

STRATEGIC PERSPECTIVES OF THE BIOTERRORISM THREAT

HEARING BEFORE THE SUBCOMMITTEE ON EMERGENCY PREPAREDNESS, RESPONSE, AND COMMUNICATIONS ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

APRIL 22, 2015

Serial No. 114-14

Printed for the use of the Committee on Homeland Security



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

U.S. GOVERNMENT PUBLISHING OFFICE

94-889 PDF

WASHINGTON : 2015

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
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Wednesday, April 22, 2015

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON EMERGENCY PREPAREDNESS,
RESPONSE, AND COMMUNICATIONS,
COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The subcommittee met, pursuant to call, at 10:07 a.m., in Room 311, Cannon House Office Building, Hon. Martha McSally [Chairman of the subcommittee] presiding.

Present: Representatives McSally, Walker, Payne, and Rice.

Ms. MCSALLY. The Subcommittee on Emergency Preparedness, Response, and Communication will come to order.

The subcommittee is meeting today to receive testimony regarding the bioterrorism threat.

Before I recognize myself for an opening statement, I want to acknowledge a special guest of the subcommittee today. I am pleased to have my goddaughter, Clare, joining us. She is shadowing me all day today to see what it is like to be serving in the House of Representatives.

I now recognize myself for an opening statement.

This morning, the Subcommittee on Emergency Preparedness, Response, and Communications will continue its examination of preparedness for the CBRN attacks to the homeland, with a focus on the threat of bioterrorism. It is what I hope will be the first conversation of many that this subcommittee will hold on biodefense. I intend for us to really dig into all aspects of biopreparedness, both for terrorism and pandemics or other emerging infectious diseases.

We received a Classified briefing last week on the threat of biological and chemical terrorism. How we prevent and prepare for WMD terrorism is a key area of oversight for the full Committee on Homeland Security, as it is for this subcommittee. Our Nation's capacity to mitigate the impacts of all types of biological events is a top National security priority.

Though many of us are new to this subcommittee or to Congress, we are not new to the issue of biodefense. I have personal interest in this area. I have a biology degree from the Air Force Academy, by the way, but I deployed six times, though, to combat zones during my military service, four of those deployments after 9/11. I was deployed to Saudi Arabia in the Middle East during the anthrax scare of 2001. I can tell you, in the military, we even were not prepared to deal with this threat at that time.

On subsequent deployments, I personally received a number of vaccines, to include the anthrax vaccine, smallpox, and we were on continuous antibiotics on my last deployment to Afghanistan. So, as we were responding militarily, we were poking and prodding all of our troops, making sure, you know, that we were ready to go for any of the common threats we thought were out there.

But that makes me wonder, just like when we talked about the chemical terrorism threat, obviously we can't have that be going on for everybody at home, so what do we need to do, you know, to protect the homeland and our society? So that is why it is imperative that we have a system in place and we exercise it, to detect and communicate and respond to this threat, to include the distribution of medical countermeasures.

We understand an attack using biological agents or weapons is a low-probability but high-consequence event. A bio-attack could cause illness or death in hundreds of thousands of people, overwhelm our public health capabilities, and have an economic impact of over \$1 trillion per incident. Furthermore, we know there would be a myriad of significant societal and political consequences.

We also understand, thanks to experts such as those that are appearing today before us, that bioterrorist attacks are an urgent and a continuing threat. The Director of National Intelligence testified in February that weapons of mass destruction continue to be a major threat to security of the United States. He noted that biological and chemical materials and technologies, as well as personnel with expertise to use and design them, move easily in the economy. The DNI also stated that infectious disease continues to threaten our security, that a more crowded and interconnected world is increasing the opportunities for human and animal diseases to emerge and spread globally.

The hearing this subcommittee held last month highlighted challenges related to mass-casualty management as it pertains to a chemical event. Bio would be equally as challenging, with the added problem of illness taking days or weeks to present symptoms sometimes.

Because of the legitimate and important life sciences reasons to do research with biological agents, we may not always be able to stop our enemies from developing a biological weapon. Therefore, we must have a robust preparedness and response infrastructure in place. The ability of our health system to respond is of critical importance.

There has been a lot of solid work in assessing biopreparedness over the years, and I am very grateful to Senator Talent, co-chair of the WMD Commission, for being here to share this history and discuss why we seem to be almost stuck in place and time, unable to take steps toward change and enhancing our resiliency in this area.

In preparing for today's hearing, I reviewed this history, and I am honestly surprised and actually shocked that some of the recommendations made 6 or 8 years ago have not been implemented and that, even after the Ebola response, if we can call it that, we cannot seem to identify the Federal official, the one Federal official, who has the responsibility and the authority to coordinate the

dozen or so senior officials whose responsibility it is for biological preparedness and defense. It is just baffling to me.

Beyond today's hearing, we will look at disease surveillance, detection, diagnosis, and reporting; we will receive a report from the formidable Blue Ribbon Study Panel on Biodefense, which plans to issue recommendations for changes to U.S. law and policy later on this year; and we will dive deeper into roles and responsibilities in the biodefense space.

But today is all about the threat. Last year, General Clapper stated that the intelligence community assessed that Syria's biological warfare program, "might have advanced beyond the research and development stage and might be capable of limited agent production".

In addition to the concern of the Syrian regime using biological weapons, we must also be concerned about ISIS and its affiliates getting ahold of them. As I have stated before, ISIS is better-resourced, more brutal, and more organized than any terrorist organization to date. We know they have an interest in using chemical and biological weapons. In fact, a laptop reportedly retrieved from an ISIS hideout in Syria last year contained plans for weaponizing bubonic plague and a document discussing the advantages of using biological weapons.

We have a very distinguished panel of witnesses here today to discuss this threat. I am hoping to hear from each of you. I want to know what keeps you up at night. How can we best position the Federal Government to respond to the threat of a biological attack? [The statement of Chairman McSally follows:]

STATEMENT OF CHAIRMAN MARTHA MCSALLY

APRIL 22, 2015

This morning, the Subcommittee on Emergency Preparedness, Response, and Communications will continue its examination of preparedness for CBRN attacks to the homeland, with a focus on the threat of bioterrorism. It is what I hope will be the first conversation of many that this subcommittee will hold on biodefense. I intend for us to really dig into all aspects of bio preparedness, both for terrorism and pandemics or other emerging infectious diseases. We received a Classified briefing last week on the threat of biological and chemical terrorism. How we prevent and prepare for WMD terrorism is a key area of oversight for the full Committee on Homeland Security as it is for this subcommittee. Our Nation's capacity to mitigate the impacts of all types of biological events is a top National security priority.

Though many of us are new to this subcommittee or to Congress, we are not new to the issue of biodefense. I have a personal interest in this area and a background in biology. I deployed six times to combat zones during my military service, with four of those deployments occurring after September 11. I was deployed in the Middle East during the Anthrax scare in 2001, and I can tell you that even we in the military weren't prepared for that. On subsequent deployments, I received a number of vaccines to counter biological agents and on my last deployment to Afghanistan they had us taking antibiotics every day to counter the potential for biological attacks on troops.

Obviously, we can't have everyone in America taking similar precautions every day. That is why it is imperative to have a system in place and exercised to detect, communicate, and respond to these threats, including the distribution of medical countermeasures. We understand that an attack using biological agents or weapons is a low-probability, high-consequence event. A bio attack could cause illness or death in hundreds of thousands of people, overwhelm our public health capabilities, and have an economic impact of over one trillion dollars per incident. Furthermore, we know there would be myriad significant societal and political consequences. We also understand, thanks to experts such as and including those before us today, that bioterrorist attacks are an urgent and continuing threat.

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There has been a lot of solid work in assessing bio preparedness over the years and I'm very grateful to Senator Talent, co-chair of the WMD commission, for being here to share this history and discuss why we seem to be almost stuck in place—unable to take steps toward change and enhanced resiliency in this area.

In preparing for today's hearing, I've reviewed this history and I am honestly surprised that some of the recommendations made 6 and 8 years ago have not been implemented, and that even after the Ebola response we cannot seem to identify the Federal official who has the responsibility and authority to coordinate the dozen or so senior officials with responsibility for biological preparedness and defense. It's just baffling.

Beyond today's hearing, we'll look at disease surveillance, detection, diagnosis, and reporting. We'll receive a report from the formidable Blue Ribbon Study Panel on Biodefense, which plans to issue recommendations for changes to U.S. law and policy later this year. And we will dive deeper into roles and responsibilities in the biodefense space.

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We have a very distinguished panel of witnesses here today. I am hoping to hear from each of you: What keeps you up at night? How can we best position the Federal Government to respond to the threat of a biological attack?

Ms. MCSALLY. Before I get to the panel, the Chairman now recognizes the gentleman from New Jersey, Mr. Payne, for an opening statement.

Mr. PAYNE. Good morning.

I want to thank Chairman McSally for continuing this subcommittee's work on ensuring that we understand and are prepared to respond to the threats posed by bioterrorism.

Just over a year ago, this subcommittee examined the history of bioterrorism threats, how bio-threats are evolving, and whether the Federal Government is doing what it needs to to prevent and effectively respond to acts of bioterrorism. The message from the hearing was clear: When it comes to biodefense, there is a leadership vacuum.

Ten months after the hearing, that leadership vacuum became publicly apparent as the Federal Government struggled to effectively coordinate its response to the U.S. Ebola case. Despite billions of dollars of investment in developing capabilities to prevent and respond to bioterror events, the lack of comprehensive Federal

strategy effectively coordinated by someone at the highest level of Government undermines every dollar we spend.

That is why, last Congress, I supported the WMD Prevention and Preparedness Act, which was introduced by my colleague from New Jersey, Congressman Bill Pascrell, and the former Chairman of Homeland Security, the Honorable Peter King. That legislation would have implemented recommendations that were made in 2008, WMD Commission Report, and, importantly, reestablished the position of Special Assistant to the President on Biodefense. Although the bill did not move in this committee last Congress, I am hopeful that it will be reintroduced and that the lessons learned from the Ebola crisis last fall will incentivize this committee and Congress to act on it.

As I have observed throughout my tenure in Congress, the attention of this body and its Federal partners ebbs and flows from crisis to crisis. I hope that we address the biopreparedness gaps we have observed last year before we become complacent and the next crisis shocks us back into action.

Along those lines, I am interested to hear Senator Talent's views on the threats posed by bioterrorism and the potential of lone-wolf actors and how we should prioritize our efforts with respect to addressing bio-threats.

Despite some challenges at the Federal level, I am encouraged to hear about efforts local public health departments are undertaking to ensure that they will be able to protect the public should a bio-event occur.

Additionally, I would like to commend Deputy Commissioner Raphael on New York City's successful response to the Ebola case last fall. I am interested in understanding how the city became prepared to respond so effectively and whether information shared by the Federal Government was consistent, coordinated, and useful.

Before an Ebola case was diagnosed in the United States, New York City was working to improve its bio-response capabilities by testing its plans to rapidly deploy countermeasures following an anthrax attack in its largest no-notice emergency response exercise to date. I am interested in learning about how lessons learned from previous exercises informed the plans tested last summer, what New York City learned from the August exercise, and whether the lessons learned are being shared with neighboring jurisdictions.

Finally, I would note that our counterparts on the Appropriations Committee are in the process of drafting the fiscal year 2016 funding bill as we speak. I would be remiss if I did not take the opportunity to highlight the important role grant programs like the Urban Areas Security Initiative, also known as UASI, have played in developing local capabilities to prepare to respond to bio-threats. I urge our colleagues to provide robust funding for UASI and to consider restoring funding for reduced or expired grant programs that bolster medical response capabilities, such as the Metropolitan Medical Response System.

I would like to thank the witnesses for being here today, and I look forward to your testimony.

With that, Madam Chairman, I yield back.

[The statement of Ranking Member Payne follows:]

STATEMENT OF RANKING MEMBER DONALD M. PAYNE, JR.

APRIL 22, 2015

I want to thank Chairman McSally for continuing the subcommittee's work on ensuring that we understand—and are prepared to respond to—the threats posed by bioterrorism. Just over a year ago, this subcommittee examined the history of bioterrorism threats, how bio-threats are evolving, and whether the Federal Government is doing what it needs to do to prevent and effectively respond to acts of bioterrorism.

The message from that hearing was clear: When it comes to biodefense, there is a leadership vacuum. Ten months after the hearing, that leadership vacuum became publicly apparent as the Federal Government struggled to effectively coordinate its response to the U.S. Ebola cases.

Despite billions of dollars of investment in developing capabilities to prevent and respond to a bioterror event, the lack of a comprehensive Federal strategy effectively coordinated by someone at the highest level of Government undermines every dollar we spend.

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I urge our colleagues to provide robust funding for UASI and to consider restoring funding for reduced or expired grant programs that bolstered medical response capabilities, such as the Metropolitan Medical Response system.

Ms. MCSALLY. Great. Thank you.

Other Members of the subcommittee are reminded that opening statements may be submitted for the record.

[The statement of Ranking Member Thompson follows:]

STATEMENT OF RANKING MEMBER BENNIE G. THOMPSON

APRIL 22, 2015

Last month, this subcommittee examined efforts to bolster the ability of Federal, State, and local governments to respond to chemical terrorism. I am pleased that

the subcommittee is now taking the opportunity to assess bio-terrorism threats and our ability to prevent and respond to such attacks.

One of the key recommendations that the 9/11 Commission made to Congress was to address the grave threat posed by the proliferation of weapons of mass destruction. Accordingly, when I was Chairman of this committee, we authorized the Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, or the WMD Commission, on which Senator Talent—who is here with us today—served as vice chair.

In 2008, the WMD Commission issued a report making a series of recommendations to address WMD threats, particularly bioterrorism. Unfortunately, the Federal Government has been slow to respond.

In 2010, a WMD Commission progress report gave the U.S. Government an “F” for failing to do enough to prevent a biological attack on the United States or to be able to respond effectively in the event of a biological attack.

In 2011, the WMD Center found that the United States was still unprepared to detect and respond to a large-scale biological attack, despite upwards of \$60 billion invested in developing those capabilities. The Federal Government’s failure to implement appropriate policies and build the robust governance infrastructure necessary to tackle biological threats came to a head last fall when an Ebola victim sought treatment in a Texas hospital.

In addition to public concern, evolving guidance regarding appropriate PPE for hospital staff, and inconsistent quarantine policies at the State and local level, it was unclear who in the Federal Government was in charge of developing, and coordinating the implementation of, policies to contain the virus and ensure that the sick could be treated safely.

The response structure was seemingly lacking. Nevertheless, although the Federal response to a low number of Ebola cases in the United States was somewhat stilted, it was successful. I worry, however, that we would not be so lucky in the event of a biological attack. It has been nearly 7 years since the WMD Commission released its report and recommendations, and 3 years since the WMD Center released its damning report card of our National Bio-Response Capabilities.

During that time, Congressman Pascarella and former Chairman King have introduced the WMD Prevention and Preparedness Act, which would implement many of the WMD Commission’s recommendations, three times. Unfortunately, the bill has never been enacted. In the absence of a comprehensive legislative remedy to our bioterrorism capability gaps, I will be interested in learning whether our witnesses believe we have made any progress in improving our response to bio-threats over the past several years. I am also interested to know how State and local governments address bioterrorism threats.

Ms. MCSALLY. We are pleased to have a very distinguished panel before us today on this important topic.

Senator Jim Talent has been active in public policy for the past 30 years, including representing Missouri in both the U.S. Senate and the U.S. House of Representatives.

Following his service in the Senate, Senator Talent served as the co-chair of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. Following the expiration of the WMD Commission’s authorization in 2009, Senator Talent joined Senator Graham, the chairman of the WMD Commission, in establishing the Bipartisan WMD Terrorism Research Center.

Senator Talent is also a senior fellow and director of the National Security 2020 Project at the American Enterprise Institute. Senator Talent has a B.A. from Washington University in St. Louis and a J.D. from the University Chicago Law School.

Dr. Charles, or “Chuck,” Cairns is an interim dean at the University of Arizona College of Medicine in my district and the assistant vice president of the Arizona Health Sciences Center. He previously served as a chair of the Department of Emergency Medicine at the University of North Carolina and as director of emergency research at the Duke Clinical Research Institute.

Dr. Cairns has been a clinician, educator, investigator, and leader in emergency care, focused upon the host responses of individual

patients and populations to acute medical conditions. Dr. Cairns was principal investigator of the National Collaborative for Bio-Preparedness and the director of the U.S. Critical Illness and Injury Trials Group. He has published over 150 scientific articles and reviews and has received numerous awards and honors.

Dr. Cairns is an honors graduate of Dartmouth College and the University of North Carolina. He completed an emergency medicine residency and EMF research fellowship at the Harbor-UCLA Medical Center. Dr. Cairns is board-certified in emergency medicine and a fellow of the American College of Emergency Physicians, the American Academy of Emergency Medicine, and the American Heart Association.

I now yield to the Ranking Member to introduce our third witness.

Mr. PAYNE. Thank you, Madam Chairman.

It is my distinct honor to introduce Marisa Raphael, who is the deputy commissioner of the Office of Emergency Preparedness and Response at the New York City Department of Health and Mental Hygiene.

Ms. Raphael's responsibilities include directing and coordinating all operational, all administrative aspects of the department's emergency preparedness and response activities, including overseeing the coordination of public health emergency preparedness planning for New York City's health care system. In other capacities at the Office of Emergency Preparedness and Response, Ms. Raphael has overseen emergency planning exercises and training and countermeasures planning.

Ms. Raphael received her master's of public health from the University of Michigan. She also attended the Harvard Kennedy School of Government Senior Executives in State and Local Government Program and Harvard's National Preparedness Leadership Initiative.

Welcome.

Ms. MCSALLY. Thank you.

Welcome to all the witness.

The witnesses' full written statements will appear in the record.

The Chairman now recognizes Senator Talent for 5 minutes.

STATEMENT OF HON. JIM TALENT, FORMER SENATOR FROM THE STATE OF MISSOURI

Mr. TALENT. Thank you, Madam Chairman.

I want to thank you and the Ranking Member and all the Members of the subcommittee for your interest in this subject. It is personally quite encouraging to me because I do have a history with it, and you are right in believing that it does present a very grave threat and that we are not responding as well as we could.

I am going to summarize very briefly. I know you probably have a lot of questions and it will help you more to ask questions than for us just to talk.

A little bit on the history, and I know the subcommittee is aware of it, so I will be brief. Senator Graham and I were asked in 2007 to co-chair the Task Force on WMD Proliferation and Terrorism. We met with Senator Reid, the Majority leader in the Senate at the time, and he urged us to consider the mandate to be a broad one,

to identify the areas where we felt Congress needed to know something that had not been highlighted enough, and to tell it to the Congress, you know, without any varnish on it, just to say it as it was. So we did that.

As we began our work, we decided to focus on the nuclear and the bio-threat. As we continued through our initial deliberations, the bio-threat kept emerging in the minds of everybody on the Commission, most of whom were nuclear experts, by the way, as actually the graver threat of the two—which, of course, is not to downgrade the danger of the use of a nuclear device against us—for several reasons.

One, the bio-threat is potentially as destructive as the use of a nuclear device. You have had the briefing; you know that. Second, we had direct intelligence that al-Qaeda was aware of the potential of a bio-threat. They had a lab in Afghanistan. They were trying to develop it. Third, we thought that acquiring and deploying a bio-weapon was actually more within their capabilities than acquiring and deploying a nuclear device because advances in life science, which have done so much to, you know, improve the quality of human life, also have lowered the bar for the production and deployment of the bioweapon.

Now, it used to be that was only within the ability of a nation-state to do this. It was developed originally and then discarded as a battlefield weapon. But, now, if you can recruit a competent life scientist and get a lab at a cost of several hundred thousand dollars, it is entirely plausible that that life scientist can isolate and weaponize a deadly bio-agent. We said in the report, I think, that we were less concerned about the terrorists becoming biologists than we were concerned about biologists becoming terrorists.

So we said that in the report. We made a number of recommendations. Congress then asked us to come back and do another report on the status of our recommendations. This was the first one. We did the second one. In the course of doing that one, we focused on the issue of preparedness for a bio-attack, and, again, for a couple reasons, one of which is, obviously, if there is an attack, we want to limit the loss of life as much as possible. The second was our feeling that, to the extent that we can really prepare and harden the target, if you will, we could actually deter such an attack. We can make bioweapons no longer weapons of mass destruction.

So we issued the second report. Then, at the urging of the other commissioners, Senator Graham and I formed a nonprofit, which did the first ever—and, I think, the only one, to this date—end-to-end strategic study of all the links in what we call the chain of resilience. We recruited the best experts to formulate the right questions so that we knew what metrics we could use in judging the resiliency of the system, and we recruited another set of experts to answer those questions.

Then we issued this report, the “Bio-Response Report Card.” We tried to be fairly nuanced, to issue grades across a spectrum of different kinds of potential attacks. We did that in 2011.

My time is running out. I will just say, you have focused, I think, your subcommittee on the areas that concerned us the most.

We are not stockpiling as well as we should. We have made some progress since then. But, to the extent that we can stockpile against the most likely agents, then we force anybody who is actually planning this to try and come up with agents that are harder for them to come up with, so we raise the bar. FDA has made some progress in trying to develop the technology to be able to go from bug to drug quickly, but they need to work harder on that.

I was also—two more things, very briefly. I may run just a little bit over. But one of them—I was personally concerned with our distribution system very much. I am going to be very eager to hear what the deputy commissioner has to say because, to me, as a representative and a public official, the idea of these drugs being available and us not having an adequate system for dispensing them to people, think of the panic, think of what would happen to the social fabric if people knew they needed these countermeasures for their families and they couldn't get them. I mean, I don't want to think what would happen under those circumstances.

Finally, Senator Graham and I felt free, having served in this body, to be very clear and direct about recommendations regarding changing the way the Government approaches this in both the Executive and the Legislative branch. Leadership is too fragmented, and, if anything, Madam Chairman, to be fair to the Executive branch, it is worse here than it is over there.

We all know the problem. We know it is difficult to solve. I was a Chairman myself. I am not underestimating that. But we need to make an effort. If I had the Speaker and the Leader here and the Majority and Democratic leaders of the Senate here, I would tell them exactly the same thing.

So I hope that a movement towards that comes out of this. Bob and I understand that Congress is not an obstacle in this kind of thing; Congress can be a tremendous influencer for good in the workings of the Executive branch. But Congress has to be able to operate, and it can't with this jurisdictional setup.

I ran a little bit over, but not bad for a former Senator, though. I mean—

Ms. MCSALLY. Very impressive, actually.

Mr. TALENT. Thank you so much.

[The prepared statement of Hon. Talent follows:]

PREPARED STATEMENT OF HON. JIM TALENT

APRIL 22, 2015

Madame Chairman, Ranking Member Payne, and Members of the subcommittee, it's a pleasure for me to appear before you today, and quite encouraging to me personally that you are holding a hearing on this subject. Congress cannot pay too much attention to the fact that we live in an era of information technology which has, unfortunately, greatly increased the danger to the United States and the world of asymmetric weapons: Weapons which have a destructive potential that is highly disproportionate to the power and resources it requires to develop and deploy them. Of the asymmetric dangers we face, the threat of a bio-attack is, in my judgment, one of the greatest and gravest.

I will address that subject later in my testimony. First I want to describe how I came to be familiar with this issue.

One of the recommendations of the 9/11 Commission was that Congress focus on the danger of weapons of mass destruction proliferating to terrorist groups. So in 2007 Congress created a Commission to study the danger and report on measures that could be taken to minimize it. I was asked to co-chair the Commission with

Senator Bob Graham of Florida. There were a total of 9 members on our bi-partisan Commission.

Shortly after our Commission was formed, we met with Senator Harry Reid at his request. Senator Reid explained his interest in the subject of our work, and encouraged us to highlight clearly those aspects of the WMD terrorism threat which we believed were the most significant; he urged us in the strongest terms to tell us what we thought Congress most needed to know about the danger. We did so in a Report released at the end of 2008 called "World at Risk."

Early in our deliberations, Senator Graham and I decided to focus on the threat posed by nuclear and biological weapons, and if anything to give the bio-threat greater emphasis. There were two primary reasons for that:

First, we knew that the terrorists had pursued bio-weapons in the past. Former CIA director George Tenet noted in his memoir that in connection with their planning of the 9/11 attacks, al-Qaeda launched a concerted effort to obtain and weaponize anthrax to use in a mass attack. They set up a biological laboratory for that purpose in Afghanistan and hired Yazid Sufaat, a former Malaysian Army officer who had been trained in microbiology at California State University, Sacramento. Fortunately, their efforts were derailed by the American invasion of Afghanistan, but the record showed that they were aware of the potential of bio-weapons for their purposes. Others such as al-Qaeda of the Arabian Peninsula (AQAP) have expressed similar intent.

Second, we judged that it was probably easier for them to secure a bio-weapon than a nuclear weapon. Before the information revolution, it required the resources of a nation-state to develop and deliver a bio-weapon. But the tremendous advances in life science over the last few decades, which have done so much to advance the quality of human life, have had the ironic side effect of reducing the barriers to developing a bio-weapon. Disease-causing microbes—anthrax is an example—are readily available in nature, or they can be acquired from a sick person. A skilled biologist, with a laboratory costing no more than several hundred thousand dollars, is capable of isolating and weaponizing a particularly deadly form of such a microbe. As we said in our Report,

"We accept the validity of current intelligence estimates about the current rudimentary nature of terrorist capabilities in the area of biological weapons but caution that the terrorists are trying to upgrade their capabilities and could do so by recruiting skilled scientists. In this regard, the biological threat is greater than the nuclear; the acquisition of deadly pathogens, and their weaponization and dissemination in aerosol form, would entail fewer technical hurdles than the theft of production of weapons-grade uranium or plutonium and its assembly into an improvised nuclear device."

There are other secondary but nevertheless significant reasons why bio-weapons might be even more attractive than nuclear weapons to terrorist groups. Such weapons are relatively easy to transport without detection; they can cause as many or more deaths than a tactical nuclear weapon; they can be more easily stockpiled, making it possible to hit several targets in succession; and—depending on the biological agent used—it is entirely possible that terrorists could launch such an attack and escape the area before the authorities even knew that an attack had occurred. The symptoms of anthrax (and many other diseases capable of being used as bio-weapons), do not manifest for several days after exposure and can easily, in the early stages, be mistaken for influenza and other naturally-occurring diseases.

The aim of the terrorists is not just to kill, but to create as much fear as possible. As we saw last year during the Ebola outbreak, societies are susceptible to panic over even natural epidemics. The subcommittee can well imagine the effect in a large city if large numbers of people became ill or died because terrorists had weaponized a deadly pathogen and spread it through urban neighborhoods or in the transportation system. The Department of Homeland Security, Office of Science & Technology has modeled the effects of a potential anthrax attack on a city like New York; I invite the subcommittee's attention to their conclusions.

So we knew the terrorists had the motivation to get biological weapons, and we were quite concerned that advances in life sciences would bring development of such weapons increasingly within their capabilities. I was particularly influenced by Senator Graham's opinion in this regard; as a former Intelligence Committee Chairman, he had and has extensive experience with how the terrorists think and plan. Even though most of the Commission members were experts primarily in nuclear proliferation, they fully agreed to highlight the bio-threat and put our recommendations in that regard first in the Report.

Of course we did not devalue the danger of nuclear proliferation to terrorists; it is a real threat, and our Report made a number of recommendations for minimizing it.

After we released “World at Risk”, the bipartisan Congressional leadership extended the life of our Commission and asked us specifically to report on the status of our recommendations and, more generally, the extent and effectiveness of our Government’s efforts to prevent and/or prepare a WMD terrorist attack. We issued a second Report in January 2010 in the form of a report card. We gave a range of grades, some of them quite high; but in the crucial area of preparedness to respond to a bio-attack, we gave the Government an “F”.

Preparedness for a biological attack, or for that matter a naturally-occurring epidemic, means having a well-developed infrastructure which can:

- detect and diagnose a biological event,
- communicate effectively and in real time the nature and spread of disease,
- stockpile and distribute medical countermeasures,
- treat large numbers of afflicted people, and
- (where necessary) remediate the environment in areas that have been exposed.

During our final meeting, the commissioners encouraged Senator Graham and me to continue our work as a not-for-profit organization. Along with our executive director at the WMD Commission, Randy Larsen, we created the Bipartisan WMD Terrorism Research Center (WMD Center). We also brought in Lynne Kidder, who was (and still is) a co-chair of the Institute of Medicine’s Forum on Medical and Public Health Preparedness for Catastrophic Events.

Senator Graham and I decided that the most helpful project for the WMD Center would be a thorough, end-to-end assessment of the country’s state of preparedness for a major biological event, either natural or because of an attack. No government or private organization had ever accomplished such an assessment.

We recruited a distinguished group of 11 senior advisors including: The former deputy commissioner of FDA, the director of the American Medical Association’s Center for Disaster Medicine and Emergency Response, a former special assistant to the President for biodefense in both the Clinton and Bush (43) administrations, a retired major general who had led medical countermeasure development for DoD, the vice president and director of RAND Health, and the former chief legal advisor to the Centers for Disease Control and Prevention.

These senior advisors wrote the questions that needed to be answered to determine America’s preparedness for bio-response. A separate consulting team of subject-matter experts then did extensive research to answer these questions.

Senator Graham and I and our staff at the WMD Center used this information to assign the grades.

A copy of the Report Card has been distributed to the subcommittee and staff. I invite your attention to our findings. Though I will not attempt to detail all of them here, I want to make a general observation and then comment on several of the findings which in my view are the most important.

While every effort should be made to prevent a bio-attack, we cannot plan on the assumption that those efforts will be successful forever. The struggle against terrorism is long-term, and as long as it lasts, there is a good chance, for the reasons I’ve noted, that at least some of the terrorist groups will continue to try to acquire and deploy a bioweapon. Our first Report noted that they may well be successful. The efforts we make now to prepare will be crucial to limiting the impact of such an attack; with a swift and effective response, the loss of life and collateral effects can be drastically reduced.

Of course any loss of life because of a bio-attack would be tragic. But the better hardened we are, the more likely it is that a bio-attack will not be a weapon of mass destruction, and the less likely it is that the terrorists will choose to use it. In other words, preparedness can be a form of prevention. This is a point Senator Graham has often made, and rightly so. We may actually be able to deter such an attack if it is clear that we are as prepared as possible to respond to it.

I want to note several specific aspects of the WMD Commission Report Card (January, 2010) and the WMD Center Report Card (October, 2011).

First and foremost, the lack of sufficient medical countermeasures (MCMs) in our Strategic National Stockpile (SNS), and the lack of a system to quickly develop and produce MCMs during a crisis was our No. 1 concern in 2011 and remains so today. This is a complex problem with many key elements: Basic science (NIH), advanced development (BARDA), and regulatory science (FDA). As we said in the WMD Center Report Card, “A bio-response enterprise without adequate medical countermeasure is like an Army without bullets—it may look good on a parade ground, but has minimal value for National security.”

The recent Ebola virus outbreak highlighted that unless countermeasures are immediately available, including diagnostics tests that can be used by clinicians who are evaluating suspected cases, therapeutics to treat cases and vaccines to protect health care workers and others at risk, we are left with fairly primitive means to respond to and contain such events.

The challenge is not unmanageable. The list of bio-threat agents for which we should have a diagnostics tests, therapeutics, and vaccines for is about a dozen. To date, our stockpile contains countermeasures for only 3 or 4. The entity in the U.S. Government responsible for developing and producing these countermeasures, the Biomedical Advanced Research and Development Authority (BARDA) at the Department of Health and Human Services has been chronically underfunded. Originally authorized by Congress in 2006 to receive about a \$1 billion annually, it has received one-quarter to half of that amount. As we witnessed with the Ebola outbreak, it is too late to develop countermeasures after an outbreak or attack has happened.

There have been some bright spots and progress. Thanks to the efforts of Dr. Luciana Borio at FDA, we have made significant progress in regulatory science since 2011, some of which was seen in the Ebola response last year when new diagnostics were approved by FDA in a matter of days. We have also seen a shift in strategy regarding MCMs in a move away from “one-bug, one-drug” to a more flexible, rapid response. However, as we noted in the WMD Commission Report, if we continue to fund BARDA at a fraction of its actual requirements, we cannot expect to dig ourselves out of this preparedness hole.

Second, at the time of our WMD Center Report Card, we had no reliable means to dispense the countermeasures quickly. A number of cities had experimented with various distribution systems, but the process was not National and was not moving quickly enough. This is a shortfall I find particularly worrisome; the prospect of what will happen if there is an attack, and our people know there are countermeasures but can’t get access to them. This is an essential, underappreciated and under-valued element of a response. We may be confronted with a situation where we have countermeasures but can’t get them to the people who need them, when they need them.

Third, our Report Card noted that there had been some significant progress in improving the public health infrastructure in the various States, though our overall evaluation was that the medical system was not capable of managing the surge in demand that would be created by a major biological event. At the time we issued our Report Card, the budgetary stresses of the Federal Government were just beginning to take their toll on the public health system, particularly at the State and local level. I fear that funding reductions since then have undermined such progress as had been made at the time we were writing.

Finally, there are significant shortfalls in how both the Executive and Legislative branches are organized to deal with this issue. Today there are more than two dozen Presidentially-Appointed, Senate-Confirmed individuals with some responsibility for bio-defense, but none of them has bio-defense for a full-time job and no one is in charge. This virtually guarantees a fragmented response. The administration appointed a WMD Coordinator, to oversee the general WMD proliferation issue; that was an improvement. But since the departure of Elizabeth Sherwood Randall from the NSC to become the deputy secretary of Energy, that position has remained vacant. Ideally, there should be a special assistant to the President devoted full-time to the bio-threat (both man-made and naturally-occurring), as existed during the both the Clinton and Bush (43) administrations.

The Congressional oversight structure is also far too fragmented. Again, a number of committees have responsibility for pieces of the effort. It’s difficult even to determine exactly how many committees and subcommittees are involved. Senator Graham and I are both well aware of the difficulties inherent in restructuring and unifying Congressional oversight. But we also know the vital contribution Congress can make in this area, if it is organized in a way that allows the full weight of Congressional influence to be brought to bear. It would be well worth a major effort by the bipartisan leadership, joined by Chairs and Ranking Members, to unify oversight to just a few committees with clearly-defined areas of authority.

A more unified chain of command within Congress and the Executive Branch would allow the development of relationships and expertise over time, and a more strategic approach by the top-level political authorities, that Senator Graham and I believed essential to the success of this vital effort.

A final word. Our Report Card was issued 3½ years ago. Some of our findings may be outdated, though given the problems I have noted above, I fear that in most areas our preparedness has declined rather than improved. In any case, the questions we developed, and asked, are still the right questions for you to ask as you do your vital work in this area. That was one of our purposes in doing the Report

Card: to give decision makers tools for understanding the global state of our preparedness to respond to a biological event. I urge the subcommittee to continue its emphasis on the urgency of this danger, and to use the questions we asked as a starting point for understand what must be done.

Ms. MCSALLY. Thanks, Senator Talent.

The Chairman now recognizes Dr. Cairns for 5 minutes.

**STATEMENT OF CHARLES B. CAIRNS, M.D., INTERIM DEAN,
HEALTH SCIENCES CENTER, UNIVERSITY OF ARIZONA COL-
LEGE OF MEDICINE**

Dr. CAIRNS. Thank you very much, Chairman McSally and Ranking Member Payne, for this opportunity to provide testimony.

The National Collaborative for Bio-Preparedness and the U.S. Critical Illness and Injury Trials Group, both are designed to improve the surveillance, the detection, and the response to and recovery from biological events. The overall goal of these programs is to intervene early enough during the bio-event to save lives. There is a National need for timely intervention in bio-events in order to save lives.

As an emergency physician, I know that timely diagnosis and clinical intervention save lives. I have been involved in a State-wide system of heart-attack care that utilizes emergency medical services, including EMTs and paramedics, to rapidly diagnose and deliver appropriate treatment. This system has been replicated across the country and has been proven to save lives.

Thus, we have shown that we can provide timely, life-saving interventions for anyone, anywhere, anytime, on a State-wide basis. We need to extend these systems Nationally and apply them to biological threats, whether they are due to bioterrorism or natural disease outbreaks.

So the NCBP system was designed to provide rapid recognition of clinically significant biological events, with the mission to provide more effective decision making in health and emergency responses at the Federal, State, and local level.

Last fall, NCBP released an operational system capable of real-time analysis of streaming health data. Users can search by clinical symptoms, syndromes, free text within health records, and incorporate data on hospital resources, weather, critical infrastructure, and internet searches. The NCBP architecture can now support the integration of virtually any data source for simultaneous analysis and layered geographical visualization.

Now, while the system was originally developed as a tool to detect incidents of bioterrorism for use by analysts within the Department of Homeland Security National Biosurveillance Integration Center, DHS now appreciates the system offers the opportunity to collaborate with State and local officials in sectors such as public health preparedness, health care, infrastructure protection, and agriculture. This collaboration provides more sensitive and specific insights than DHS attempting to monitor the Nation single-handedly.

For example, local jurisdictions have a difficult time correlating DHS BioWatch environmental measures data to clinical data. Local officials are challenged to take action in the event of a biological attack without a keen understanding of whether people will become

ill. The NCBP system is designed to provide this important perspective and to support the decisions necessary to deploy public health countermeasures.

I suggest Congress support the efforts of the NBIC program to provide NCBP information to local officials.

EMS data, emergency medical services data, has turned out to be most timely and consistent. We have shown that EMS records can detect flu outbreaks earlier than the standard hospital- and laboratory-based approaches. Indeed, we have shown that free text analysis of EMS records can readily identify patients at risk for emerging infections. If Texas had been part of the NCBP system, it likely would have rapidly detected that initial case of Ebola in Dallas last September.

With adequate funding, NCBP will incorporate additional States, implement additional analytic and visualization tools and other data types, as well as engage new local, State, and Federal users.

But there is also a National need for a rapid, effective clinical response system in bio-events. During public health emergencies, reliable patient data are needed to identify groups at high risk for severe illness and death and to assess the impact of the event on critical health care resources. Yet experience with influenza and Ebola indicate that real-time clinical data aggregation, analysis, and reporting remain a strategic vulnerability.

Many of these logical challenges stem from the distributed, even silent, approach we have to emergency preparedness, as delineated by Senator Talent. The good example is, yet again, our response to Ebola. There was no preparedness on how to collect data longitudinally as to whether the medical conditions of the patients presenting were similar, whether medical countermeasures worked, or if any of those measures had any toxicity or interacted with other therapies, or even if they had any effect on long-term outcomes.

The U.S. Critical Illness and Injury Trials Group Program on Emergency Preparedness, which has been supported by ASPR, has been partnering with DHS and HHS agencies to begin to foster collaboration and build new capacities for data collection and research in order to address key questions of a successful response and address these challenges to the chain of resiliency. Failure to aggressively extend, support, and fund this initiative will amount to yet another potential failure of imagination for the next outbreak or act of bioterrorism.

Thank you again for the opportunity to testify today, Madam Chairman.

[The statement of Dr. Cairns follows:]

PREPARED STATEMENT OF CHARLES B. CAIRNS

APRIL 22, 2015

INTRODUCTION

Chairman McSally and Ranking Member Payne, my name is Dr. Charles Cairns and it is an honor to be providing this testimony. I currently serve as the interim dean of the College of Medicine, professor of Emergency Medicine, and vice president of clinical research of the University of Arizona.

Prior to Arizona, I served as the chair of the Department of Emergency Medicine at the University of North Carolina and as director of Emergency Research at the Duke Clinical Research Institute of Duke University.

I have served as the principal investigator of the National Collaborative for Bio-preparedness and as the director of the United States Critical Illness and Injury Trials Group.

In both of these programs, the Government has invested in improving its surveillance and detection capability in support of, and enabling of more efficient response to and recovery from biological events. The overall goal is to intervene early enough during a bio-event to save lives.

NATIONAL NEED: TIMELY INTERVENTION

As an emergency physician, I know that timely diagnosis and clinical intervention can save lives—both for individual patients and across populations and geographies. I have been involved in the development and implementation of a State-wide system of heart attack care that has resulted in having a rapidly diagnosis and treatment plan for every emergency medical services agency in every county of North Carolina every day. The system integrates the State-wide 9–1–1 system with pre-hospital technology to diagnose heart attacks with destination plans to deliver heart attack patients directly to the right health care resource or hospital (Mears, et al, *Curr Opin Crit Care* 2009). The result of this system has been to have a plan to rapidly diagnose every heart attack in the State and rapidly deliver life-saving care. This system has been shown to save lives (Glickman, et al, *Ann Emerg Med* 2012) and has been replicated across the country.

Thus, we have proven that we can effectively develop and implement systems that can provide timely, life-saving interventions for anyone, anywhere, anytime (Cairns, et al, *Ann Emerg Med* 2012) and to extend these systems to biological threats.

NATIONAL COLLABORATIVE FOR BIO-PREPAREDNESS

The National Collaborative for Bio-Preparedness (NCBP) is a system designed to provide rapid recognition of clinically significant biological events, whether they are due to disease outbreaks, contaminations or poisonings due to either natural causes or terrorism. (Arasaratnam M, et al. *Online J Public Health Inform*, 2013). NCBP utilizes a web-based system (<https://ncbp.bioprep.us/>) of near real-time data collection, automated assessment and analysis to detect relevant disease conditions and symptoms. The system is designed to meet the bio-surveillance needs of key local and regional stakeholders while providing awareness and transparency of events to State and National decision makers. In addition, the NCBP system is providing information on critical health care infrastructure and relevant interventional needs and care resources. Thus, rapid recognition of events can be matched to the necessary resources on a timely and geographically relevant basis, providing a context of when local or State resources are insufficient to match the needs of the affected population.

The NCBP is a project sponsored by the U.S. Department of Homeland Security (DHS) through a cooperative agreement with the University of North Carolina at Chapel Hill (UNC). Begun in 2010, the NCBP mission is to:

“Enable its users to recognize events occurring in the biosphere that have significance to the health and security of people and infrastructure in users’ jurisdictions, leading to more effective decision making in health and emergency response at the Federal, State and Local level.”

On September 15, 2014, NCBP released an operational data visualization and analytics system capable of real-time analysis of streaming health data to detect meaningful changes in the data and visualizing the information in a geographic format. The system also enables users to search records by clinical symptoms, user-defined syndromes, and free text within the health records. The system has been developed using human health data from Emergency Medical Services (EMS), 9–1–1, Emergency Department (ED) and Poison Control Centers, with incorporation of State-wide hospital bed and resource availability, live weather data, critical infrastructure (schools, roads, hospitals, Federal facilities) and internet search feeds (Google searches). NCBP architecture can now support the integration of virtually any data source for simultaneous analysis and layered visualization to provide greater insight and fidelity for the Nation’s preparedness resources and decision makers.

NCBP is unique in offering near real-time clinical data and custom analytics that generate signals and communicate them to users as the analysis occurs, with the goal of providing warnings of significant anomalies, in time to inform decision makers and support a response. The system is available to users 24/7/365.

The system was originally developed for analysts within DHS’ National Bio-surveillance Integration Center (NBIC), the project’s sponsor, as a tool to detect

incidences of bioterrorism. However, DHS appreciates that the system offers the opportunity to collaborate with State and local officials in the sectors of public health preparedness, human health, infrastructure protection, and agriculture. This collaboration provides more sensitive and specific insights, and thus a higher level of security for the Nation, than DHS attempting to monitor the Nation singlehandedly. NCBP is therefore offering the system to State and local officials and infrastructure owners who can contribute to the system's development and design.

For example, DHS has operated the Nation's environmental detection system for bioterror events, known as BioWatch. To date, local BioWatch jurisdictions have a difficult time correlating these environmental measurements to clinical data. In other words, local officials are not in the position to take action with public health countermeasures needed in the event of biological attack without a keen understanding of whether people and animals are becoming ill or are likely to become ill. The NCBP system and the US Critical Illness and Injury Trials (USCIIT) Group are designed to provide this important perspective and to support the decisions necessary to deploy public health countermeasures. Local jurisdictions have long recognized this need for clinical context to the BioWatch signals and I suggest Congress support the efforts of the DHS NBIC program to provide NCBP information to them. Local officials are the ones making the decision to deploy public health countermeasures and thus, Federal agencies should be providing local officials the information needed for effective decision support.

Among various sources of human health data, data from Emergency Medical Services (EMS) has turned out to be the most timely and consistent. These near real-time data are entered by trained providers utilizing standardized forms and our group has pioneered the development of these systems, especially for EMS (Mears, et al, *Prehosp Emerg Care* 2010). EMS data is population-based and is gathered by local EMS professionals who record emergency health data in free text, and they transmit it daily to the NCBP data center partner. NCBP currently incorporates every EMS call in NC, SC, and (soon) WV, MS, IN, and AZ into its analysis, most within 24 hours. EMS data are acquired in a Nationally-standardized format National EMS Information System (NEMSIS), containing patient complaints, provider assessment, time stamps, and the geocoding that enables geospatial analysis. As a result of this standardization, EMS data will be the most expedient source for NCBP to expand rapidly to other States.

In 2015, NCBP is entering the phase of development for expansion of the system toward a Nation-wide network of biosurveillance users, in order to provide ultimate value to the Federal Government, and enables a wide network of State and local users to contribute to the Nation's biopreparedness. With adequate funding, NCBP will incorporate additional States, implement additional analytic and visualization tools, add other data types (such as animal health and agricultural data) and engage new users from those disciplines. The goal for NCBP is to transition the system into a self-sustaining, not-for-profit entity to provide service to the Federal Government.

NATIONAL NEED: A RAPID, EFFECTIVE CLINICAL RESPONSE SYSTEM

The appropriate treatment of critically ill or injured patients can vary minute-to-minute. Thus, timely access to reliable data is one of the foundations of contemporary intensive care. It follows then that optimal responses during public health emergencies, for both clinicians and decision makers, would benefit from comprehensive, real-time event reporting. This should include physiological patient data that are needed to provide immediate insight into the impact of the event on critical health care resources and to identify groups with high risk for morbidity and mortality.

Importantly, this reporting should include the highly granular patient data that is needed to: (1) Characterize clinical features, (2) provide immediate insight into the impact of the event on critical health care resources (e.g., mechanical ventilation, dialysis, medication availability), (3) assess health care staffing availability and training/educational needs, (4) identify groups of patients with high risk for morbidity and mortality, and (5) determine the efficacy and safety of treatment and medical countermeasures. Recent experiences globally, however, indicate that real-time clinical data aggregation, analysis, and reporting remain a strategic vulnerability during public health emergencies. (Lurie, et al. *N Engl J Med* 2013).

The United States Critical Illness and Injury Trials Group (<http://www.usciitg.org>) through its Program for Emergency Preparedness (USCIITG-PREP) aims to significantly enhance the National capability to rapidly glean crucial information regarding the clinical course of acute illness and injury and guide clinical resource requirements during emergent events:

- Real-time collection of clinical data by a coordinating center during a regional or National public health emergency;
- Rapid analysis of clinical data to address key analytic outcomes, answering both clinical and operational questions:
 - What was the nature of the clinical insult and the resulting phenotype?
 - As a clinical responder, what, if anything, did you have to do differently?
 - Did clinical diagnostics, countermeasures, and therapies work as expected?
 - What was the operational impact on the patient and care setting?
 - Was there anything essential needed that you did not get?
 - What is the best/worst case that could happen next time?
- Timely dissemination of event-related information to inform front-line treatment of disease and resource allocation, assuring patient confidentiality, data security, and strict version control.

Working with the Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR), leading professional organizations, and the Homeland Security Information Network (HSIN), USCIITG-PREP has been developing mechanisms for rapid clinical data collection, analysis, and dissemination of findings during public health emergencies. Pre-event work on protocols, data collection processes, rapid analysis techniques, and means to quickly disseminate findings to stakeholders are all crucial to making clinical science networks effective at enhancing the response. The USCIIT Group will leverage existing infrastructure to both strengthen prevent operational science capabilities and provide timely data and situational awareness across the emergency care continuum during public health emergencies. Critical illness and injury professional organizations will use this rapid dissemination plan to inform their membership, in aggregate representing over 150,000 front-line clinicians, thereby saving lives and minimizing suffering based on the timely accurate guidance gleaned from operational science.

Furthermore, optimal outcomes in response to public health emergencies require rapid feedback on how well medical countermeasures (MCM) work to protect and treat affected individuals and their families. This information is used by clinicians in the field to guide therapy and by public health agencies responsible for mobilizing the necessary resources at both the regional and National levels. The overarching goal of USCIITG-PREP is to facilitate development of MCM's to protect against threats, specifically, select public health emergencies. USCIITG-PREP is working to develop and implement strategies to assess, evaluate, and monitor medical countermeasure safety, performance, and patient compliance in response to a public health emergency. The communication systems, infrastructure, data analysis and reporting algorithms, and sample collection and processing protocols that USCIITG-PREP develops for seasonal influenza could be applied directly to protect against other threat agents, including pandemic influenza (such as 2009 pH1N1), emerging respiratory viruses (such as H7N9, MERS-CoV, Ebola), and other biothreats agents such as inhalational anthrax. This work is also important because USCIITG-PREP uniquely catalyzes communication and builds infrastructure across the care continuum (prehospital, emergency department, intensive care units, rehab, adult and pediatric), linking HHS agencies, academic medical centers, community medical centers, critical illness and injury professional organizations, and industry. The USCIITG-PREP Steering Committee includes representatives from FDA, NIH, CDC, ASPR, and BARDA.

UNITED STATES CRITICAL ILLNESS AND INJURY TRIALS GROUP

The United States Critical Illness and Injury Trials (USCIIT) Group serves as a "network of networks", with the dual missions to *foster investigator-initiated hypothesis testing and to develop recommendations for strategic plans at a national level*. (Cobb JP, et al. *J Trauma* 2009; Blum, et al. *Chest* 2013). To these ends, the USCIIT Group provides a venue for investigator communications, supports a multi-society task force for research strategic planning, catalyzes HHS inter-agency dialog for endorsement of transforming initiatives (e.g., NIH-ASPR-FDA-CDC-BARDA), and fosters innovative, multidisciplinary, multicenter studies the results of which will improve clinical care and preparedness (Cobb, *Crit Care Med* 2009; Deutschman CS, *Crit Care Med* 2012). The USCIIT Group is endorsed by all major U.S. critical illness and injury professional organizations spanning the specialties of anesthesiology, emergency medicine, internal medicine, nursing, pediatrics, pharmacy and nutrition, surgery and trauma, and respiratory and physical therapy. The USCIIT Group has grown to include over 200 investigators across more than 30 academic and community hospitals. *Collectively, USCIIT Group investigators have enrolled over 10,000 patients in studies during the last four years*. For more details, please visit the USCIIT Group web page at www.usciitg.org.

The USCIIT Group organizes some of its investigator-initiated projects (now numbering more than 50) into several, large-scale, collaborative programs, consistent with the recent consensus strategic plan for critical illness and injury research in the United States.

- *Program for Prevention of Organ Failures (USCIITG-PROOF)*.—Efforts to prevent organ failure are hampered by three barriers: (i) Compartmentalization of care (emergency department, operating room, ICU, *etc.*), (ii) the difficulty of identifying early those at risk, and (iii) lack of proven, effective preventative interventions. Building on the success of the Lung Injury Prevention Study (USCIITG-LIPS),¹ the unique, multidisciplinary, USCIIT Group network, and CTSA-funded infrastructure, USCIITG-PROOF addresses all three barriers simultaneously through rapid cycle, multicenter clinical trials that span clinical domains to test a variety of interventions that prevent organ failure in those at risk.
- *Program for Critical Illness Outcomes (USCIITG-CIOS)*.—Care delivered in intensive care units is high-intensity, high-cost, and has tremendous geographic and organ-specific variation. Little is known about which ICU organizational and structural factors are associated with high-quality care and optimized outcomes. To determine which of these factors are most strongly associated with high-quality critical care, USCIITG-CIOS enrolled ~66,400 patients across 69 ICU's in the United States.² CIOS-2 planning is underway with grant submissions planned for this calendar year. There are numerous new collaborative opportunities for ancillary studies for those interested (we're especially interested in supporting new investigators).
- *Program for Early ICU Rehabilitation (USCIITG-PEIR) and USCIITG-Burn*.—Physical therapists, respiratory therapists, speech language pathologists, and occupational therapists are essential for coordinating rehabilitation of critically ill or injured patients. Early rehabilitation can help to ameliorate and even avoid severe deconditioning associated with post-ICU syndrome (PICS), which presents as long-term physical, cognitive, and mental health problems after severe critical illness or injury. USCIITG-PEIR seeks to identify areas of heterogeneity of care and to improve early rehabilitation for critically-ill or injured patients. Funded by the DOD, USCIITG-PEIR collaborates with USCIITG-Burn to actively enroll patients in a multi-center, randomized controlled clinical trial to measure the effect of early rehabilitation on hospital stay, muscle loss, and functional outcomes in burn patients with acute respiratory failure.
- *Program for Emergency Preparedness (USCIITG-PREP)*.—There are insufficient capabilities internal to HHS to rapidly collect clinical data to inform decision makers and key end-users in public health emergencies, especially on illness severity and physiology. The USCIITG-PREP Group was funded by the Office of the Assistant Secretary for Preparedness and Response (ASPR/HHS) to create an electronic Core Data Set for public health emergencies.³ Version 1 of the data set was tested and validated across 12 clinical sites (HHS contract, Rapid Assessment of Acute Illness and Injury to Enhance the U.S. Response to Public Health Emergencies) with data analysis and dissemination within 24 hours of data collection. USCIITG-PREP is seeking support to operationalize data set capabilities at the National level, including IRB innovations to insure patient safety and protect privacy during emergent events as well as data analysis and rapid dissemination plans.
- *USCIITG-PREP PULSE Project*.—USCIITG-PREP has been supported by ASPR to convene internet forums to address preparedness and response for threats to public health. The goal is to get near real-time feedback from USCIITG critical care volunteers distributed across the United States. For example, some parts of the country are experiencing a shortage of normal saline and others a resurgence of severe respiratory failure from H1N1; other regions are not. This new tool is designed for USCIITG-PREP to document this variance in experience and assess health system stress. For USCIITG-PREP and ASPR to keep its fingers on the “pulse” of a potential threat, feedback from our investigators in the form of answers to a few questions, say weekly, would be extremely helpful. Thus, we've called this internet-based tool “USCIITG-

¹Mears GD, Pratt D, Glickman SW, Brice JH, Glickman LT, Cabanas JG, and Cairns CB. The North Carolina EMS Data System: a comprehensive integrated emergency medical services quality improvement program. *Prehosp Emerg Care*, 14, 85–94. 2010.

²Blum JE, Morris PE, Martin GS, Gong MN, Bhagwanjee S, Cairns CB, Cobb JP: U.S. Critical Illness and Injury Trials Group. *Chest*. 2013 Mar 1;143(3):808–13.

³Laurie N, Manolio T, Patterson AP, Collins F, Frieden T. Research as a part of public health emergency response. *N Engl J Med*. 2013 Mar 28;368(13):1251–54.

PREP Pulse”, or simply Pulse, for short. After a successful pilot project on saline shortages, we are compiling a list of additional investigators/members who are interested in participating in Pulse. The project is sensitive to investigator time with the expected response burden for each forum will be minimal (less than 10 questions). We also expect that use of the tool will quickly evolve, making the response network more efficient and robust, and the Pulse tool easier and easier to use.

- *USCIITG–PREP Medical Countermeasures Project.*—Optimal outcomes in response to public health emergencies require rapid feedback on how well MCM’s work to protect and/or treat affected individuals and their families. This information is used by clinicians in the field to guide therapy and by public health agencies responsible for mobilizing the necessary resources at both the regional and National levels. The overarching goal of USCIITG–PREP is to facilitate development of MCM’s to protect against threats, specifically, select public health emergencies. The overarching goal of this FDA proposal is to develop and implement strategies to assess, evaluate, and monitor medical countermeasure safety, performance, and patient compliance in response to a public health emergency. Influenza was chosen as the prototypic test case for this FDA proposal as it is one of the most predictable and serious public health threats. Moreover, the communication systems, infrastructure, data analysis and reporting algorithms, and sample collection and processing protocols that USCIITG–PREP develops for seasonal influenza could be applied directly to protect against other threat agents, including pandemic influenza (such as 2009 pH1N1), emerging respiratory viruses (such as H7N9 or MERS–CoV, Ebola), and other biotreats agents such as inhalational anthrax. This work is also important because USCIITG–PREP uniquely catalyzes communication and builds infrastructure across the care continuum (prehospital to rehab, adult and pediatric), linking HHS agencies, academic medical centers, community medical centers, critical illness and injury professional organizations, and industry. The USCIITG–PREP Steering Committee includes representatives from FDA, NIH, CDC, ASPR, and BARDA.

NATIONAL NEED: COOPERATION AND COLLABORATION

None of these initiatives will be successful ultimately, without the full cooperation and collaboration across Federal agencies, the States, and local governments. However, the current climate is not necessarily one of collaboration and cooperation. The reasons for this are multi-factorial and probably rooted in interagency claims of primacy and in segregated budget lines and Congressional oversight. The Nation’s biodefense effort requires high-level direction and coordination from The White House. In past years, the various initiatives and programs of the Nation’s biodefense apparatus were overseen and coordinated directly by The White House, through a Special Assistant to the President for Biodefense. This position was vacated in 2009 and has not been filled. I would urge the Congress to unify its oversight of these biodefense programs so that money is spent more wisely and the agencies are working on behalf of each other rather than in competition.

This lack of programmatic unity is most felt at the State and local level, which is the tip of the spear for the Nation’s biodefense. It will be the hospital systems and EMS agencies that will first detect abnormalities in illness patterns. These same health care institutions will be expected to deliver life-saving care in real time, currently without the perspective of what resources will need to be available and consumed during such an event. Local emergency managers will need to execute their contingency plans well before any Federal disaster is declared or FEMA shows up.

CONCLUSION

The programs I have described above are important examples of programs that capitalize on local health and safety officials and practitioners’ information and awareness to inform the Federal agencies. I encourage Congress to ensure that any biodefense program take into account the capabilities and the responsibilities of local and State institutions, which must be weaved into the fabric of National preparedness.

Thank you for the opportunity to testify before the subcommittee today.

REFERENCES

- Mears G, Glickman SW, Moore F, Cairns CB: Data based integration of critical illness and injury patient care from EMS to emergency department to intensive care unit. *Curr Opin Crit Care* 2009 Aug;15(4):284–9.
- Glickman SW, Greiner MA, Lin L, Curtis LH, Cairns CB, Granger CB, Peterson ED: Assessment of Temporal Trends in Mortality With Implementation of a State-wide ST-Segment Elevation Myocardial Infarction (STEMI) Regionalization Program. *Ann Emerg Med.* 2012 Apr;59(4):243–252.
- Cairns CB, Glickman SW: Time Makes a Difference to Everyone, Everywhere: The Need for Effective Regionalization of Emergency and Critical Care. *Ann Emerg Med.* 2012 Nov;60(5):638–40.
- Arasaratnam M, Potenziani D, Hoit M, Jenkins C, and Cairns CB. National Collaborative on Biopreparedness. *Online J Public Health Inform*, 5, e198. 2013.
- Cobb JP, Cairns CB, Bulger E, et al. The United States critical illness and injury trials group: an introduction. *J Trauma* 2009;67(2 Suppl):S159–160.
- Cobb JP, Ognibene FP, Ingbar DH, et al. Forging a critical alliance: Addressing the research needs of the United States critical illness and injury community. *Critical Care Medicine* 2009;37(12):3158–3160.
- Deutschman CS, Ahrens T, Cairns CB, et al. Multisociety Task Force for Critical Care Research: key issues and recommendations. *Critical Care Medicine* 2012;40(1):254–260.

Ms. MCSALLY. Thank you, Dr. Cairns.

The Chairman now recognizes Ms. Raphael for 5 minutes.

**STATEMENT OF MARISA RAPHAEL, DEPUTY COMMISSIONER,
OFFICE OF EMERGENCY PLANNING AND RESPONSE, NEW
YORK CITY DEPARTMENT OF HEALTH AND MENTAL HY-
GIENE**

Ms. RAPHAEL. Good morning, Chairman McSally, Ranking Member Payne, and Members of the subcommittee. On behalf of Mayor Bill de Blasio and Health Commissioner Mary Bassett, thank you for the opportunity to testify on New York City's efforts to prepare for and respond to public health emergencies.

I am here today to discuss the vital role that public health plays in detecting and responding to emergencies, the importance of Federal public health and health care preparedness funding, and examples of how these investments have increased preparedness.

Our Nation's public health and health care infrastructure play a critical role in protecting our citizens by quickly detecting acts of bioterrorism or naturally-occurring outbreaks, containing the spread of disease, and mitigating the health impacts of emergencies.

The department currently receives Federal emergency preparedness funding from the CDC Public Health Emergency Preparedness program, the ASPR Hospital Preparedness Program, and the Department of Homeland Security Urban Areas Security Initiative. As a result, the department's public health and health care emergency response capabilities have been expanded, and we have made vital investments in planned development, training and exercises, and skilled and experienced personnel. I want to thank the committee and subcommittee for their continued recognition of the need for these critical Federal programs.

As the largest point of entry in the United States, New York City recognizes the increased likelihood that a naturally-occurring disease in any area of the world can quickly spread to New York City.

In July 2014, New York City began a highly coordinated and expensive multi-agency and multi-jurisdictional response to Ebola. To

prepare, we addressed hospital readiness, risk communication, increased lab capacity, and community engagement. We began developing detailed plans for disease surveillance and managing a person under investigation, and our public health surveillance staff investigated hundreds of suspect cases. The public health lab quickly became proficient in testing for and rapidly diagnosing Ebola in record time.

The city chose to focus on readying Bellevue Hospital as New York City's primary Ebola treatment center. Bellevue's quarantine and isolation unit had been supported over the past decade through HPP funding, and, therefore, we could focus on enhancing existing capabilities. When the first confirmed Ebola case in New York City was identified, we were in a strong position to respond.

One of the biggest challenges we currently face is maintaining a permanent state of readiness among city agencies in the health care system. This brings us back to the original impetus for the Federal preparedness funds: September 11 and the subsequent anthrax attacks.

The receipt of letters tainted with anthrax in 2001 led to a State and local requirement to develop mass prophylactic capabilities. The primary method of rapidly dispensing medication in response to a wide-spread aerosolized anthrax attack is through points of dispensing, or PODs, which are temporary emergency sites established to provide free medication to large numbers of people.

Years of planning, training, and exercises culminated in August 2014, when the department conducted the largest no-notice exercise on record, the Rapid Activation for Mass Prophylaxis Exercise, or RAMPEx. This exercise involved notifying and mobilizing over 1,500 city employees and setting up and opening 30 PODs simultaneously.

RAMPEx tested all components of our mass prophylaxis response and definitively demonstrated our ability to rapidly open 30 PODs city-wide in less than 8 hours, with some ready within 6 hours.

RAMPEx also helped identify critical planning gaps and solutions. First, all PODs are ready to open 4 hours before medication from CDC's Strategic National Stockpile would arrive. To address this gap, the department has requested that SNS assets be forward-deployed to New York City and other high-threat, high-density urban areas that have demonstrated an ability to stand up PODs faster than SNS medications can be delivered.

Second, we have not met our POD staffing goals. City-wide prophylaxis distribution requires 33,000 POD staff to support 48 hours of dispensing operations. New York City has made great efforts to recruit, pretrain, and assign staff to a POD site close to home. We are advocating for non-mission-critical Federal staff who live locally to be similarly identified and trained to support POD operations.

Our successful Ebola response and medical countermeasure exercise are a direct result of a decade of Federal investments in local preparedness. However, the greatest danger to our progress is the decline in Federal funding. While overall preparedness funding should be increased, allocations should also be based on risk to reflect the scale-of-threat impact to high-density urban areas and complexity of response.

The department relies on dedicated Federal funding streams to build and maintain critical public health and health care capabilities. Significant cuts in funding jeopardize our existing capabilities. PHEP funding for New York City has decreased 35 percent from its peak in fiscal year 2005, which has led to a 47 percent reduction in the public health preparedness workforce, compromising our ability to detect and respond to disease outbreaks.

I am reading as fast as I can, but I may run a little over.

Similarly, drastic cuts of nearly 40 percent to HPP have impeded health care-sector preparedness and response efforts. There are 55 hospitals, 259 long-term-care facilities, 303 primary care centers, 50 urgent care centers, and 101 dialysis centers in New York City. Preparing a health care system of this size and complexity requires significant resources.

In the immediate months following a particular emergency, jurisdictions have occasionally received one-time funding. New York City is thankful to have received funds to address our Ebola response. However, singular funding allocations are not an adequate substitute for sufficient and sustained base funding.

There is also a critical need for a real-time funding mechanism to support public health emergency response, not just preparedness efforts. Currently, we must use Federal preparedness funds to cover response costs. Federal budgets designed to support public health and health care system preparedness and response capabilities must be increased and sustained.

Chairman McSally and Ranking Member Payne, thank you for inviting me to testify today. We are grateful for your continued support, and I look forward to your questions.

[The prepared statement of Ms. Raphael follows:]

PREPARED STATEMENT OF MARISA RAPHAEL

APRIL 22, 2015

Good morning Chairman McSally, Ranking Member Payne, and Members of the subcommittee. I am Marisa Raphael, deputy commissioner for the Office of Emergency Preparedness and Response at the New York City Department of Health and Mental Hygiene. Our mission is to promote New York City's ability to prevent, prepare for, respond to, and recover from public health emergencies. I have been privileged to serve in a leadership role in this field for more than a decade. On behalf of Mayor Bill de Blasio and Health Commissioner Mary Bassett, thank you for the opportunity to testify on New York City's efforts to prepare for and respond to emergencies with public health and medical consequences.

PUBLIC HEALTH AND EMERGENCY PREPAREDNESS

I am here today to discuss the vital role that public health plays in detecting and responding to emergencies, the importance of Federal public health and health care preparedness funding, and examples of how these investments have increased preparedness. I will focus on our most recent and on-going Ebola response and the Rapid Activation and Mobilization Point of Dispensing Exercise, called RAMPEX, which the Health Department conducted in August 2014.

Our Nation's public health and health care infrastructure play a critical role in protecting our citizens by quickly detecting acts of bioterrorism or naturally-occurring outbreaks, containing the spread of disease, and otherwise mitigating the public health impacts of emergencies. State and local health departments along with their local health care systems play equally vital roles as that of first responder agencies—we prevent illness and save lives. The Department currently receives Federal emergency preparedness funding from the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness program (PHEP), the Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Pro-

gram (HPP) cooperative agreements, and the Department of Homeland Security Urban Area Security Initiative (UASI) grant awards. As a result, the Department's public health and health care emergency response capabilities have been expanded, and we have made vital investments in plan development, training and exercises, supplies and equipment, and skilled and experienced personnel to respond to a broad range of emergencies. In New York City, a perpetual target for terrorism, focal point for disease outbreaks, and victim of natural disasters, these investments have been critical to shoring up our public health and health care system. I want to thank the committee and subcommittee for their continued interest and recognition of the need for these critical Federal programs.

EBOLA IN NEW YORK CITY

As the largest point of entry in the United States, we recognize the increased likelihood that a naturally-occurring disease in any area of the world can quickly spread to New York City. This was demonstrated during our recent and on-going response to Ebola. Beginning in July 2014, when it became apparent that cases of Ebola were increasing in West Africa and that an individual with Ebola would likely reach New York City, the city activated a highly-detailed, coordinated, and expensive multi-agency and multi-jurisdictional effort. The Mayor convened interagency preparedness meetings to discuss various scenarios and ensure our health care system and first responders were aware of their roles and familiar with protocols. I would be remiss to not mention the over 20 agencies, including the NYC Health and Hospitals Corporation (HHC), FDNY, NYPD, and NYC Office of Emergency Management that worked hand-in-hand with our team at Health and City Hall to ensure a coordinated response. Each city agency dispensed invaluable expertise and leadership and I cannot emphasize enough how critical coordination is in the face of threats like this.

To give you a sense of our preparation at the Health Department, we addressed hospital readiness, risk communication and emergency transport, increased lab capacity, and community engagement. The Health Department began developing detailed plans for disease surveillance, emphasizing early detection, isolation and rapid notification, as well as plans to manage a person under investigation. Our public health surveillance and epidemiology staff investigated hundreds of suspect cases; the Public Health Laboratory quickly became proficient in testing for Ebola to facilitate rapid diagnosis and delivered test results in record time. We also prioritized community engagement, distributing over 100,000 "Am I at Risk?" palm cards and speaking at over 115 public events to address the public health concerns of New York City's diverse communities. For example, our Commissioner personally went out into West African immigrant communities and other vulnerable areas of the city to begin a dialogue about, not only of the risks of infection, but also discussing issues of tolerance to ensure immigrants were being treated fairly.

Most notably, HHC proactively conducted extensive staff training at each of its 11 hospitals, to be prepared to receive and screen individuals potentially exposed to the disease. Additionally, the city chose to focus on readying Bellevue Hospital as the primary NYC Ebola treatment center. Bellevue was selected because its "quarantine and isolation" unit has been supported over the past decade through HPP funding and we could focus on enhancing existing capabilities by further training staff and hiring additional personnel, as well as outfitting of isolation rooms to properly handle additional electrical and laboratory capacity. The fact that Bellevue was the sole facility ready to receive and treat an Ebola patient when that capacity was actually needed—and that it did so with successful outcome for the patient and all the personnel who care for and supported the patient—is merely part of the remarkable preparedness and response work overseen by Dr. Raju, HHC's president.

Years of planning made possible through the previously-mentioned funding gave the city the capacity to quickly prepare and respond to the Ebola threat. On October 23, 2014, when the first confirmed case in New York City was identified the city was in a strong position to respond because of these Federal dollars. Nonetheless, funding is still needed to reimburse the city for the costs incurred in transporting, screening, treating, and monitoring persons with or potentially exposed to Ebola.

MASS PROPHYLAXIS CAPABILITY AND RAMPEX

One of the biggest challenges we currently face is maintaining a permanent state of readiness among city agencies and the health care system. This brings us back to the original impetus for the Federal preparedness funds—the September 11 attacks and the subsequent anthrax attacks.

The receipt of letters tainted with anthrax in multiple cities in 2001 led to a State and local requirement to develop mass prophylaxis capabilities. PHEP funds support

State and local health departments to develop and execute plans for the mass dispensing of medication in response to a biological attack. In the case of a widespread, aerosolized attack, all potentially exposed people must begin taking antibiotics within 48 hours to prevent illness and death. While 48 hours is the target, modeling has shown that the more rapidly medication is provided to the public, the more lives will be saved. The primary method of rapidly dispensing medication is through Points of Dispensing, or PODs, which are temporary emergency sites established to provide free medication to large numbers of people to prevent them from becoming sick. Years of planning, training, and exercises as well as our investment in a team of experienced, highly-skilled Health Department emergency managers culminated on August 1, 2014, when the Health Department conducted the largest no-notice emergency response exercise on record: The Rapid Activation for Mass Prophylaxis Exercise, or RAMPEX. This exercise involved notifying and mobilizing over 1,500 city employees and setting up and opening 30 PODs simultaneously, and was funded by UASI.

RAMPEX tested all components of our mass prophylaxis response to an aerosolized anthrax attack from the mobilization of our Receipt, Stage, and Store (RSS) warehouse, to the coordination of our command and control center and mobilization of PODs. RAMPEX definitively demonstrated our ability to rapidly open 30 PODs city-wide in less than 8 hours, with some fully set up, staffed, and ready to open within 6 hours.

RAMPEX helped identify critical planning gaps and solutions. First, all PODs were ready to open up to 4 hours before medications from CDC's Strategic National Stockpile (SNS) would arrive at New York City warehouses. In an effort to close this gap, the Health Department has requested that SNS assets be forward-deployed in reasonable and useful quantities to NYC and other high-threat, high-density urban areas that have demonstrated an ability to stand up PODs faster than SNS medications can be delivered. The consequence of the failure to forward-deploy SNS assets may ultimately be measured in the numbers of lives lost because of delayed access to medication.

Second, we have not met our POD staffing goals for both leadership and general staff. In NYC alone, city-wide prophylaxis distribution will require 33,000 POD staff to support 48 hours of dispensing operations. In anticipation of "role abandonment" or failure to report, NYC has made great efforts to recruit, pre-train, and assign staff to a POD site close to home. We are advocating for non-mission-critical Federal staff, who live locally, to be similarly pre-identified and pre-trained to support POD operations. There are many areas in which Federal staff could be utilized to augment local response efforts during a large-scale emergency, PODs being one such opportunity.

RAMPEX demonstrated New York City's extensive medical countermeasure capabilities and high level of readiness for this type of scenario, and the importance of Federal preparedness funding to sustain such efforts.

IMPORTANCE OF FEDERAL EMERGENCY PREPAREDNESS FUNDING

Our successful Ebola response and medical countermeasure exercise are a direct result of a decade of Federal investments in local preparedness. However, the greatest danger to our progress is the decline in Federal emergency preparedness funding. Preparedness is an on-going effort that must be sustained over time. While the overall emergency preparedness and response funding should be increased, funding allocations should also be based on risk to reflect the scale of threat, impact to high-density urban areas, and complexity of response. These funds support the development, maintenance, testing, and continued improvement of these public health and health care capabilities and without these funds, lives would be lost.

Federal funds have allowed us to build critical capabilities so that when faced with public health emergencies, we have the tools necessary to protect the public. The Department relies on the dedicated emergency preparedness Federal funding streams of PHEP, HPP, and UASI to build and maintain these critical public health and health care capabilities. Significant cuts to the PHEP award, combined with similar cuts to the HPP award jeopardize NYC's, and other State and local jurisdictions' existing capabilities and impede planning to address known gaps. I will speak to the cuts New York City has endured specifically.

PHEP funding for New York City has decreased 35% from its peak in fiscal year 2005, which has led to a 47% reduction in our public health preparedness and response workforce. The erosion of a skilled, dedicated workforce including epidemiologists, laboratory technicians, and preparedness planners threatens to compromise our ability to detect and respond to disease outbreaks. In New York City, for example, the cuts have reduced the ability of the Public Health Lab to respond to after-

hours lab testing needs, which is critical to the 24/7 response needed for bioterrorism incidents and public health emergencies such as pandemic influenza and Ebola.

Similarly, drastic cuts of nearly 40% to HPP have impeded preparedness and response efforts necessary to shore up our Nation's health care sector. Health care system preparedness is essential to responding to all types of public health emergencies. During the recent Ebola response, every hospital had to be ready to identify, isolate, and stabilize any patient with potential Ebola disease and a handful of hospitals had to be ready to provide intensive treatment for a confirmed Ebola patient. There are 55 hospitals, 259 long-term care facilities, 303 primary care centers, 50 urgent care centers, and 101 dialysis centers in New York City. Preparing a health care system of this size and complexity requires significant resources, and as the funding has declined, NYC's ability to fully prepare its health care system has been compromised.

In the immediate months following a particular emergency, jurisdictions have occasionally received one-time funding to supplement the PHEP and HPP grants. New York City is thankful to have received such an allocation for our Ebola response. However, these singular funding allocations are not an adequate substitute for sufficient and sustained base funding. There is also a critical need for a real-time funding mechanism to support public health emergency response. Currently, we must use Federal preparedness funds to cover response costs, however with decreasing budgets that are already allotted to preparedness projects, this is unrealistic. Generally speaking, Federal budgets designed to support public health and health care system preparedness and response capabilities must be increased and sustained; this is as true for New York City as it is for localities Nation-wide, particularly dense urban centers.

Chairman McSally and Ranking Member Payne, thank you once again for inviting me to testify today. We are grateful for your and your colleagues' work to protect our citizens. I look forward to your questions.

Ms. MCSALLY. Thank you, Ms. Raphael.

The Chairman now recognizes myself for 5 minutes for questions. I appreciate all the testimony and the expertise at the table here.

Senator Talent, I want to start with you. I mentioned in my opening statement about the threat coming, potentially, from ISIS and, you know, those that are inspired by ISIS. Obviously, we have foreign fighters that are flowing in and out of the area. We have home-grown, lone-wolf—but we had somebody testify saying they prefer to call them “stray dogs” instead of “lone wolf” in one of our previous hearings. But, also, obviously, the capability is right there in Iraq and Syria, the potentiality.

I learned in my military career, obviously, threat equals intent and capability. So you have to have those two together. I think we can all agree that extremist organizations out there certainly would want to have the intent if they could, so the issue related to the threat is the capability.

In order to have that capability, you must be able to isolate, weaponize, and then disperse the agent. So, of those three steps, which do you think is the biggest challenge or barrier for extremists out there, both organized and inspired, less organized, so that we can try and get a good sense of what we are dealing with in the threat?

Mr. TALENT. My understanding of the science—and I will certainly invite Dr. Cairns and the deputy commissioner to weigh in here—is that probably, of the three, the weaponizing it would be the most difficult but, nevertheless, within the capability of a fairly wide range of professionals in life science. So, really, the issue is can they have a long enough period of sanctuary where they can plan, recruit, get the necessary lab facilities so that the experts that they have can isolate and weaponize.

That is one of the things that concerns me. Because we are seeing areas now—you mentioned Iraq, Syria, but Yemen—there are places in North Africa, which you are more well aware of than I, where they may have the necessary time and the necessary sanctuary to be able to develop this. So that is my concern.

You know, you said it at the beginning, and correct, it is a low-probability but very highly destructive event if it were to occur. The problem is, when you keep running risk and the risk continues to grow, even gradually, you know, eventually, the bullet is in the chamber, if you will. This is really what concerns me.

So I am concerned that the risk that they will be able to acquire it is growing because they are spreading, they are getting more sophisticated, and the logic of this, from their strategic point of view, is, I think, very strong.

Ms. MCSALLY. Thank you. Yeah, no, I agree; the ungoverned spaces that are continuing to grow around the world provide that space for this kind of activity to happen. If we don't have partners in the region to be able to provide governance and oversight of those activities, that is where the threat can continue to grow, I think, so——

Mr. TALENT. I don't want to take your 5 minutes——

Ms. MCSALLY. Yeah.

Mr. TALENT [continuing]. But whoever did——and we know who the FBI thinks sent the letter here, for example.

Ms. MCSALLY. Right.

Mr. TALENT. Well, if that had been put into the heating and air conditioning system instead of sent in a letter with a warning note——

Ms. MCSALLY. Right.

Mr. TALENT [continuing]. I mean, the destruction would have been much, much greater, and the damage.

Ms. MCSALLY. Thank you.

Dr. Cairns, in Ms. Raphael's testimony, she talked about the preparedness of New York City related to the Ebola crisis. We often talk about New York City as a potential target area, and we have talked about it even in the chemical threat. So it seems the preparedness and the efforts that you took are very admirable.

Do you see, Dr. Cairns, that type of preparedness around the country? I would think other cities, other smaller cities, you know, even Phoenix or Tucson, other places, would not have had that same capability or response. Have we spread the lessons learned from the Ebola event to other areas so that we can learn from their preparedness?

Dr. CAIRNS. Well, thank you very much for the question.

I think that the deputy commissioner outlined what is a best practice, in terms of response to these kinds of entities. So, no, I don't think Tucson and Phoenix would have that same experience, nor would they have those resources.

So we need to incorporate, of course, the learnings from New York City, but we have to think about: How do we have a dedicated isolation unit the way Bellevue was set up? Our hospitals are overwhelmed now, so having that dedicated space just in case is just a luxury we haven't been able to invest in. Then how do we deal with other issues that involve the populations outside—Tucson,

Phoenix, or any number of Western States? How do we make a difference for everywhere for anything at anytime, I think, would be one of our big challenges.

Ms. MCSALLY. Great. Thank you.

My time has expired. We might have time for a couple rounds of questions here, but I want to now recognize Ranking Member Payne for 5 minutes.

Mr. PAYNE. Thank you, Madam Chairman.

You know, if you could describe some of the lessons learned from the Ebola cases in the United States last year and how they might apply to a biological attack scenario, Dr. Cairns.

Dr. CAIRNS. Thank you very much for the question.

I think some of the lessons we learned from Ebola is that we need to be prepared to be able to collect data rapidly, have a system in place to understand the place of countermeasures, and then look at the effect of countermeasures on both individual patients and as a collective. We currently don't have that system in place. So I think the first lesson is we need to be prepared not only for operational experiences but also to better understand the impact and value of our countermeasures.

I think another key lesson is that it has been very difficult. It has been my experience, working with DHS and HHS across multiple agencies on how we might develop that, both across the clinical groups, professional organizations, and coordinate with the rest of the world, that it became very difficult. Frankly, we had more interactions on a standardized case form with our clinical trial groups in Canada, New Zealand, Australia, and the Europeans and the World Health Organization than we did within the United States.

So I think we really need to start addressing this as a National priority and be prepared to get timely information, effective assessment to countermeasures, and a system to deliver those countermeasures to the patients that would benefit most.

Mr. PAYNE. Thank you.

Senator Talent.

Mr. TALENT. I was discouraged by several aspects of the Ebola response.

In our last report, we actually gave the best grade for our Government's preparedness to communicate, both among health care professionals, to the public, and within the Government. That seemed, to me, to be a major failure. This was a small-scale event. I mean, it is important to think of this in terms of from small-scale noncontagious to large-scale contagious. So that was very distressing.

I don't—we established an Assistant Secretary for Preparedness and Response, who I had hoped was the one coordinating all this, and didn't see the Assistant Secretary for Preparedness and Response. So there were malfunctions there.

What we are seeing here is, when we have, as in New York, unified authority which sets priorities, we have good use of dollars, you know, we spotlight the weaknesses, we know what we need to do. When we don't have that, we have problems on the ground that we didn't expect, and we are not sure what to do about it.

So I think, again, it points back to the need for a greater unit of leaderships either in a person or in a small group of people who are able to look at the whole picture from the Federal point of view, identify what needs to be done, and have the authority to act when the crisis arises.

Mr. PAYNE. Thank you.

Ms. Raphael.

Ms. RAPHAEL. So I think I want to make three key points.

So one is just how resource-intensive this kind of response is. I think sometimes we slip in to referring to Ebola as past tense, but our reality is this is still going on. We have hit the 2,300 mark in terms of number of people monitored. We are monitoring over 190 people on any given day. So this is an incredibly resource-intensive response. We have been using over a thousand of our staff. Many millions of dollars have been expended on the part of the city.

I think one of the key challenges is maintaining a permanent state of readiness. I can't stress enough how the success of our response was really built on all of the capabilities that we have developed over the last decade. We would not have had the response we had if we hadn't had those investments in basic surveillance, labs, communications capabilities.

Obviously, the health care system played a critical role in this response. They are required to also have a baseline level of readiness, not only for Ebola but for any emerging infectious disease. So continuing to invest in the preparedness and readiness of the health care system is critical.

Then, finally, we are dependent on the Federal Government for consistent guidance that is based on best practices that we can all look to and be on the same page.

Mr. PAYNE. Thank you.

You know, that harkens back to my point and being adamant about, you know, the Commission's report that talked about reestablishing the position of special assistant to the President on bio-defense. The coordination that you speak of would be enhanced by someone that that was their job and their due diligence every single day, to advise the President.

Senator Talent, in your testimony, you stressed that the Government's preparedness for biological attacks received an F in your 2010 report. You specifically mentioned the lack of sufficient medical countermeasures as your No. 1 concern.

What can the Government and private sector do right now to improve preparedness for biological incidents?

Mr. TALENT. I think this should be a focus of the subcommittee, in part because this is the one area, one link in the chain where it is really Federally dominated, right? I mean, you all have control, as a jurisdictional matter, over what FDA is doing, what BARDA is doing, what HHS is doing.

So I think we have to improve the stockpile. We ought to do for other biological agents what we have done for smallpox and, to some extent, for anthrax; and then continue to support FDA. They are moving in the direction of having the resident capacity to be able to respond and come up with new drugs quickly.

I think it is also very important—one of the things Ebola showed us is diagnostics is hugely important. We have to put effort into

being able to diagnose quickly. If you can't do that, you can't respond.

I would also say to you that it is important that the drugs that we stockpile, that we take into account the need of particular populations—the elderly, women who are pregnant, children—because countermeasures that will work with young, healthy people may be too much for them. So I think that is definitely an area where we ought to move.

Again, this unifying responsibility—I just leaned over to Dr. Cairns a minute ago because he said, how can we have an isolation unit the way they do in Bellevue? Well, you all know, as all of us do who have served here, VA has a lot of excess capacity, right? So if we had a sort of unified leadership response, this is an area you would at least like to look into: Could we use some of the VA's excess capacity to supply—and it is all throughout the country, too, right, or at least through a lot of places.

But, at least as of the time we did our report, VA wasn't really even involved in the Federal response. Again, I think the problem is there is no special assistant and then, within the Congress, there is no way to move in a unified way to send a signal from the highest level of political authority.

Mr. PAYNE. Okay.

Well, Madam Chairman, I see my time is up, so I will yield back.

Ms. MCSALLY. We should be able to come back to you, though.

The Chairman recognizes Mr. Walker from North Carolina.

Mr. WALKER. Thank you, Madam Chairman.

I wanted to follow up on what my colleague was just talking about. I am married to a family nurse practitioner who works in a Level 1 trauma center, but, over the last month, she spent about five or six shifts on a trauma helicopter as their chief trauma nurse and really works a lot with these first responders on different issues. These are really the salt-of-the-earth people who face and run into situations without asking questions, whatever it might be. I particularly am concerned about, are we looking out for these guys in the best capacity?

In driving to my question for both Dr. Cairns and former Senator Talent, the medical community seems to have a knowledge or understanding—or they are getting there—of what is going on, of what they might be facing, yet it seems the larger communities, whether you want to call it awareness or the action steps or whatever, it just seems like the threat isn't really understood or appreciated to that level.

My question is, what is it that can be done from local communities, out of our positions here in Congress? What is it that you see would be not just awareness—we talk so much about awareness—but what are the action steps that we could take to bring some of the awareness?

I would address that to both of you gentlemen.

Mr. TALENT. It is tough. The Chairman mentioned, you know, you don't want to panic people, but you want them to be aware of the threat.

A couple of small steps. I mean, we could do a better job within this body of making sure that Members are aware. Now, obviously, the Members of this subcommittee and the committee are more

aware. I am not so sure that your colleagues who are not sitting here are aware. I said to the Chair before the hearing: We do a lousy job of orientation on National security issues in general for new Members coming into this body. As the Members know more—because you all network so much back home; you talk to your press—I think that would help a lot.

HHS, as of the time we did our report, they had some websites, they were doing some things. As we said, we felt a little bit better about communications. But my sense is it has probably declined, and I think the funding cuts are one of the reasons.

I mean, one of my real concerns—I agree with the deputy commissioner on this. When we issued our report, it was just when the funding cuts for public health were coming into play, and it is hard for me to believe that any link in this chain has gotten better given what has happened to the budget situation.

Mr. WALKER. Okay.

Mr. Cairns.

Dr. CAIRNS. Again, thank you for that question.

Indeed, one of the things that we think is very important, Congressman, is for first responders to be integrated into the system. So we developed the NCBP system based on the experiences and the perspectives of EMTs and paramedics and increasingly are trying to reach out to highway patrol, police, and fire so that they at least have the information needed to both understand a situation they might be going into as well as contribute information that can be integrated into the larger collective.

They are just a critical component of our Nation's health care system. They clearly are going to be not just the tip of the spear, but they are first in time, in getting an understanding. They need to be protected.

Mr. WALKER. Sure.

Dr. CAIRNS. They need to be aware.

Mr. WALKER. I had a meeting this morning where I found out for the first time a piece of legislation—I believe it is H.R. 1300 that is out there that would specifically allow first responders to some of the vaccines in our medical database. Do you agree with that? Do you approve of that? Or what would your position be?

Dr. CAIRNS. I would approve of that; in fact, a movement towards community paramedicine, where we take advantage of the prehospital care system and EMS system to help take care of patients every day—people who are in assisted living facilities, people who have to have care at home, those special populations that Senator Talent referred to. Why not utilize these people and their expertise and their interaction with the community to facilitate every-day care?

So, most certainly, giving them an option to participate in a response, I think, would be a valuable adjunct.

Can I make one comment about medical countermeasures?

Mr. WALKER. Sure.

Dr. CAIRNS. I do believe the FDA is making progress. In fact, they have supported the U.S. Critical Illness and Injury Trials Group to try to come up with ways to be proactive in data collection and assessment of medical countermeasures.

So continuing to work with ASPR, FDA, as well as Homeland Security, in order to empower and embrace the effective countermeasures for use by paramedics, EMTs, and first responders, I think, should also be a priority.

Mr. WALKER. Senator, did you want to add anything to that as far as—

Mr. TALENT. I think, in terms of communication, one of the things I always believed is that people will pay more attention if there is something they can do. So, I mean, to the extent that we can give advice to people about how maybe they could prepare, again, you want to be careful.

I think I would start with some of the bigger cities that are at a higher risk and give people an idea—and, generally, I think, when you are talking about management of these things, you are working through local authorities, as in New York. Okay? So the logical way to approach it would be to have a best practices out there; let other cities, maybe in order to get funding, present plans, one of which ought to include public awareness and also would include protecting local responders, taking advantage of resources outside of the traditional medical system—because if we get a big event, there is just no way that the surge capability of the hospital is going to be able to deal with it. I think they have estimated hospitals can surge to, like, 20 percent, something like that, and you could have many, many times that.

As far as FDA is concerned—and I just don't know because it has been, like, 3 or 4 years—have they used—now I don't want to ask the question. They were considering approving new drugs based on animal testing, which we thought was important, but, as of that time, they hadn't ever done it. I don't know if that is being pursued, but it is a question I would ask if I were you.

Mr. WALKER. Thank you, Madam Chairman. I yield back.

Ms. MCSALLY. Great. Thank you.

You guys up for a second round here of questions while we have our distinguished panel here?

So I believe in one of the testimonies or some of the background we talked about there is about maybe 15 different agents that potentially we think could be used for bioterrorism, but we really only have countermeasures available for about 2 or 3 of them.

What is the barrier for us to be able to have, you know, the countermeasures for the other 12? Is it a resource issue only? Is it a political will or a biological solution? I just want to get a sense of what are our barriers.

Because I agree with Senator Talent that we are talking about the threat today, but the one way to reduce the threat is to be prepared. One way to be prepared, obviously, is to have those countermeasures in place.

So, Dr. Cairns, what is the barrier to having countermeasures available for the rest of those so that the bad guys would have to go further down the list developing capabilities?

Dr. CAIRNS. Well, we need to emphasize the development of these countermeasures. We have to facilitate pathways, including animal testing, that then can be applied in like clinical scenarios. Frankly, that is one of the things we have just developed with FDA, in con-

junction with ASPR, is a way to think about how to do that for one of those key agents on that list.

But we also have to think about how we can rapidly adapt to changes either in virulence of a particular organism or the emergence of something we have known about for a long time like Ebola. So being prepared about how we not only test and reassess the value of those countermeasures, but to have it as a priority to have them developed.

There were so many countermeasures available for Ebola, for example, yet we didn't test any efficacy on most of these, and yet that program could be vital in the future. Imagine all the rest of the 15 agents on that list and how we might actually apply them to people who need them.

Ms. MCSALLY. Great.

Senator Talent, do you have—

Mr. TALENT. Yeah, I think part of the issue is, as I understand it, okay, NIH does a lot of the basic science. HHS is supposed to coordinate setting priorities and requirements, and then BARDA is supposed to actually develop the countermeasures. I think there has been a lack of, again, coordination in decision making about what are we going to focus on, you know, decisions about when animal testing is good enough—I don't want to get into the science of it.

Then BARDA has been underfunded. It is being funded at a fraction of what it needs. You know, I know we don't just throw dollars at a system that is not working otherwise, but I think we are going to have to do more in terms of funding there.

Since that is the one aspect of this that is the complete Federal responsibility, really—I mean, if you don't have the countermeasures, you can have all the rest of it done—it is like an army without bullets, I think I said in the testimony.

Ms. MCSALLY. Great. Thank you.

In the fiscally-constrained environment that we are in, I am always going to be asking what is doable. Like, you know, as we talked in the back earlier, Senator Talent, like, what is the low-hanging fruit that is actually doable in this fiscal environment, in this divided Government, that we could maybe get some bipartisan agreement on and to address some things incrementally. I mean, we have a whole host of challenges, some of which have been brought up today, some we haven't even touched on.

But what do you think, Senator Talent, is actually doable in this environment, that this subcommittee could move through in a bipartisan way and get signed by this President, that isn't, you know, significant resources? We have to make that case, certainly, to our colleagues and others, but I also want to get something done and not have the perfect be the enemy of the good.

Mr. TALENT. Well, I do think—and Mr. Payne mentioned this—fixing the authority situation. I am not sure how to go about it from an Executive branch point of view. I would support the legislation you all have sponsored. At the same time, it is not the best thing in the world in legislation to tell the President how he has to organize his own staff. But I support what you are doing because I think it is so urgent.

So, just as a practical matter, this might be an opportunity for the leadership or your Chair and Ranking Member to go talk to the chief of the staff, if you haven't done it, and just say, "Hey, how come you haven't done this?"

I mean, the President is personally, obviously, aware of this. He has talked about it in his National security strategy. He has responded personally and taken a lot of initiative on cyber, for example. That is clearly something he is interested in. So I think sometimes it is just making somebody personally aware of it.

I would look at how you can empower all these tremendous assets we have out there—local health departments, first responders. They have such a tradition of partnership and mutual aid anyway. I would ask people like the deputy commissioner, are there issues relating to potential liability that has hampered you in New York, for example, in distribution? Are the big box retailers—I don't know how many you have in New York—but are they not—so I would look at some of the non-money things.

Then, in terms of what you are doing with the money, I would focus on two things: Offering funding to localities that come up with really good plans for distribution and managing surges; and fixing the stockpiling issue. That is going to take more money. I know it is hard, but—and it is going to take consistency, too. You know, it is hard when you are planning this and then one year it is here and the next year it is here. So speak to the appropriators and get them to be consistent in funding. Good luck with that, right?

Ms. MCSALLY. Yeah, thanks. Thanks a lot. We will get right on that.

So it seemed to me also that just sharing information is important, that when we have best practices or lessons learned—in the military, we would call them lessons identified, because it seems like we constantly are identifying issues but we are not learning them—how do we share them across both, you know, the levels of Government and how do we share them across metropolitan areas?

That should not be very costly, just being able to share information.

Ms. Raphael or Dr. Cairns, do you have any comments on—it seems to me we could do that kind-of on the cheap, you know, just setting up procedures to collaborate and share information.

Ms. RAPHAEL. Sure. So, I mean, I think New York City certainly recognizes that we outresource many jurisdictions and we are much further along in our planning. So we always welcome the opportunity to present on our work, share our work. We see a lot of what we are doing as really a National model. So we take that very seriously. We just spent last week at an annual preparedness summit, where we did a number of presentations and had a lot of interest in the work we are doing.

I have, over many years now, stressed to both CDC and ASPR that they have a very particular perspective, in terms of who is strong in what, and that they should really be sharing that information. They are assessing, essentially—they have a viewpoint of where each jurisdiction is in their capability development. I think they could be doing more to match those that are stronger in cer-

tain capabilities with those that are weaker. But it is only the Federal Government that I think has that higher level of perspective.

Ms. MCSALLY. Dr. Cairns.

Dr. CAIRNS. I agree that we need to share information and, frankly, need to share data, not just with local groups and the Federal Government but across the Federal Government.

The National Biosurveillance Integration Center, for example, has been kind-of pigeonholed into looking at open-source data, and my understanding is that they are not getting data from the CDC BioSense Program, for example. So having data shared across Federal agencies and made available to State and local officials who have this responsibility to respond and understand the situation and employ countermeasures would be a very valuable step forward.

Speaking of the VA, you know, I think there is a real opportunity to utilize the VA system and VA data, which is standardized and available across the country, but those data aren't integrated into the system either.

So I think having shared data, shared information, and a collective response to this issue of preparedness as well as countermeasures would be a very valuable first step.

Ms. MCSALLY. Great.

Senator Talent, final comments on that?

Mr. TALENT. Just 30 seconds. We haven't mentioned remediation here with the last link in the chain. Anthrax is the classic one. That could be an area, also, where the Federal Government—we all could act pretty much as a Government.

I mean, I have often thought that this capacity ought to be resident maybe in DOD or the Reserves because they do so much anyway in terms of chem-bio, in terms of battlefield preparation. It is not fair to task all these localities to come up with their own remediation when you really only need, like, one team that can go in and do it.

I bet that could be done pretty inexpensively, too. I wouldn't just add it without any funding, but we need the ability to come in and clean up. You know how long it took them to clean up the Hart Building after Senator Daschle's office got—it took 6 months, I think, or longer.

So that is another area you could explore.

Ms. MCSALLY. Great. Thank you.

You just reminded me—I know we are out of time here, but the use of the National Guard, is that a part of, Ms. Raphael, your planning for distribution?

Ms. RAPHAEL. So, just to note, we did use the National Guard for our Hurricane Sandy response. They were a prominent part of our response, but it is not currently our plan. So something that has been drilled in State and locals from very early on is that you need to be ready to prepare at that level. You know, yes, Federal Government will provide assistance, but don't, sort-of, bank on that on the first hours. So all of our staffing is sort of local-based.

That said, the two things we are really asking of Federal Government is, No. 1, to give us access to their non-mission-critical staff that are locally-based. As I mentioned, we need a lot of staff to run these PODs. We need to run them in 48 hours and get meds into

people as quickly as possible. So that is something we have been really pushing for.

Then the other thing we are completely dependent on the Federal Government for is the Strategic National Stockpile. We are in a position where our distribution plans are so advanced that we are ready to open before the medications arrive. We will literally be ready, public standing at the door, and we will not have the medication. That is just a huge problem.

Ms. MCSALLY. Okay. Great. Thank you.

My time is very expired, so I will hand it over to Mr. Payne now.

Mr. PAYNE. Thank you, Madam Chairman.

Deputy Commissioner Raphael, I understand that the RAMPEX began with a fictitious BioWatch Actionable Result, or BAR. What happens after a BAR? Does the Federal Government provide adequate support in evaluating how to respond to a BAR?

Ms. RAPHAEL. Funny you should ask that. So, you know, we, sort of, got these BioWatch filters and were told: Okay, figure out what you are going to do with them. So, we have no funding, so we have figured out, sort-of, at the local level what we would do if there was a positive hit.

Something we have been asking of the Federal Government for literally years is for there to be some sort of interagency working group among all the different Federal agencies so we could understand what every Federal agency's role is. Because it is not clear to us exactly what the Federal Government would do in the case of there being a positive result.

We know what we will do as a city. Obviously, requesting and receiving the SNS as quickly as possible will be a key component to that. But in regards to some of the remediation issues, a lot of those issues are really outstanding, and we really need the Federal Government's help.

Mr. PAYNE. Thank you.

Also, during the Ebola crisis last fall, you know, State and local public health organizations and hospitals were bombarded with guidance materials and updated protocols.

Can you talk about what worked and what needed improvement with respect to the Federal Government's efforts to push guidance and other information out to the local and public health organizations?

Ms. RAPHAEL. So I think one thing that would be helpful, to the extent possible, is having some sort of State and local representation on some of these guidance discussions so that there is an understanding of what it would mean on the ground in terms of implementation, or at least having more of a heads-up in terms of what is coming.

Because I think a huge challenge for us was constantly changing guidance on a regular basis. Here we were, trying to implement a response, be flexible, be nimble, and then the guidance would change the next day.

So I think, you know, having thoughtful guidance coming out, with appropriate input into the process.

Mr. PAYNE. Okay.

Just one last question to Ms. Raphael. I felt like you weren't given much opportunity, so I am going to focus down your alley for a bit.

But, you know, in your testimony, you discussed the planning for role abandonment—basically, workers not showing up to operate the PODs. What can the Federal Government do to help prevent role abandonment?

Ms. RAPHAEL. Give us money.

So I think the most important—

Mr. PAYNE. Never mind.

Ms. RAPHAEL. No, I mean, continue to provide us with funding.

I think the No. 1 investment for us as New York City—you know, I think we have been held up as a best practice. The reason why our planning is so advanced is because we have dedicated staff that are working on this every day.

Some of the advancements include pre-identifying and pre-assigning every single health department staff to a POD role, to a POD site. They know exactly what POD location they are going to. They are assigned based on their home address so that they can walk there if mass transit goes down.

We pre-developed, sort-of, phase one PODs, where we have pre-identified the first 30 through 80 PODs that would open up. Everyone knows what those are; the police department knows what they are. We literally hit a switch, and it happens.

So I think we just really need sustained funding to maintain this capability. If the funding goes down more or goes away, we will not have this capability.

Mr. PAYNE. Thank you.

You know, just in wrapping up, you know, those are the type of examples that deserve funding. If, you know, you are being that conscientious and that dedicated to it, those best practices and the things that you are doing in New York City should be held up as an example of what and how to do this and, based on your success rate, all should be part of the factor in funding, I believe.

So thank you to all of the witnesses today.

Madam Chairman, I yield back.

Ms. MCSALLY. Thank you, Mr. Payne.

I thank all the witnesses here today and your testimony. This is the start of a discussion with this subcommittee. For sure, there is a lot more work to be done, and I think we will be probably following up with you, additional questions on individuals we can meet with or in our other role of oversight, in addition to hearings on legislation to address some of these issues.

So I really appreciate your testimony today and your expertise and what you are doing to address this threat.

Members of the subcommittee may have additional questions for you in writing, and so we will pass those on to you if they do. Pursuant to committee rule 7(e), the hearing record will be open for 10 days for those questions.

Without objection, the subcommittee stands adjourned.

[Whereupon, at 11:17 a.m., the subcommittee was adjourned.]

