optimize our medical countermeasure enterprise.

Question#:	19
Topic:	Blue Ribbon Study Panel Recommendation #28
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

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#28 - Fully prioritize, fund, and incentivize the medical countermeasure enterprise.

Response: Our nation must have the nimble, flexible capability to produce medical countermeasures rapidly in the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional. The Department agrees with the panel recommendation that the medical countermeasure enterprise is important and investment in this area should continue.

To that end, DHS participates in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). Membership is comprised of HHS, DHS, DoD, VA, and USDA.

DHS is the lead agency responsible for conducting threat and risk assessments that are utilized during PHEMCE requirements setting. DHS is also a key partner in PHEMCE response planning, policy, guidance, and communication. DHS is charged with securing the nation from the many threats we face. These threats include natural and man-made biological, chemical, radiological, and nuclear threats. The enterprise provides member agencies to represent their equities and work collaboratively to optimize our capabilities in this key area.

Question#:	20
Topic:	Blue Ribbon Study Panel Recommendation #29
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

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#29 - Reform Biomedical Advanced Research and Development Authority contracting.

Response: The Biomedical Advanced Research and Development Authority (BARDA) is a core component of the Office of the Assistant Secretary for Preparedness and Response within the Department of Health and Human Services (HHS). DHS defers to HHS on answers to BARDA contracting questions.

Question#:	21
Topic:	Blue Ribbon Study Panel Recommendation #30
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#30 - Incentivize development of rapid point-of-care diagnostics.

Response: Development of Point-of-Need Diagnostics is a high priority for the DHS Science & Technology (S&T) Directorate. DHS programs in this specialized, niche technology area are exclusively developing assays and equipment for known and emerging biological threat agents that could be used by a terrorist against the U.S. civilian population. These assays and equipment are being evaluated for use by the Center for Disease Control and Prevention's Laboratory Response Network (LRN). Assays deployed to the LRN would be used to confirm the presence of a biological threat agent in a clinical sample while equipment and devices would be used by the USSS or FRC to test environmental samples, i.e., unknown white powders, for the presence of a threat agent. In FY16, the S&T Directorate increased funding to this area by $5 million in response to requirements identified by DHS Component activities via the new Integrated Product Team process.

Question#:	22
Topic:	Blue Ribbon Study Panel Recommendation #31
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#31 - Develop a 21st Century-worthy environmental detection system.

Response: Since the April 2014 DHS Acquisition Decision Memorandum, the DHS Science and Technology (S&T) Directorate and the Office of Health Affairs (OHA) have been collaborating to advance a plan for enhancing BioWatch technologies to increase coverage and speed of detection. Early warning of a biological attack provides critical time before symptoms manifest in the public - a critical window of time in order to dispense lifesaving medical countermeasures. These improvements are intended to advance the current "detect to treat" capability, which will further enable us to deploy medical countermeasures before the population is symptomatic. The BioWatch Program is the Nation's only biodetection capability that provides early warning and facilitates preparedness in 30+ jurisdictions deemed to be at high risk. There is no other program that provides this layer of biological defense for our most populous cities.

Together, DHS OHA's BioWatch Program and DHS S&T developed a Technology Road Map outlining near-term (1-3 years) and mid- to long-term (3+ years) BioWatch technology enhancements with an estimated deployment of near-term enhancements in Fiscal Year 2018, pending appropriate funding.

In the late fall of 2014, DHS S&T released five RFIs on technologies that can address critical BioWatch capability gaps, and a total of 56 responses were received and subsequently reviewed. In the spring/summer of 2015, Sandia National Laboratories completed a Market Survey on potential technologies that can address identified BioWatch capability gaps. The technologies identified through the Market Survey were reviewed during two Focus Group meetings held in September 2015 by eighteen BioWatch stakeholders (representing BioWatch Laboratory and Field Operations and Public Health Preparedness). The results of the RFIs, Market Survey, and Focus Group meetings were documented by Sandia National Laboratories in a final report titled: BioWatch Capability Enhancement Assessment Report in December 2015.

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BioWatch is currently conducting risk analysis and management in the acquisition process and developing realistic requirements that are linked to the BioWatch mission and capability gaps. BioWatch is currently working with DHS leadership to plan for and develop the required documentation for Acquisition Decision Event (ADE) 1, planned for fiscal year 2016. The required ADE-1 documents, including a Mission Needs Statement, a Capability Development Plan, and a cost estimate, have been completed.

In addition, improved BioWatch situational awareness tools are targeted for deployment in select jurisdictions in late Fiscal Year 2016 and subsequently across all BioWatch jurisdictions by mid to late Fiscal Year 2017.

Toward the longer term, the S&T Directorate established the Biosurveillance Apex program in FY15 in direct support of BioWatch and the National Biosurveillance Integration Center (NBIC). This Apex, planned through the end of FY22 and beyond if needed, is dedicated to developing near- and mid-term technology enhancements for each of the OHA biosurveillance programs. Other technology plans are being formulated for investments in next generation systems with the goal of providing the BioWatch program with options for continued far-term system enhancements beyond the current acquisition plans.

Question#:	23
Topic:	Blue Ribbon Study Panel Recommendation #32
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please explain what activities your Department or Agency is taking to address the select recommendations listed below from the report and note whether the activities have begun, are completed or have not yet started. Please also note recommendations that you do not intend to fulfill and why not. Please provide a response for each recommendation below that applies to your Department or Agency:

#32 - Review and overhaul the Select Agent Program.

Response: The DHS Science and Technology (S&T) Directorate is a participating member of the National Security Council's (NSC) Interagency Policy Committee (IPC) on Biological Select Agent & Toxins (BSAT). This committee is supported by a number of working groups on which S&T Directorate Subject Matter Experts (SME) participate. The BSAT IPC has developed a multi-agency approved process to review agents currently listed on the Select Agent Program, and is reviewing at least five recommendations for pathogen delisting. Candidate agent listing or delisting is supported by data from the intelligence and law enforcement communities to ensure national security objectives are met in addition to the recommendations from USG SMEs. DHS S&T Bioterrorism Risk Assessment (BTRA) tools were used to evaluate the risk to humans posed by each agent under evaluation. The BTRA incorporates the latest assessments from the IC and LE communities, and provides a comprehensive assessment of Risk. However, there is currently no systematic process or policy to evaluate agents that are on or off of the list for determining those that meet the criterion of being "a national security threat." This should be the role of the DHS CBRN Terrorism Risk Assessments, however there is currently no agreed-upon definition of what metrics should be used to define "national security threat."

Question#:	24
Topic:	Unified National Strategy
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: The Blue Ribbon Study Panel, GAO and other experts have recommended the development of a national biodefense strategy. To date, federal agencies have produced several strategic documents that address different aspects of biodefense, including the National Health Security Strategy and the National Biosurveillance Strategy. Do you believe that existing strategy and policy documents provide sufficient coordination of biodefense activities across the federal government? What elements should be included in a unified national strategy for biodefense?

Response: Existing strategic documents, such as HSPD-10 (often referred to as the "National Biodefense Strategy") and also PPD-2 "National Strategy for Countering Biological Threats," provide an effective high level framework for coordination of biodefense activities. However, as the Blue Ribbon Study Panel on Biodefense noted, clear leadership and accountability across the federal biodefense enterprise are critical in the response to a biological incident. Given the diverse range of departments and agencies involved in countering biodefense, each with its own statutory obligations and responsibilities, providing unity of federal effort is challenge that requires continual engagement and collaboration.

The bulk of the national response to a biological attack or incident will be performed by approximately 3000 state, local, territorial, and tribal (SLTT) jurisdictions. Therefore, any new or updated strategies for biodefense should take into consideration the federal government's role and ability to meet SLTT needs, including the provision of specialized resources that SLTT jurisdictions cannot fill.

Question#:	25
Topic:	Unified Budget
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: The Blue Ribbon Study Panel recommended the development of a unified budget for biodefense spending, and estimated that roughly $6 billion is spent every year on biodefense and related hazards. Please detail how much your Department or Agency spent on biodefense efforts (categorized by Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery activities, as defined by Homeland Security Presidential Directive 10) from Fiscal Years 2007-2016.

Response: The below is a table representing the funding that the Science and Technology Directorate and the Office of Health Affairs spent on biological Surveillance and Detection from Fiscal Years 2007-2015, and the funding planned for FY2016.

	S&T Fiscal Year Expenditures on Biodefense	OHA Fiscal Year Expenditures on Biodefense
2007	$306,566,402	$7,287,647
2008	$248,848,853	$85,108,000
2009	$184,018,747	$119,606,000
2010	$145,960,987	$101,113,000
2011	$144,968,954	$107,796,674
2012	$109,963,555	$121,707,000
2013	$95,984,421	$93,341,657
2014	$77,198,803	$95,277,000
2015	$92,010,501	$97,391,000
2016*	$79,565,634	$92,578,000
Total	$1,485,086,857	$921,205,978

*amount budgeted in FY16

Question#:	26
Topic:	National Biosurveillance Strategy Implementation
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: Upon the release of the National Biosurveillance Strategy in July 2012, a strategic implementation plan for the strategy was slated for completion within 120 days. What is the status of the implementation plan? Please describe how the Office of Health Affairs coordinates biosurveillance programs and policy with other federal agencies, per the National Biosurveillance Strategy. If the implementation plan has been completed, please provide it to this Committee.

Response: The National Strategy for Biosurveillance, released in July 2012, and the corresponding implementation plan were the products of an extensive interagency process reflecting DHS expertise and that of other federal departments and agencies. It represents a whole-of-government effort designed to facilitate early detection and enable ongoing situational awareness of the potential human, animal, or plant health impacts from chemical, biological, radiological, nuclear, or environmental incidents. The scope of this effort covers a range of threats, including a weapon of mass destruction or other deliberate attack, an emerging infectious disease, a pandemic, an environmental disaster, or a widespread food-borne illness. Biosurveillance capabilities provide essential information that contributes to broaden situational awareness. The Strategy's goal is to achieve a well-integrated nationwide biosurveillance capability that provides essential information quickly to inform decision-making at all levels. The implementation plan was completed on February 15, 2013, as required in the Strategy.

Within DHS Office of Health Affairs, the National Biosurveillance Integration Center (NBIC) regularly collaborates and coordinates with federal partners in the interagency community, including key public health agencies, to provide situational awareness of key biological events on a daily basis. NBIC reports provide a valuable cohesive picture, particularly for stakeholders without a biodefense mission but whose operations may be impacted by biological incidents. NBIC regularly fields requests from federal partners for information during ongoing biological incidents and delivers tailored reports for significant events requested by local partners that are evidence of ongoing demand for integrated information products that NBIC provides. NBIC leverages its governance boards (the Advisory Board and NBIC Interagency Working Group) and interagency liaisons across federal agencies, and regularly conducts surveys to federal partners to better assess its progress, improvements, and future capabilities.

DHS is glad to provide information to the Committee on Departmental actions and activities related to implementing the Strategy.

Question#:	27
Topic:	Biosurveillance Mandate
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Thomas R. Carper
Committee:	HOMELAND SECURITY (SENATE)

Question: Both the Blue Ribbon Study Panel and GAO have examined the Department of Homeland Security's mandate to integrate and analyze data relating to human, plant and animal biosurveillance, and have questioned whether the Department can fulfill that mandate due to a lack of access to the information necessary for its mission. What steps could be taken to further enhance the National Biosurveillance Integration Center's ability to carry out its mission? Is there anything Congress can do to assist in such improvements?

Response: While federal partners are often willing to share information with National Biosurveillance Integration Center (NBIC), agencies have also noted that sharing raw data presents a number of challenges including the need for personnel to interpret data, a lack of resources and the IT infrastructure, and restrictions to sharing data such as privacy concerns. NBIC is working with its partners to address these issues and facilitate information sharing to support national biosurveillance.

For example, NBIC is working with the Department of Veterans Affairs on a data sharing initiative that will help to create a de-identified, aggregated national view of disease trends for NBIC, while also facilitating understanding of those trends in our veteran population for the VA. NBIC plans to replicate this shared value model with other interagency partners to increase the integration of information across the interagency. Similarly, NBIC is working with the Department of Defense's Defense Threat Reduction Agency to deploy new collaboration and analytic tools within the Biosurveillance Ecosystem platform that will enable biosurveillance analysts from across the government, including DOD Armed Forces Health Surveillance Branch and HHS Assistant Secretary for Preparedness and Response, to collaboratively report on emerging biological threats identified through examination of open source and agency-specific data sets.

While these efforts will greatly improve the Center's ability to integrate and analyze interagency data, progress towards achieving the mission of integrated biosurveillance will be difficult to achieve without additional funding to support both the Center's operations and the operations of those federal agencies that collect and provide data related to biological threats.. In a recent report on NBIC, the Government Accountability Office also noted concerns about the imbalance between the size and nature of NBIC's mission and the resources that it had available to achieve it.

Post-Hearing Questions for the Record
Submitted to Dr. Aaron Firoved
From Senator Claire McCaskill

"Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

Question#:	28
Topic:	Material Threat Determinations
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: DHS has indicated that the Material Threat Determinations (MTD) and BioShield procurements are based on "plausible, high consequence events."

How does DHS define "plausible?" Is there a specific probability that constitutes a "plausible" event, such as 1-in-a-thousand or 1-in-a-million?

What is the involvement of the intelligence agencies in determining whether an event is plausible? Is there any requirement that such an event is being discussed within the intelligence community?

What does "high consequence" mean? Is there a specific number of possible deaths or illnesses that would trigger a procurement?

Response: "Plausible" is an indicator of relative risk or threat. That is, of all possible terrorist activities within the chemical-biological-nuclear-radiological (CBRN) threat space, plausible designates a higher probability of occurrence vs. other events. It is not possible to calculate a quantitative probability of an event, only relative ranking amongst possible events.

All MTDs and supporting analyses are dependent upon input from the intelligence and law enforcement communities. The DHS Science & Technology (S&T) Directorate maintains a strong linkage to the Intelligence Community, Federal Bureau of Investigation and U. S. Secret Service, who provide the information used to draft MTDs and the resulting Material Threat Assessments (MTA) of chemicals, toxins and pathogens. Results of the MTAs are used by the Biomedical Advanced Research and Development Authority (BARDA), a core component of the Office of the Assistant Secretary for Preparedness and Response within the Department of Health and Human

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Committee:	HOMELAND SECURITY (SENATE)

Services (HHS) for their analyses of medical countermeasures needed for the Strategic National Stockpile (SNS).

"High consequence" implies 100,000 people exposed to a chemical, biological, radiological or nuclear threat.

Question#:	29
Topic:	MTD for Ebola
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: It is my understanding that the foundation of DHS's Material Threat Assessments (MTAs) and MTDs are focused exclusively on terrorist or other foreign or domestic attacks against the U.S., not on naturally-occurring national security threats like the spread of an infectious disease from an infected person getting on a plane and travelling to the U.S., as was the case with Ebola or could be with the Zika virus.

Is that correct, and if so, please describe the plausible, high consequence scenario that resulted in an MTD for Ebola, which, based on the vast majority of medical opinion, is extremely unlikely to be weaponized.

Response: The concern with Ebola has its foundation in the U.S. and Soviet Union's biological weapons programs of the Cold War Era. Both countries had active programs in researching approaches to weaponizing Ebola and related filoviruses. While neither country was successful in achieving their goals with this pathogen, we remain worried about this virus because of the amount of press it has received during the past several years. Scenarios exist for the introduction of Ebola in the U.S. via a terrorist act. Given the public reaction to the eleven Ebola infections found in the U.S. during 2014 (7 transported from other countries for medical treatment, 4 diagnosed within the U.S.), there is concern that wide-spread panic could result if the virus were to be introduced. Therefore, preparation for this unlikely, but possible, event remains a priority.

All MTDs and MTAs are focused on materials which could be used by terrorists in Weapons of Mass Destruction (WMD) attacks; no analyses are performed for naturally occurring biological or chemical agents.

Question#:	30
Topic:	BioShield MTD
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: It is my understanding that the first step in the BioShield acquisition process is to conduct a Material Threat Assessment. On the basis of this MTA assessment, the DHS Secretary issues a Material Threat Determination. The Project BioShield Act of 2004 requires this written MTD for procurement using BioShield funds and authorities.

Am I correct that, in order to issue an MTD, an MTA must first be published, and, if so, why were MTDs were issued before MTAs were published for 11 of the CBRN threats DHS has assessed (see attached)?

Response: Under the Project BioShield Act, a material threat determination has two steps: first, the Department conducts ongoing assessments of current and emerging threats of chemical, biological, radiological, and nuclear agents; second, the Department determines which of such agents present a material threat against the U.S. population sufficient to affect national security. As a matter of DHS policy, the Department performs Material Threat Assessments to determine if a Secretarial Material Threat Determination is appropriate. However, a discrete material threat assessment of a specific agent is not required by the BioShield Act and the Secretary can make a material threat determination without an MTA for that threat. Material Threat Determinations (MTD) are issued in response to an identified threat. Upon issuance of an MTD, the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a multi-agency panel, requests that the DHS Science & Technology (S&T) Directorate's Chemical-Biological Defense Division perform analysis on specific agents of concern. This analysis is the Material Threat Assessment (MTA), which is provided to the Health & Human Services/Assistant Secretary for Preparedness & Response/Biomedical Advanced Research & Development Authority (HHS/ASPR/BARDA) for presentation to PHEMCE. An MTA is an analysis of unmitigated impact of a chemical or biological event (the Domestic Nuclear Detection Office is responsible for radiological and nuclear event scenario analyses). That is, the number of people exposed to a chemical or biological material in a variety of scenarios. BARDA performs a subsequent analysis on mitigation effects. Following an MTD, the Secretary of Health and Human Services is required to assess the potential public health consequences for the U.S. population of exposure to agents identified in MTDs, determine the agents for which countermeasures are necessary to protect the public health, assess the availability and appropriateness of specific countermeasures to address MTD threats, and determine which countermeasures are appropriate for the Strategic National Stockpile (SNS) as required by the BioShield Act of 2004.

Question#:	30
Topic:	BioShield MTD
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

An MTA is not required to issue an MTD. MTD's are written in response to information received from the intelligence and law enforcement communities on potential threats, and when available, the CBRN Terrorism Risk Assessments. Most of the MTD's and original MTA's predate the CBRN terrorism risk assessments and the original MTAs are being updated to reflect a more thorough analyses provided by DHS CBRN Terrorism Risk Assessment.. Upon issuance of an MTD, MTA's are performed to assess possible threat scenarios if a terrorist were to use chemical, biological, radiological and nuclear materials.

Question#:	31
Topic:	MTA & MTD Advisory Committees
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: I understand that there are several advisory committees that are involved in the MTA and MTD process that include non-governmental experts.

What role do these advisory committees play?

Is anyone on any of these committees associated with any of the companies that have received contracts for countermeasures that are in the strategic national stockpile, and, if so, what controls are in place to identify conflicts of interest?

Has the threat assessment process ever been audited by an outside group to see if DHS is identifying real risks and utilizing a sound methodology?

Response: The MTAs and MTDs are produced by DHS, per 42 U.S.C. § 247d-6b(c)(2), in partnership with other federal agencies, including Health & Human Services Assistant Secretary for Preparedness & Response (HHS/ASPR). Follow-on analyses are performed by HHS to provide guidance to several downstream federal government end users. The medical countermeasure needs are determined by the (HHS/ASPR)-led Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE is staffed by U. S. Government personnel from several agencies including HHS, Department of Defense (DoD), Department of Homeland Security (DHS), and Department of Veterans Affairs (VA). All members of the PHEMCE are government agencies; no individuals who are not government employees are members. The DHS S&T Bioterrorism Risk Assessment (BTRA), Chemical Terrorism Risk Assessment (CTRA), Integrated CBRN Terrorism Risk Assessment (ITRA), and MTAs are managed by U. S. Government employees. These DHS analyses are performed by a mix of government, Federally Funded Research & Development Center (FFRDC) and 501(c)(3) Non-profit Organization personnel. Interagency Working Groups for each of these DHS products provide input and guidance. DHS assembles and leads the necessary subject matter experts and analysis teams to create the MTA. These working groups have participants from all necessary government agencies to ensure an acceptable and usable product is delivered.

No representatives from private pharmaceutical or medical equipment companies participate in any of the DHS S&T processes or analyses, including MTAs.

Because of the type of classified material used to develop an MTA, there is a close-relationship with the intelligence and law enforcement communities and the information is tightly controlled and communicated at the appropriate classification levels.

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The DHS S&T BTRA was reviewed by NAS, but also GAO and another independent contracting firm. Additionally, Working Groups comprised of Federal and FFRDC stakeholders meet regularly to provide input and evaluate the data, methodology, assumptions, and results of the various CBRN Terrorism Risk Assessments. These recommendations have been incorporated into later iterations of the analyses.

An external group audit or study of the PHEMCE processes has not been performed.

Question#:	32
Topic:	Biological Threat Exposure
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: With Ebola, the President had to appoint an "Ebola Czar" in the middle of a crisis to coordinate the government's response to the outbreak when it reached the U.S. It raises some serious concerns about our current state of readiness in the event of another outbreak or terrorist event.

When there is an event in the future where United States civilians are exposed to a biological threat like Ebola, who is in charge of coordinating a response?

Who is ultimately responsible for the distribution of countermeasures?

Does responsibility change depending on the size of the event?

Response: Under Homeland Security Presidential Directive 10, "Biodefense in the 21st Century" (HSPD-10, 2004), the Secretary of Homeland Security is responsible for coordinating and leading domestic Federal operations to prepare for, respond to, and recover from biological weapons attacks, while the Department of Health and Human Services is responsible for coordinating all federal-level assets supporting the state and local medical and public health response.

Section 2801 of the PHS Act, 42 U.S.C. 300hh, as well as a number of National Strategies and Presidential Directives[2] establish the Secretary of Health and Human Services as the federal lead responsible for the protection of the health of the civilian population against both intentional and accidental or naturally occurring threats. One part of this responsibility includes coordination of medical countermeasure-related activities, including distribution, across multiple federal departments.
These responsibilities do not change depending on the size of the event.

[2] These include but are not limited to the National Strategy for Public Health and Medical Preparedness (Homeland Security Presidential Directive-21, October 2007); the National Response Framework (January 2008); the National Health Security Strategy (December 2009); and the National Preparedness Goal (Presidential Policy Directive – 8, March 2011).

Question#:	33
Topic:	Training Exercises
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: Presumably, in the case of a large-scale event, we will not have enough countermeasures to save everybody.

Are training exercises done on distribution to handle mass panic, large crowds or mobs?

Who is responsible for educating the public on what the threat is and in the case of Ebola helping to mitigate the panic that ensues from the lack of coordinated information?

Response: DHS defers the answer to this question to the Department of Health and Human Services (HHS), the federal agency charged with ensuring public health preparedness for the United States. HHS is the principal entity responsible for educating the American public on health threats.

Question#:	34
Topic:	Hearings
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Claire McCaskill
Committee:	HOMELAND SECURITY (SENATE)

Question: Too often when I have chaired hearings, I hear that witnesses from federal agencies refuse to sit on the same panel as non-federal witnesses, particularly contractors. We end up either having 2-panel hearings, which no one wants, or 2 separate hearings, which is also a waste of time and resources.

Would you be willing to sit on a hearing panel with non-Governmental witnesses?

Response: As you know, the Department of Homeland Security (DHS) receives a high volume of requests for witnesses at congressional hearings. In calendar year 2015, DHS provided 159 Department officials to testify at 114 congressional hearings. In calendar year 2016 as of Friday, May 13th, DHS provided 76 Department officials to testify at 53 hearings. Except under extraordinary circumstances, DHS observes the historical practice of not appearing with non-federal witnesses on a single panel. In making its determination, the Department considers whether such appearance would: (1) draw the DHS witness into conflicts that may compromise the legal, commercial or security interests of the United States; (2) introduce subject matter beyond the scope of the hearing or expertise of the witness; and/or (3) undermine the DHS witness' ability to communicate clearly with the Committee.

I believe in transparency and I am committed to working in strong partnership with Congress in fulfilling its important oversight role.

Post-Hearing Questions for the Record
Submitted to Dr. Aaron Firoved
From Senator Rob Portman

"Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

Question#:	35
Topic:	Deployment of Bio Detection Systems
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	Senator Rob Portman
Committee:	HOMELAND SECURITY (SENATE)

Question: One of the most concerning trends we've seen in terrorist attacks by groups like ISIS is the shift from targeting symbolic targets like we saw on 9/11 to focusing more on softer targets of opportunity like airports and concert halls, like we saw in the Paris attacks and most recently, in Brussels. My concern is that the same logic that applies to kinetic attacks using bombs and bullets also applies to an attack using chemical or biological weapons.

What specific steps are you and the National Bio-surveillance Integration Center (NBIC) taking to improve the cost effectiveness, responsiveness, and broader deployment of bio detection systems to protect the American public in these areas that are softer targets?

Response: The Department of Homeland Security (DHS) constantly monitors trends in terrorist targeting and tactics. There is the recognition that as we develop tactics and practices of our own to counter these efforts, terrorists, criminals, and violent extremists will look to adapt how they operate to defeat them. Our work is constantly evolving and we must be responsive to changes in the operating environment.

Some of the Department's programs are designed to address current and anticipated threats, while others are designed to reduce the level of risk our nation and our people face should an adversary choose a particular method or tactic. This two pronged approach to addressing the landscape is important for us to be responsive to both enduring challenges as well as evolving threats.

BioWatch is an example of a program designed to reduce risk. The program's goal is to provide early warning of a large scale attack with certain biological threat agents in high population concentration areas. Effective response to such a scenario requires adequate time to provide medical countermeasures and treatment to those affected. Knowing of an

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Committee:	HOMELAND SECURITY (SENATE)

attack prior to symptoms of illness presenting in people provides us the best chance of providing timely treatment and saving the most lives.

In response in part to changes in thought about threat and how best to support decision makers at the local level, there has been increasing interest in operating environmental detection capabilities in indoor environments, especially transportation hubs and large public event venues. The Department works with thought leaders in the public health and medical community, as well as with partners across the federal government to ensure that DHS's work in environmental detection is an effective part of overarching national biodefense and remains responsive to changes in the threat environment while continuing to support the reduction in risk it affords.

Biosurvelliance is a key layer of national biodefense. The National Biosurveillance Integration Center (NBIC) seeks to coordinate and disseminate key biosurveillance information to federal, state, local, tribal, and territorial (SLTT) communities. NBIC monitors, integrates, and analyzes information to identify and provide situational awareness of not only naturally occurring diseases outbreaks and emerging infectious diseases but also potential bioterrorism-related incidents. And while NBIC is designed to primarily identify biological threats, it also serves to monitor accidental or intentional use of chemical agents and associated effects on animals and people around the globe. NBIC utilizes access to Intelligence Community (IC) information as well as law enforcement information, and travel and trade information to provide context to traditional biosurveillance information.

NBIC is also exploring opportunities for enhanced collaboration and feedback from SLTT and private sector partners. NBIC is working with partners who integrate and analyze state and local data sets, like Emergency Medical Services, 911, and poison control center data, for possible early indicators of disease trends and biological incidents. This effort targets development of grass roots biosurveillance capabilities that can be networked across the country, inclusive of communities not traditionally considered "iconic" targets.

Question#:	36
Topic:	BioWatch Gen-2 GAO Report
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	Senator Rob Portman
Committee:	HOMELAND SECURITY (SENATE)

Question: What efforts are being undertaken by the Department to address the recommendations of the recent GAO report of 23 October 2015 on the lack of effectiveness of the current BioWatch Gen-2 system?

Response: DHS does not necessarily concur with the characterizations of the BioWatch system. The effectiveness of the system has been affirmed in multiple ways. The Program's detection capabilities have been independently tested and validated by 4 testing events conducted over the last 5 years, including testing in a laboratory, in an aerosol chamber environment, and in an open air environment. The operational demonstration conducted by the Naval Surface Warfare Center (NSWC) successfully confirmed that the BioWatch operational system can detect an intentional aerosol release of a biological simulant in an operationally relevant (semi-urban) environment. The cumulative results of all tests reinforce the Department's confidence in the system's ability to perform the mission for which it was intended: detecting a large-scale aerosol release of specific threat agents in our most populous cities.

Last year the BioWatch Program analyzed over 237,000 samples from across all BioWatch jurisdictions, with 8 detections that qualified as a BioWatch Actionable Result. Detections that occurred in the Denver jurisdiction correctly correlated with a recent uptick in Tularemia (human and animal cases), a disease that can be naturally occurring in some parts of the United States. The accuracy of the BioWatch data is further affirmed by the BioWatch Quality Assurance (QA) program. The QA program has analyzed over 35,800 QA samples since 2011, enhancing defensibility and confidence in the results.

Though DHS does not concur with the GAO's characterizations of BioWatch, DHS does concur with the four recommendations made by the GAO. The four recommendations are:

1. Establish technical performance requirements, including limits of detection necessary for a biodetection system to meet a clearly defined operational objective for the BioWatch program by detection attacks of defined types and sizes with specific probabilities.
2. Assess the Gen-2 system against these performance requirements to reliably establish its capabilities.
3. Produce a full accounting of statistical and other uncertainties and limitations in what is known about the system's capability to meet its operational objectives.

Question#:	36
Topic:	BioWatch Gen-2 GAO Report
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	Senator Rob Portman
Committee:	HOMELAND SECURITY (SENATE)

4. To help reduce the risk of acquiring immature detection technologies…use the best practices outlined in this report to inform test and evaluation actions for any future upgrades or changes to technology for BioWatch.

BioWatch has engaged 3 national laboratories to address the recommendations. The national laboratories have completed the following:

- Identify and define an alternate BioWatch system performance measure other than *Fraction of Population Covered* (Fp) *(Addresses GAO Rec. 1 and 2).*
- Develop a model for the alternate performance measure and run it using current BioWatch system performance parameters - the result of the modeling expanded upon previously conducted BioWatch system performance assessments and should yield a specific measurement for each jurisdiction *(Addresses GAO Rec. 1 and 2).*
- Develop and document the new program performance measure, modeling and outcomes, and provide a description of uncertainties and limitations associated with BioWatch Program measures *(Addresses GAO Rec. 2 and 3).*

In addition, the DHS Science and Technology Directorate (S&T) Director for Test and Evaluation is currently evaluating all test and evaluation conducted of the current system to date in order to identify any potential gaps in the BioWatch approach. The Program has and will continue to adhere to acquisition management guidance provided by DHS, and is ensuring that the recommended best practices are incorporated into its approach and documentation (*Addresses GAO Rec. 4).*

Question#:	37
Topic:	Next Generation Bio Detectors
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	Senator Rob Portman
Committee:	HOMELAND SECURITY (SENATE)

Question: What efforts is the Science & Technology Directorate (S&T) pursuing to leverage existing testing and evaluation by DoD to more rapidly and cost-effectively field next generation Bio detectors that could be incorporated into the BioWatch system?

Response: The DHS Science & Technology (S&T) Directorate has established working relationships with the DoD Joint Program Executive Office for Chemical & Biological Defense (JPEO (CBD)) and the Defense Threat Reduction Agency (DTRA) J9 Chemical and Biological Technologies Department. Test & Evaluation (T&E) information from the JPEO program on biological detectors is shared with the DHS S&T Directorate. The primary source of information is the DoD's Joint U.S. Forces Korea (USFK) Portal & Integrated Threat Reduction (JUPITR) Advanced Technology Demonstration. JUPITR has provided the foundation for many of the planned near-and mid-term acquisitions for BioWatch. In turn, DHS has provided the DoD with information and lessons-learned from BioWatch to further enhance the military's biosurveillance programs. A notable example of the DHS-DoD partnership is the joint DHS-DoD-EPA HIBRID Program which is developing requirements for a national systems architecture for biosurveillance and response. For far-term system improvement options, the S&T Directorate has a strong partnership with DTRA J9 with the goal of leveraging investments in technology development programs.

Post-Hearing Questions for the Record
Submitted to Dr. Aaron Firoved
From Senator Tammy Baldwin

"Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

Question#:	38
Topic:	Wildlife Disease Surveillance
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Tammy Baldwin
Committee:	HOMELAND SECURITY (SENATE)

Question: The Blue Ribbon Study Panel on Biodefense cited the need for implementing optimal surveillance and detection techniques, requiring a nationwide array of sensors and detectors at many levels, to rapidly detect emerging diseases, including those in wildlife. The USGS National Wildlife Health Center has been conducting wildlife disease surveillance for over 40 years with state, federal and tribal partners. How can wildlife disease surveillance efforts become more effective? Does DHS coordinate efforts to conduct active, designed surveillance among high-risk wildlife populations across our nation?

Response: While DHS does not coordinate these efforts, the National Biosurveillance Integration Center (NBIC)'s mission is to integrate and analyze a variety of information sources, including information collected from the animal and wildlife domains. In order to more effectively provide situational awareness on wildlife issues, NBIC has a liaison at the U.S. Geological Survey's National Wildlife Health Center in Madison, Wisconsin. NBIC also has a liaison at USDA that provides surveillance information. These liaisons contribute to the daily operations and analysis activities at NBIC and provides important information on biosurveillance events involving wildlife, such as Highly Pathogenic Avian Influenza.

In addition, the Science and Technology Directorate is funding the development of an Enhanced Passive Surveillance system, which will enable the collection of animal health surveillance data from the livestock and wildlife sectors. While DHS does not control the missions of other agencies, we are working to design a system that will meet their diverse animal health surveillance needs so that all data can be collected in the same system and viewed in a holistic manner. This will greatly enhance the effectiveness of our federal animal health surveillance picture. This project is guided by an Interagency Project Team with members from USDA APHIS (both Wildlife and Veterinary Services), DHS Office of Health Affairs, USGS, and the Department of Defense.

Question#:	39
Topic:	National Biosurveillance Integration Center
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Tammy Baldwin
Committee:	HOMELAND SECURITY (SENATE)

Question: The Blue Ribbon Study Panel also emphasized the need for partnerships and active data sharing to bolster biodefense mechanisms in the US. It also recognized the National Biosurveillance Integration Center (NBIC) and identified potential mechanisms to make NBIC more effective. Several federal agencies actively collaborate with NBIC (including the USGS National Wildlife Health Center) by providing interagency liaisons that afford domain expertise and facilitate information transfer. How can agencies better collaborate to bolster the effectiveness of NBIC to provide a centralized repository for collection, analysis and distribution of national biosurveillance data? What additional capacity and resources at the National Wildlife Health Center are needed to serve the mission of the NBIC?

Response: The National Biosurveillance Integration Center (NBIC) works closely with its interagency partners on a daily basis to gather relevant information and provide shared situational awareness. The Center leverages its governance boards (the Advisory Board and NBIC Interagency Working Group) to identify and address operational, programmatic, and scientific challenges that face NBIC. Federal partners from 14 agencies are represented and participate in the governance process.

Although NBIC works closely with its partners, agencies could bolster the effectiveness of NBIC through providing liaisons that would help connect the Center to important interagency subject matter expertise, data and information, and resources. In addition, the Center is working with agencies to identify opportunities for its partners to share relevant data sources that would facilitate a One Health approach to emerging disease detection and situational awareness. Lastly, NBIC is working to build a number of tools and capabilities that will help facilitate better collaboration and information sharing across the interagency. NBIC partner participation in the development and use of these capabilities will ensure maximum benefits to the Center and its partners.

Post-Hearing Questions for the Record
Submitted to Dr. Aaron Firoved
From Senator Kelly Ayotte

"Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

Question#:	40
Topic:	First Responder Anthrax Preparedness Act
Hearing:	The Federal Perspective on the State of Our Nation's Biodefense
Primary:	The Honorable Kelly Ayotte
Committee:	HOMELAND SECURITY (SENATE)

Question: Recommendation 15 of the Blue Ribbon Commission's report reads, in part: "Provide emergency services providers with the resources they need to keep themselves and their families safe. This will fulfill the Nation's commitment to these professionals while also helping to ensure their participation in the event of a biological emergency." One "action item" listed is: "Provide vaccines to first responders who request them. The Secretary of Homeland Security must ensure that the DHS pilot program to provide emergency service providers with anthrax vaccines is implemented. The Secretary should make doing so an immediate priority. If successful, the Secretary should formalize the program and extend it to meet other threats."

I've introduced a bill to better support our first responders in just this way. The First Responder Anthrax Preparedness Act, which Senator Booker joined me in introducing, would direct the Secretary of Homeland Security, in consultation with the Secretary of Health and Human Services, to carry out a pilot program to provide short dated vaccines from the Strategic National Stockpile to emergency response providers on a voluntary basis.

How will this legislation help you better prepare and support the first responder community?

Response: After an anthrax attack, first responders may find themselves having to react immediately to the incident before complete information is available, which may increase their risk for exposure. Pre-event voluntary anthrax vaccinations will help reduce the risk and strengthen first responder preparedness and protection.

Since 1998, anthrax vaccine has been used primarily by the Department of Defense (DoD) to protect military forces from weaponized anthrax as part of the DoD mandatory Anthrax Vaccine Immunization Program. The intentional distribution of anthrax in the

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U.S. in 2001 demonstrates the importance of also providing the same opportunity for first responders to protect themselves against an anthrax attack. However, although the anthrax vaccine has been licensed for pre-event use in the U.S. since the 1970s, it is not available for purchase by first responders who want to be vaccinated because the bulk of the vaccine is purchased by the federal government and stored in the Strategic National Stockpile as a medical countermeasure to protect the public against an anthrax attack.

The First Responder Anthrax Preparedness Act will provide authorities for the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, to release and provide anthrax vaccine nearing the end of its labeled dates of use from the Strategic National Stockpile (SNS) to a few participating states (2-5) in support of a pre-event voluntary anthrax vaccine pilot among first responders.

The specific aims of the Anthrax Vaccine Pilot are: (1) to evaluate the feasibility of a voluntary pre-event anthrax vaccine program in first responder communities; and (2) to evaluate the acceptance of pre-event anthrax vaccinations among individual first responders.

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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May 27, 2016

The Honorable Ron Johnson
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate

The Federal Perspective on the State of Our Nation's Biodefense: Responses to Posthearing Questions for the Record

Dear Mr. Chairman:

On April 14, 2016, I testified before the United States Senate Committee on Homeland Security and Governmental Affairs on the challenges the nation faces in building and maintaining biodefense and biosurveillance.[1] This letter responds to the questions for the record that were submitted for the official record from the hearing. The responses are based on work associated with our previously issued products, as described in the enclosure. Your questions and my responses are enclosed.

If you have any questions about this letter or need additional information, please contact me at (404) 679-1875 or curriec@gao.gov.

Sincerely yours,

Chris P. Currie

Chris P. Currie
Director, Homeland Security and Justice

Enclosure

[1]GAO, Biodefense: *The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance, GAO-16-547T, (Washington, D.C., Apr. 14, 2016).*

Post-Hearing Questions for the Record
Submitted to Mr. Chris Currie
From Senator Thomas R. Carper

"The Federal Perspective on the State of Our Nation's Biodefense"

April 14, 2016

1. **In its 2011, the General Accounting Office reported that there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise and recommended that the Homeland Security Council consider establishing a focal point to oversee these efforts. The number one recommendation included in the Bipartisan Report of the Blue Ribbon Study Panel on Biodefense is to institutionalize biodefense in the Office of the Vice President of the United States to ensure that biodefense will be addressed by every Administration at the highest levels. The second recommendation is to establish a Biodefense Coordination Council at the White House, led by the Vice President.**

    a. **Do you support establishing one individual or entity to coordinate these efforts or think that the existing structure is sufficient?**

We continue to believe that an entity with sufficient time, resources, and authority to provide strategic oversight across the enterprise—including by tracking total spending and aligning budget requests with priorities identified in a national strategy—would enhance assurance that biodefense investments are both effective and efficient. However, we have not independently evaluated any specific leadership models Therefore, we cannot comment on the appropriateness of institutionalizing leadership in the Office of the Vice President.

Because the nation cannot afford to protect everything against all threats, choices must be made about protection priorities given the risk and how to best allocate available resources. Currently, neither the Office of Management and Budget nor the federal agencies account for biodefense spending across the entire federal government. Because responsibilities are dispersed across a multitude of federal agencies and oversight is dispersed across Congressional committees, no one has visibility over how much is being spent, much less whether investments—in routine operations, nonfederal capabilities, crisis response, and major acquisitions and research agendas—respond to the highest priorities and align across the four pillars of biodefense.[1] A focal point that was managing to robust national strategy (one that addresses each of the elements we have prescribed for effective national strategies) would be

[1]The four biodefense pillars are (1) threat awareness, (2) prevention and protection; (3) surveillance and detection; and (4) response and recovery.

in a position to create and sustain mechanisms and provide better information to help executive and legislative decision makers ensure alignment across federal biodefense investments.[2]

That is not to say, however, that the biodefense enterprise is completely void of leadership and coordination. We are encouraged by reports from senior federal officials with key biodefense roles, that they believe they have benefited from coordination activities undertaken to carry out select mission responsibilities. For example, in 2011, representatives from the Department of Homeland Security (DHS) and Health and Human Services (HHS) testified before this committee that they routinely work together on preparedness and response activities. Specifically, HHS's Assistant Secretary for Preparedness and Response noted that DHS officials help determine priorities for medical countermeasure development by participating on the interagency coordination body—Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). She also noted that ongoing interagency coordination had enhanced their ability to work through plans and operational responses during crisis. Similarly, during this committee's April 2016 hearing on Biodefense, Dr. Hatchett testified that there are effective cross government mechanisms in place to ensure that threats can be identified and responded to appropriately, and he also pointed to the PHEMCE as a positive example of interagency coordination.

Nevertheless, we remain concerned that, without a single entity with strategic oversight of national biodefense efforts, fragmentation exists within and particularly across the four biodefense pillars—(1) threat awareness, (2) prevention and protection; (3) surveillance and detection; and (4) response and recovery. The biological threat landscape is complex and multifaceted. Biological threats that could result in catastrophic consequences exist in many forms—for example viruses can be transmitted through the air, by insects, in body fluids, and by contact with objects or materials such as clothes, utensils, and furniture. Diseases that infect humans can be carried and transmitted by other humans, in food, in water, by domestic food animals, and by wildlife. Diseases that infect animals can inflict catastrophic economic consequences, sometimes without infecting a single human. Biological threats also arise from multiple sources—for example, we have recently seen how Ebola and Zika virus outbreaks have had serious global consequences; while our enemies, like the Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) have advocated for the use of biological weapons.

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[2] *GAO, Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism,* GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

Naturally occurring outbreaks and intentional attacks can vary in size and other key characteristics that change the nature of preparedness and response.

Weaknesses in the linkages between any two of the pillars undermine the effectiveness of the intended effort within each pillar. For our nation's biodefense to be strongest, we need to look collectively across the pillars of biodefense, not only for individual programs or efforts, but across the entire biodefense enterprise to identify and address gaps. Our body of work on DHS's BioWatch program serves as concrete example of the need for alignment across the biodefense pillars. The BioWatch program is designed to detect a catastrophic aerosolized bioweapon attack. We found in 2012 that in pursuing a new generation of BioWatch detectors that would reduce the time to detect a release, DHS did not follow its own established acquisition policies, which were designed to ensure that significant investments are based on a well-considered mission need and consider multiple solutions to meet that need in the most cost effective manner possible. We recommended that DHS revisit the mission need and the alternatives, fully exploring costs and benefits, before proceeding with that project. When DHS did so, it canceled the acquisition because its analysis of alternatives did not confirm an overwhelming benefit to justify the cost.

When we made this recommendation in 2012, we also reported that beyond uncertainty related to the costs and benefits of the planned approach, there was additional uncertainty about the benefit of this kind of environmental monitoring that BioWatch detectors provide because as a risk mitigation activity it has a relatively limited scope. In 2011, a report from the National Academies' evaluation of BioWatch noted that there is considerable uncertainty about the likelihood and magnitude of a biological attack, and how the risk of a release of an aerosolized pathogen compares with risks from other potential forms of terrorism or from natural diseases.[3] The National Academies also called for the BioWatch program to have a better understanding of how any changes it would make to the program would be expected to reduce mortality or morbidity in conjunction with clinical case finding and public health. Similarly, we found in October 2015, there is uncertainty in the technical capabilities of the current deployed BioWatch detectors' ability to detect biological attacks of various types and sizes, which could potentially undermine its purpose as an early warning system. When contemplating significant investments in detection technologies like the next generation of BioWatch or in any other resource intensive

[3]See Institute of Medicine and National Research Council, *BioWatch and Public Health Surveillance,* 2011.

programs, it is important for the entire enterprise to have the best available information about threat characteristics and common understanding of what the highest priority risks are—information that comes out of the threat awareness pillar.

Similarly, investments in the surveillance and detection and the response and recovery pillars should align with the threat awareness pillar, so that based on threat information the nation can detect what it is prepared to treat and can treat what it has invested in detecting. In the BioWatch program example, as outlined in Homeland Security Presidential Directive-10, once a biological weapons attack is detected, the speed and coordination of the Federal, state, local, private sector, and international response will be critical in mitigating the lethal, medical, psychological, and economic consequences of such attacks. As we described in October 2015, because there are so many partners that must come together to initiate a response protocol, there is uncertainty in the life saving benefits of early warning systems, like BioWatch. Once an alleged attack is initially detected and before the dissemination of medical countermeasures, decisions must be made regarding the characterization of the incident, determine who was exposed, make decisions regarding evacuation of contaminated regions and relocation of individuals, determine where to set up medication "points of dispensing" and to actually mobilize the medication stockpile, and distribute medication to potentially exposed people and keep track of who received medication. Finally, and perhaps most importantly, in order to maximize the lifesaving benefits of an early detection system, like Biowatch, there must be a stockpile of medical countermeasures to disseminate that correspond to the threats the system is designed to detect. The Biowatch program is just one example to illustrate the need for an entity to have the visibility and provide the authority necessary to help ensure the alignment of priorities and investments across all four biodefense pillars.

b. How else could we improve coordination across the government in biodefense activities?

As part of a national biodefense strategy or apart from it, a better shared understanding of what constitutes a national biodefense capability may help improve federal biodefense coordination. In 2011, the DHS Undersecretary for Science and Technology testified in a hearing about biodefense before this committee that the nation needs to have an agile capacity to assemble and reassemble capabilities, and it needs to get very efficient to do that. Although DHS and HHS each employ capabilities-based investment in grants programs for their state and local partners that include key biodefense-related activities, there is no crosscutting definition for

federal biodefense capabilities; nor is there such a framework within any of the four biodefense pillars. The lack of clearly defined capabilities may limit federal agencies' ability to plan, train, and exercise to assemble and reassemble capabilities, as described by the DHS Undersecretary, in a way that best prepares the nation to respond to whatever aspect of the diffuse uncertain set of biological threats manifests. Moreover, it may complicate attempts to understand what investments have been made and where additional investments are required, because there may not be governmentwide agreement on the exact activities that qualify as biodefense activities. Moreover, it makes it more difficult for federal agencies to assess where there are gaps or potentially unnecessarily redundant activities across the federal biodefense enterprise.

2. **In its final report, the Blue Ribbon Study Panel issued more than 33 recommendations for action by the Executive Branch. Please provide any feedback or analysis you may have on the Panel's recommendations listed below and whether they could or should be implemented by the relevant Departments or Agencies:**
    a. **#4 – Unify biodefense budgeting.**
    b. **#6 – Improve management of the biological intelligence enterprise.**
    c. **#7 – Integrate animal health and One Heath approaches to biodefense strategies.**
    d. **#8 – Prioritize and align investments in medical countermeasures among all federal stakeholders.**
    e. **#9 – Better support and inform decisions based on biological attribution.**
    f. **#10 – Establish a national environmental decontamination and remediation capacity.**
    g. **#11 – Implement an integrated national biosurveillance capability.**
    h. **#12 – Empower non-federal entities to be equal biosurveillance partners.**
    i. **#13 – Optimize the National Biosurveillance Integration System.**
    j. **#14 – Improve surveillance of and planning for animal and zoonotic outbreaks.**
    k. **#15 – Provide emergency responders with the resources they need to keep themselves and their families safe.**
    l. **#16 – Redouble efforts to share information with state, local, territorial, and tribal partners.**
    m. **#18 – Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.**
    n. **#22 – Develop and implement a Medical Countermeasure Response Framework.**
    o. **#23 – Allow for forward deployment of Strategic National Stockpile assets.**
    p. **#24 – Harden pathogen and advanced biotechnology information from cyber attacks.**
    q. **#26 – Implement military-civilian collaboration for biodefense.**

r. **#27 – Prioritize innovation over incrementalism in medical countermeasure development.**
s. **#28 – Fully prioritize, fund, and incentivize the medical countermeasure enterprise.**
t. **#29 – Reform Biomedical Advanced Research and Development Authority contracting.**
u. **#30 – Incentivize development of rapid point-of-care diagnostics.**
v. **#31 – Develop a 21st Century-worthy environmental detection system.**
w. **#32 – Review and overhaul the Select Agent Program.**

We have not systematically evaluated each of the Study Panel's recommendations and cannot speculate on whether or not they should be or could be implemented. We can, however, offer insights based on our larger body of biodefense-related work over the past decade in several of the areas that the Study Panel's recommendations touch upon. In some cases, our findings are similar to those made by the Study Panel. In other cases, we highlight challenges and our own recommendations in topics covered by the Study Panel recommendations. As noted in our April 2016 testimony statement, we identified several similar observations made by the Study Panel's report that mirror findings in our prior biodefense work.

Leadership of the Biodefense Enterprise

Our findings about the need for leadership of the biodefense enterprise mirror the Study Panel's findings; however, we have not assessed any specific leadership models and cannot comment on the appropriateness of the Study Panel's recommendation to institutionalize leadership in the Office of the Vice President.

The Biosurveillance Strategy

Much like with biodefense, the nation faces key challenges with biosurveillance that transcend what any one agency can address on its own. We have identified challenges at all levels of government related to the nation's ability to detect and respond to biological events.[4] In June 2010, we found that there was no integrated approach to help ensure an effective national biosurveillance capability and to provide a framework to help identify and prioritize investments.[5] We recommended the Homeland Security Council (HSC) establish a focal point to lead the development of a national biosurveillance strategy that clarifies roles and responsibilities, provides goals and performance measures, and identifies resource and investment needs, among other elements. The July 2012 *National Strategy for Biosurveillance* did not fully meet

[4]See GAO-10-645; GAO-12-55; GAO-15-793; and GAO-16-99.
[5]GAO-10-645.

the intent of our recommendation because, among other things, it did not provide the mechanism we recommended to identify resource and investment needs, including investment priorities. Subsequent to the release of the strategy, the National Security Council (NSC) staff published a companion implementation plan, but it is not yet clear the extent to which the plan has been widely shared among and adopted by interagency decision makers as a means to help identify opportunities to leverage resources and direct priorities. This may be why in October 2015, the Study Panel report called for the finalization and release of the implementation plan for the *National Strategy for Biosurveillance*.

The *National Strategy for Biosurveillance* also does not address issues we raised related to state and local biosurveillance efforts, and on which we previously made recommendations. In October 2011, we reported that nonfederal capabilities should also be considered in creating a national biosurveillance strategy. Because the resources that constitute a national biosurveillance capability are largely owned by nonfederal entities, a national strategy that considers how to strengthen and leverage nonfederal partners could improve efforts to build and maintain a national biosurveillance capability. While the size, variability, and complexity of the biosurveillance enterprise makes an assessment difficult, we concluded in our October 2011 report that the federal government would lack key information about the baseline status, strengths, weaknesses, and gaps across the biosurveillance enterprise until it conducts such an assessment. To address these issues, and building on our June 2010 recommendation to develop a national biosurveillance strategy, we recommended for such a strategy to (1) incorporate a means to leverage existing efforts that support nonfederal biosurveillance capabilities, (2) consider challenges that nonfederal jurisdictions face, and (3) include a framework to develop a baseline and gap assessment of nonfederal jurisdictions' capabilities. However, the July 2012 strategy did not adequately address the issues we raised related to state and local biosurveillance and acknowledged but did not meaningfully address the need to leverage nonfederal resources.

In October 2015, the Study Panel report also called for empowering non-federal entities to become equal biosurveillance partners. While the Study Panel report called for an interagency biosurveillance planning committee to be the nexus for active collaboration with non-federal government and non-governmental partners, we have not evaluated any specific mechanisms for carrying out our 2011 recommendation.

Biosurveillance Integration and Environmental Detection

In 2015, we identified persistent challenges related to two of DHS's biosurveillance capabilities, the National Biosurveillance Integration Center (NBIC) and the BioWatch program.[6] We reported in 2009 that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel—from its partner agencies, which may have been at least partially the result of collaboration challenges it faced.[7] In order to help NBIC enhance and sustain collaboration, including the provision of data, personnel, and other resources, in 2009, we recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. In August 2012, NBIC issued the NBIC Strategic Plan, which is intended to provide NBIC's strategic vision, clarify the center's mission and purpose, articulate the value that NBIC seeks to provide to its partners, and lay the groundwork for setting interagency roles, responsibilities, and procedures.

Although NBIC had made efforts to collaborate with interagency partners to create and issue a strategic plan that would clarify its mission and the various efforts to fulfill its roles, we reported a variety of challenges that remained when we surveyed NBIC's interagency partners for our 2015 report. Notably, many of these partners continued to express uncertainty about the value NBIC provided. NBIC officials stated that the center is working to improve its products and its ability to contextualize the information it collects from open sources, and has sought partner input to do so. Nevertheless, a persistent challenge NBIC faces is skepticism on the part of some of the NBIS partners regarding the value of the federal biosurveillance mission as well as NBIC's role in that mission. In September 2015, the NBIS partners and other major stakeholders in the biosurveillance community acknowledged—and we agreed—that no single problem limits NBIC's mission to integrate biosurveillance data. Rather, over the years, several long-standing problems have combined to inhibit the achievement of this mission as envisioned in the 9/11 Commission Act.

In October 2015, the Study Panel report also highlighted challenges to biosurveillance integration and data sharing. The report called for an assessment to determine the viability of NBIS as the primary integrator of biosurveillance information and recommended that the NSC convene data owners and stakeholders to evaluate incentive options for data sharing. We have

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[6]See, GAO-15-793 and GAO-16-99.

[7]GAO-10-171.

not evaluated the Study Panel's specific recommendations, but in our 2015 report, we identified options for policy or structural changes that could help better fulfill the biosurveillance integration mission.[8] More detail on these options and their benefits and challenges is in our September 2015 report.[9]

Regarding environmental detection, the Study Panel report noted that the nation continues to lack a rapid and reliable environmental detection system for known and unknown biological threats, and called for the development of one to replace the current DHS BioWatch detectors. In October 2015, we reported on the uncertainty of the technical capabilities of the BioWatch program detectors' ability to detect biological attacks of various types and sizes. We found DHS lacks reliable information about the current BioWatch system's (Gen-2) technical capabilities to detect a biological attack, in part, because in the 12 years since BioWatch's initial deployment, DHS has not developed technical performance requirements for Gen-2.[10]

The reason it is critical to have a clear understanding of Gen-2's technical capabilities is to inform the next steps, including those suggested by the Study Panel report. At the time DHS canceled the acquisition of a next generation of BioWatch in April 2014, it also announced that the Science and Technology Directorate (S&T) will explore development and maturation of an effective and affordable automated aerosol biodetection capability, or other operational enhancements, that meet the operational requirements of the BioWatch system. As such, DHS officials told us they are considering potential improvements or upgrades to the Gen-2 system. However, because DHS lacks reliable information about Gen-2's technical capabilities, decision makers are not assured of having sufficient information to ensure future investments are actually addressing a capability gap not met by the current system.

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[8]We identified these options and their benefits and limitations, on the basis of the roles of a federal-level biosurveillance integrator we identified in the 9/11 Commission Act, NBIC's strategic plan, and the perspectives of the NBIS partners obtained using structured interviews. The options we identified are not exhaustive, and some options could be implemented together or in part. In developing these options, we did not evaluate the financial implications of implementing each option, to the extent they are knowable, but we acknowledge they are likely to result in an increase, decrease, or shifting of funding based on the changes described.

[9]GAO-15-793

[10]GAO-16-99. See also Institute of Medicine and National Research Council, *BioWatch and Public Health Surveillance* (Washington, D.C.: National Academies Press, 2011).

In our October 2015 report, to help ensure that biosurveillance-related funding is directed to programs that can demonstrate their intended capabilities, and to help ensure sufficient information is known about the current Gen-2 system to make informed cost-benefit decisions about possible upgrades and enhancements to the system, we recommended that DHS not pursue upgrades or enhancements to the current BioWatch system until it establishes technical performance requirements necessary for a biodetection system to meet a clearly defined operational objective for the BioWatch program; assesses the Gen-2 system against these performance requirements; and produces a full accounting of statistical and other uncertainties and limitations in what is known about the system's capability to meet its operational objectives. DHS concurred and is taking steps to address the recommendation. We believe that despite the age of the Gen-2 system and its manual detection process which the Study Panel report noted, more information is needed to make informed decisions about upgrades to or enhancements of the current BioWatch system.

One Health Approach and Surveillance of Animal and Zoonotic Outbreaks

While we have not made any direct recommendations along the lines of those regarding the One Health concept in the Study Panel report, we have reported over the past decade on the importance of agencies working together to address a common outcome. As the One Health concept recognizes, human and animal diseases are interconnected. For example, in 2010 we reported that the Animal and Plant Health Inspection Service (APHIS), Customs and Border Protection (CBP), Centers for Disease Control and Prevention (CDC), and Fish and Wildlife Service (FWS) have engaged in strategic planning that recognizes the need for joint efforts to reduce the risks of zoonotic and animal diseases from live animal imports. As we have previously reported, federal agencies can use their strategic and annual performance plans as tools to drive collaboration with other agencies and partners and establish complementary goals and strategies for achieving results.[11] While the agencies' strategic planning addresses some concerns about the disease risk from live imported animals, it does not specify how they will collaborate to address the risk of disease from live animal imports. In particular, experts responding to our survey noted that because each of the agencies is focused on a different aspect of live animal imports, no single entity has comprehensive responsibility for the zoonotic and animal diseases risks posed by live animal imports. As one expert noted, the principal barrier to collaboration is agencies' "failure to take a broader view of the entire importation

[11]GAO-06-15.

process," focusing instead on only those components of the process each agency controls under its statutory authority. As we have previously reported, when agencies do not have a compelling rationale, such as legislation, directives, or their perceptions of the benefits from collaboration, it is difficult to overcome differences in missions and priorities and to define and articulate a common outcome that is consistent with their respective agency missions. Although we made recommendations to the relevant agencies to strengthen collaboration on the importation of animals, not all were implemented.[12]

In May 2013, we also reported on efforts the U.S. Department of Agriculture (USDA) started to take to advance animal health surveillance.[13] However, we noted that USDA had not integrated its efforts into an overall strategy with associated goals and performance measures that are aligned with the nation's larger biosurveillance efforts. For example, the APHIS had begun broadening its previous disease-by-disease approach to disease surveillance to one in which the agency monitors the overall health of livestock and poultry and uses additional sources and types of data to better detect and control new or reemerging diseases. However, we found that none of the planning documents related to this effort indicate how they individually or collectively support national homeland security efforts called for in Homeland Security Presidential Directive 9, which assigns several federal agencies, including USDA, responsibility for establishing a comprehensive and coordinated surveillance system to support early detection of biological threats, including infectious diseases. Without integrating its vision into an overall strategy with goals and measures aligned with broader national homeland security efforts to detect biological threats, APHIS may not be ideally positioned to support national efforts to address the next threat to animal and human health. We recommended that APHIS integrate its surveillance approach with an overall strategy that guides how its new approach will support national homeland security efforts to enhance the detection of biological threats. However, while the agency agreed, this recommendation has not been implemented.

Finally, USDA has drafted guidance for responding to emerging animal diseases and has proposed a comprehensive list of animal diseases that must be reported by anyone with

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[12]GAO-11-9

[13]GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry*, GAO-13-424 (Washington, D.C.: May 21, 2013)

knowledge of the diseases.[14] The draft guidance describes USDA's goals for addressing emerging diseases as to (1) undertake global awareness of, assessment of, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications; (2) detect, identify, and characterize disease events; (3) communicate findings and inform stakeholders; and (4) respond quickly to minimize the impact of disease events. However, USDA has not defined roles and responsibilities or criteria for actions that are included in its response to emerging diseases. We made recommendations to help improve USDA's ability to respond to and protect against future emerging animal diseases, and USDA generally agreed with the recommendations.

Medical Countermeasures and the Strategic National Stockpile

In October 2011, we reported on HHS's and PHEMCE's efforts to develop and procure priority medical countermeasures and found that some improvements were needed for HHS to effectively oversee these efforts.[15] For example, we found that HHS lacked an adequate strategy to monitor the implementation of recommendations from its 2010 PHEMCE review. We also found that HHS had not yet updated the first PHEMCE implementation plan containing its chemical, biological, radiological, and nuclear (CBRN) countermeasure procurement priorities, published in 2007, even though HHS had planned to update it biennially. We recommended that the department update the plan, include more specific information about anticipated spending, and strengthen its oversight of how HHS was implementing certain activities intended to enhance PHEMCE. HHS agreed with our overall recommendations, but did not fully address all of them. For example, while HHS developed the PHEMCE Multi-year Budget for Fiscal Years 2014-2018, HHS officials told us that it does not plan to make the multi-year budget document publicly available because of national security concerns. We believe that the transparency of budget information is necessary for medical countermeasure developers to make investment decisions, and we recommended inclusion of this information in the strategy and implementation plans for this purpose.

In 2014, we also reported that to make medical countermeasures available for the warfighter, DOD and HHS also have developed interagency agreements that allow DOD to purchase, and

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[14]GAO, *Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks,* GAO-16-132 (Washington, D.C.: Dec. 15, 2015).

[15]ee GAO, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources* , GAO-12-121 (Washington, D.C.: Oct. 26, 2011).

HHS to rotate, certain products from HHS's Strategic National Stockpile for use by DOD's military personnel.[16] For example, DOD and HHS have agreements that establish a framework allowing DOD to purchase smallpox and anthrax vaccines from the Strategic National Stockpile.[17] According to DOD officials, DOD's ability to purchase the vaccines from the Strategic National Stockpile benefits both departments financially and minimizes duplicative efforts. A similar agreement facilitates coordination in the event of a shortfall in critical medical countermeasures needed by either department in the event of a public health incident related to a domestic catastrophic incident.[18] Under this agreement, HHS and DOD agree to share medical countermeasures, including pharmaceuticals, biologics, medical and surgical supplies and equipment that are needed by HHS or DOD to prepare for, respond to, or recover from a public health incident of national significance. The agreement is intended to create a standardized approach to coordinate mutual support in the event of a medical countermeasures shortfall during an emergency. DOD officials said that the agreement includes materials and products from the Strategic National Stockpile as well as DOD contingency materiel stockpiles. DOD officials said that the shared stockpile benefits DOD both financially and in terms of logistics. For example, DOD is able to access products it needs through the Strategic National Stockpile, which provides efficiencies for the federal government because the Centers for Disease Control and Prevention is able to rotate medical countermeasures out of its stockpile. HHS officials agreed that the ability to share stockpiles of medical countermeasures contributes significantly during federal emergencies.

Biological Attribution and Point-of-care Diagnostics

We currently have ongoing work in the areas of biological attribution and point-of-care diagnostics for this committee. While our work is still ongoing, we are happy to brief you and your staff on our preliminary findings once we have completed more work.

3. The Blue Ribbon Study Panel, GAO and other experts have recommended the development of a national biodefense strategy. To date, federal agencies have

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[16]GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization.* GAO-14-442. (Washington, D.C.: May 15, 2014).

[17]Interagency Support Agreement between the Department of Defense Chemical Biological Medical Systems Joint Vaccine Acquisition Program (supplier) and Department of Homeland Security US Coast Guard (receiver) for Anthrax and Smallpox Vaccines (Feb. 2012).

[18]Interagency Agreement between the Department of Health and Human Services and the Department of Defense for Support of Contingency Medical Materiel Requirements (May 2005).

produced several strategic documents that address different aspects of biodefense, including the National Health Security Strategy and the National Biosurveillance Strategy. Do you believe that existing strategy and policy documents provide sufficient coordination of biodefense activities across the federal government? What elements should be included in a unified national strategy for biodefense?

In 2011, we reported that the overarching biodefense enterprise would benefit from strategic oversight mechanisms, including a national strategy, to ensure efficient, effective, and accountable results, and suggested the HSC take action. However as of February 2016, NSC staff had not developed a biodefense strategy like the one we envisioned. Rather, the NSC staff assert that the *National Strategy for Countering Biological Threats*, the *National Biosurveillance Strategy*, and *Presidential Policy Directive*-8 work in concert to provide comprehensive strategic guidance to stakeholders with biodefense responsibilities. Although these documents demonstrate clear commitment to coordinating interagency biodefense efforts, they do not provide the strategic approach that we suggested in March 2011. The primary element lacking in the existing strategies is a mechanism to identify capability gaps and prioritize investments across the entire biodefense enterprise. As described earlier, although agencies collaborate on various biodefense efforts, no single agency has the oversight or authority to guide investments across the enterprise. For example, the *National Health Security Strategy*, while detailed and ambitious, is primarily focused on human health security and resilience. While it describes the interconnectedness between human and animal health, and environmental factors that impact the spread of disease among human and animal populations, the efforts identified are primarily aimed at strengthening or protecting human health. The strategy is not broad enough to capture the elements needed to protect and strengthen the health of domesticated and wild animal populations, or describe the economic impact a devastating outbreak in our domesticated animal population, such as avian influenza or foot and mouth disease. By the end of 2015, the avian influenza outbreaks in the United States alone cost taxpayers over $950 million in response efforts, not to mention the economic damage to the producers of the nearly 50 million chickens and turkeys that needed to be destroyed because of the outbreak. Consumers were also impacted, as the cost of eggs rose as a result of the outbreaks. Moreover, the *National Health Security Strategy* does not contain a mechanism to ensure alignment across the four biodefense pillars.

Post-Hearing Questions for the Record
Submitted to Christopher P. Currie
From Senator Rob Portman
"The Federal Perspective on the State of Our Nation's Biodefense"
April 14, 2016

1. **Are the impediments to creating a comprehensive national strategy for biodefense centered on interagency or intra-agency conflicts?**
   a. **Could these impediments be dealt with effectively by appointing a focal point as recommended by the Blue Ribbon Study Panel and GAO reports?**

We have not specifically studied the sources of any impediments—conflicts or otherwise—to creating a comprehensive national strategy for biodefense. In 2011 when we reported that the overarching biodefense enterprise would benefit from strategic oversight mechanisms, we intended that the recommendations for a national strategy and for a focal point would work in concert to ensure efficient, effective, and accountable results across a complex and fragmented enterprise. Currently, neither the Office of Management and Budget nor the federal agencies account for biodefense spending across the entire federal government. Because responsibilities are dispersed across a multitude of federal agencies and oversight is dispersed across Congressional committees, no one has visibility over how much is being spent, much less whether investments—in routine operations, nonfederal capabilities, crisis response, and major acquisitions and research agendas—respond to the highest priorities and align across the four pillars of biodefense.[1] Specifically, we expected that a focal point—such as a national biodefense coordinator or an interagency body—would lead development and ensure ongoing implementation of a strategy that addresses all of the elements we previously outlined for effective national strategies. Those elements include: 1) identifying the purpose, scope, and particular national problems and threats the strategy is directed towards; (2) establishing goals, subordinate objectives and activities, priorities, milestones, and performance measures; (3) defining costs, benefits, and resource and investment need (4) delineating roles and responsibilities; and (5) integrating and articulating the relationship with related strategies' goals, objectives, and activities.[2]

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[1]The four biodefense pillars are (1) threat awareness, (2) prevention and protection; (3) surveillance and detection; and (4) response and recovery.

[2]*GAO, Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism,* GAO-04-408T (Washington, D.C.: Feb. 3, 2004).

Although the biodefense enterprise is not entirely without leadership and coordination, this vision of a focal point using a strategy that defines enterprisewide priorities and ensures that investments across the interagency are compatible with those priorities has not materialized. As we reported in our April 2016 statement, officials from the National Security Council (NSC) staff told us that that two of its directorates work together to provide strategic leadership on all federal biodefense efforts. We recognize the policy work of the directorates as an important step in promoting a comprehensive and coordinated approach to biodefense, but strategic leadership issues persist. For example, the Blue Ribbon Study Panel found that mechanisms to centralize leadership, such as White House councils and offices or naming a czar, like the Ebola czar, generally only become involved when a specific biodefense issue affects a prominent ongoing responsibility— methods which are not consistent with our call for a strategic approach.

We continue to believe that an entity with sufficient time, resources, and authority to provide strategic oversight across the enterprise—including tracking total spending and aligning budget requests with priorities identified in a national strategy—would enhance assurance that biodefense investments are both effective and efficient. However, we have not independently evaluated any specific leadership models. Therefore, we cannot comment on the appropriateness of institutionalizing leadership in the Office of the Vice President, as suggested by the Study Panel report.

2. Are there any external impediments that may be preventing the creation of a comprehensive national strategy and designating a focal point to lead the federal biodefense efforts?

We have not specifically studied the causes of impediments to creating a national biodefense strategy or designating a focal point to lead federal biodefense efforts. The challenges agencies within the biodefense enterprise face are complex, inherent to building capabilities that cross mission areas and agencies, and not easily resolved. However, as we have previously reported, when agencies do not have a compelling rationale, such as legislation, directives, or their perceptions of the benefits from collaboration, it is difficult to overcome differences in missions and priorities and to define and articulate a common outcome that is consistent with their respective agency missions.[3]

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[3]GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.; Oct. 21, 2005).