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# H.R. 5498: THE WMD PREVENTION AND PREPAREDNESS ACT OF 2010

## HEARING

BEFORE THE

## SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

OF THE

## COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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# CONTENTS


Page

STATEMENTS

The Honorable Yvette D. Clark, a Representative in Congress From the State of New York, and Chairwoman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology:
Oral Statement ..... 1
Prepared Statement ..... 2
The Honorable Daniel E. Lungren, a Representative in Congress From the State of California, and Ranking Member, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology ..... 5
The Honorable Bennie G. Thompson, a Representative in Congress From the State of Mississippi, and Chairman, Committee on Homeland Security:
Prepared Statement ..... 39
The Honorable Bill Pascrell, Jr., a Representative in Congress From the State of New Jersey ..... 4

WITNESSES

Ms. Sara (Sally) T. Beatrice, Assistant Commissioner, Public Health Laboratory Director, New York City Department of Health and Mental Hygiene:
Oral Statement ..... 6
Prepared Statement ..... 8
Mr. Randall S. Murch, Associate Director, Research Program Development, National Capital Region, Virginia Polytechnic Institute:
Oral Statement ..... 12
Prepared Statement ..... 14
Dr. Robert P. Kadlec, Vice President, Global Public Sector, PRTM Management Consulting:
Oral Statement ..... 20
Prepared Statement ..... 22
Ms. Julie E. Fischer, Senior Associate, Global Health Security Program, Henry L. Stimson Center:
Oral Statement ..... 25
Prepared Statement ..... 27

FOR THE RECORD

Submitted for the Record by Hon. Bill Pascrell, Jr., a Representative in Congress From the State of New Jersey:
Chart ..... 39

# H.R. 5498: THE WMD PREVENTION AND PREPAREDNESS ACT OF 2010

**Tuesday, June 15, 2010**

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY,
*Washington, DC.*

The subcommittee met, pursuant to call, at 1:04 p.m., in Room 311, Cannon House Office Building, Hon. Yvette D. Clarke [Chairwoman of the subcommittee] presiding.

Present: Representatives Clark, Thompson, Lungren, and Austria.

Also present: Representative Pascrell.

Ms. CLARKE [presiding]. The Committee on Homeland Security will come to order. The committee is meeting today to receive testimony on H.R. 5498, the Weapons of Mass Destruction Prevention and Preparedness Act of 2010. Good afternoon.

The Commission on the Prevention of WMD Proliferation and Terrorism, the WMD Commission, put out a report entitled "World at Risk" in 2008. In that report they told us that they believe that a terrorist act would occur somewhere in the world by 2013 and that it was more likely to be an act of biological terrorism.

Although we have not seen WMD attacks here in the United States really come to fruition since 9/11 and the anthrax events of 2001, the threat is real. We have heard it from the WMD Commission. We have heard it from the 9/11 Commission. We have heard it from the intelligence community. We have heard it from law enforcement. We have heard it from the military. We have heard it from State and local officials. We have heard it from the private sector. We have seen successful attacks occur overseas, and we have seen aborted and failed terrorist attempts actually occur here in the United States.

While we continue to reach out through diplomatic channels to those who may wish to do us harm, we fully realize that the diplomatic solution may not be possible. Therefore, it is clear that we need to enhance our homeland security by improving efforts to counter a WMD attack, especially using a biological weapon.

This is the purpose of H.R. 5498, the WMD Prevention and Preparedness Act of 2010. With this bill we recognize that we will need to prevent and deter the threat; that we must prepare for an attack if prevention and deterrence fail; that while we are continuing to prepare, an attack may occur that we will need to detect before people and animals get sick or injured, or die; that once we

detect an event, we need to attribute the crime to someone or some entity; that we need to respond immediately; that we will need to recover from the attack, and that all of these actions are not the sole responsibility of the Federal Government, so we need to integrate partners in the public, private, and global sectors.

We addressed each of these elements—prevention, deterrence, preparedness, detection, attribution, response, and recovery—in H.R. 5498.

One of the determinations of the WMD Commission was that the Nation has not done enough to counter the biological threat. I agree, but I also want to point out that much has been done and is being done.

In H.R. 5498 we take this into account, and authorize and address a number of things that already exist in the Executive branch, including but not limited to the National intelligence strategy for countering biological threats, export enforcement for counter proliferation, material threat determinations, promotion of the Biological and Toxin Weapons Convention (the BWC), BioWatch, System Assessment and Validation for Emergency Responders (the SAVER program), the Laboratory Response Network for Bioterrorism, training to investigate biological threats and demonstration projects to recover from a biological attack.

Still, we agree with the WMD Commission that much more needs to be done to counter the WMD threat in general, and the biological threat specifically.

With this in mind, through H.R. 5498, we call for a number of new programs and activities, such as the National Intelligence Strategy for Countering the Threat from WMD, the creation of a top tier of select agents that pose a material threat to the Nation—the Tier 1 Material Threat Agents—enhanced measures to better secure these Tier 1 Material Threat Agents, grants to help laboratories that possess Tier 1 Material Threat Agents increase their security, sharing laboratory biosecurity information and threat-related information and guidance with State and local officials, reviewing criminal statutes to ensure their application will result in the prosecutions we need, a policy review to allow for first responders and others to get immunized for different threat agents as a preventive measure before attacks occur, international engagement to enhance biodefense and biosecurity, a study of forensic science in homeland security by the National Academy of Science, and the National Medical Countermeasure Dispensing Strategy.

Finally, in H.R. 5498, we are looking to fix some problematic programs, such as the National Biosurveillance Integration Center.

This is a bipartisan bill, developed through careful consideration of varying viewpoints and the input of experts and interested parties in both the public and private sectors.

We look forward to continuing that process with our witnesses today, and I thank you for appearing today.

[The statement of Chairwoman Clarke follows:]

PREPARED STATEMENT OF CHAIRWOMAN YVETTE D. CLARKE

JUNE 15, 2010

The Commission on the Prevention of WMD Proliferation and Terrorism—"the WMD Commission"—put out a report entitled "World at Risk" in 2008. In that re-

port, they told us that they believed that a terrorist act would occur somewhere in the world by 2013, and that it was more likely to be an act of biological terrorism. Although we have not seen WMD attacks here in the United States really come to fruition since 9/11 and the anthrax events of 2001, the threat is real.

We have heard it from the WMD Commission; we have heard it from the 9/11 Commission; we have heard it from the intelligence community; we have heard it from Federal law enforcement; we have heard it from the military; we have heard it from State and local officials; we have heard it from the private sector; we have seen successful attacks occur overseas; AND we have seen aborted and failed terrorist attempts actually occur here in the United States.

While we continue to reach out through diplomatic channels to those who may wish to do us harm, we fully realize that the diplomatic solution may not be possible. Therefore, it is clear that we need to enhance our homeland security by improving efforts to counter a WMD attack—especially using a biological weapon. This is the purpose of H.R. 5498, the WMD Prevention and Preparedness Act of 2010.

With this bill we recognize:

- That we need to prevent and deter the threat;
- That we must prepare for an attack if prevention and deterrence fail;
- That while we continue to prepare, an event may occur that we will need to detect before people and animals get sick or injured, or die;
- That once we detect an event, we need to attribute the crime to someone or some entity, and we need to respond immediately;
- That we will need to recover from the event; and
- That all of these actions are not the sole responsibility of the Federal Government, so we need to integrate partners in the public, private, and global sectors.

We addressed each of these elements—prevention, deterrence, preparedness, detection, attribution, response, and recovery—in H.R. 5498, the WMD Prevention and Preparedness Act of 2010.

One of the determinations of the WMD Commission was that the Nation has not done enough to counter the biological threat. I agree, but I also want to point out that much has been done and is being done. In H.R. 5498 we take this into account, and authorize and address a number of things that already exist in the Executive branch, including but not limited to:

- The National Intelligence Strategy for Countering Biological Threats;
- Export Enforcement for Counter Proliferation;
- Material Threat Determinations;
- Promotion of the Biological and Toxin Weapons Convention (the BWC);
- BioWatch;
- System Assessment and Validation for Emergency Responders; and
- The Laboratory Response Network for Bioterrorism.

Still, we agree with the WMD Commission that much more needs to be done to counter the WMD threat in general, and the biological threat specifically. With this in mind, through H.R. 5498, we call for a number of new programs and activities, such as:

- A National Intelligence Strategy for Countering the Threat from WMD;
- The creation of a top tier of Select Agents that pose a material threat to the Nation—the Tier 1 Material Threat Agents;
- Enhanced measures to better secure these Tier 1 Material Threat Agents;
- Grants to help laboratories that possess Tier 1 Material Threat Agents to increase their security;
- Sharing laboratory biosecurity information, and threat-related information and guidance with State and local officials;
- Reviewing criminal statutes to ensure their application will result in the prosecutions we need;
- A policy review to allow first responders and others to get immunized for different threat agents as a preventive measure, before attacks occur;
- International engagement to enhance biodefense and biosecurity;
- A study on Forensic Science in Homeland Security by the National Academy of Science; and
- A National Medical Countermeasure Dispensing Strategy.

Finally, in H.R. 5498, we are looking to fix some problematic programs, such as the National Biosurveillance Integration Center.

This is a bipartisan bill, developed through careful consideration of varying viewpoints, and the input of experts and interested parties in both the public and private sectors. We look forward to continuing that process with our witnesses today.

Ms. CLARKE. I would now like to ask for unanimous consent for Mr. Pascrell, who is not a Member of this subcommittee, to participate in this hearing.

Without objection, the gentleman from New Jersey, Mr. Pascrell, is authorized to question the witnesses and obtain testimony for this subcommittee hearing.

I now yield 2 minutes to the gentleman from New Jersey and the sponsor of this legislation, Mr. Pascrell, for an opening statement.

Mr. PASCRELL. Chairwoman, I want to thank you for yielding me as much time, or 2 minutes of yours—I want to thank you for your leadership and the leadership of Ranking Member Lungren. He and I have been talking for many a moon regarding what we need to do to defend the Nation and the Weapons of Mass Destruction Prevention and Preparedness Act, H.R. 5498, which Mr. King and I introduced last week. Mr. King, of course, is the Ranking Member of the entire committee.

This hearing is critical to understand the necessity for our legislation and to highlight our lack of preparedness at all levels for the threat of weapons of mass destruction. I would like to be here today to say that the threat of weapons of mass destruction is one restricted only to Hollywood thrillers or is a distant reality we need not worry about today. This is not the case.

Let me be clear about the reality. In all that we have read, all that we have heard, we can conclude in unison that weapons of mass destruction constitute the greatest catastrophic risk we face anywhere in the world today. We know from reports that terror groups like al-Qaeda remain committed to obtaining nuclear and biological weapons.

The Weapons of Mass Destruction Commission has said that under current readiness, a weapons of mass destruction attack is likely to occur by 2013. Recent terror attempts, including the incident at Times Square, demonstrate that our enemies continue to probe our homeland security infrastructure, looking for weaknesses, probing, probing every day. The message is clear. We need to be more than vigilant.

Let me be even more clear. Either we can pass the legislation and be prepared for this threat or we can ignore it, hope that the best-case scenario plays out. That is the kind of short-term thinking that BP used for the disaster we see in the Gulf of Mexico.

The Weapons of Mass Destruction Commission has made one thing very clear in the reports, Madam Chairwoman. Almost 9 years after 9/11, we still do not have a comprehensive National strategy to counter the grave threat that weapons of mass destruction pose for our Nation. You referred to this in your opening.

I am proud to say that the Weapons of Mass Destruction Commission, headed by former Senator Graham and former Senator Talent, has endorsed our legislation. That it has a truly comprehensive approach within it to securing the Nation against weapons of mass destruction by looking at all angles—prevention, deterrence, preparedness, detection, attribution, response, and finally, recovery. We did it all within 100 pages.

Madam Chairwoman, I look forward to hearing the testimony today, moving forward with the Weapons of Mass Destruction Pre-

vention and Preparedness Act. I yield back and thank you for yielding to me.

Ms. CLARKE. Thank you, Mr. Pascrell.

I now recognize the Ranking Member of the subcommittee, the gentleman from California, Mr. Lungren, for an opening statement.

Mr. LUNGREN. Thank you very much, Chairwoman Clarke, for your leadership on this critical issue and for your willingness to begin this hearing early to accommodate a scheduling conflict I have. I have to go be part of a panel to interview the three finalists for the job of inspector general of the House of Representatives. It was scheduled with four other people, so I can't change that. So I thank you for that.

The American people face no greater or more urgent threat in my estimation than a terrorist attack with a weapon of mass destruction. It is my greatest fear, shared by others, that a WMD would be used against our Nation. We have no greater responsibility as Members of Congress to protect the American people from such a horrific attack and to do everything in our power to try and accomplish that.

The WMD Commission predicted in 2008 that "a terrorist attack with a WMD weapon is more likely than not to occur in 2013." Some people, I think, want to shy away from that, because they think that means that it will be a completed or successful attack. They didn't say that. They said that they believe there will be a terrorist attack with that weapon. So we have to do everything we can to ensure that does not occur, and if it does occur, to minimize the damage as best we can and to recover from it.

The commission also reminded us in last January's report card that the Government's progress in preventing and responding to nuclear biological attack is inadequate, and so much more work needs to be done.

As one who believes that intelligence is our best defense against terrorist attack, particularly a WMD attack, I am strongly supportive of Title 1 of the bill, which establishes a National intelligence strategy to improve U.S. capability to collect, analyze, and disseminate weapons of mass destruction intelligence. Better intelligence will hopefully prevent such an attack from ever happening, which is the only satisfactory outcome.

We also need to prepare for and recover from such attack. However, my focus will be on prevention. This legislation is urgently needed and long overdue. It does provide a comprehensive approach to enhance DHS' effort to both prevent and deter as well as detect, respond to, and recover from a WMD attack.

While New York City and the New York, New Jersey area is unquestionably a terrorist target, all urban areas in this country and critical infrastructure across our Nation could be devastated by a nuclear biological attack. We need to understand that. The American people need to understand that this is not just for the New York area. This is for the entire Nation.

As a result, this bipartisan legislation is urgently needed, and I look forward to working with both of you and the other Members of our committee to enact this legislation.

I do want to thank our witnesses for their testimony on this legislation—more importantly, for the work that you have done in the

past and the expert advice that you have given us, we appreciate that. We have tried to benefit from suggestions from you and your colleagues, and this piece of legislation is a product of that consultation, and we hope it will continue. I look forward to hearing your comments.

Thank you very much.

Ms. CLARKE. Thank you very much, Ranking Member Lungren.

We will be joined by our Chairman, Mr. Thompson, shortly, but we are going to proceed with this hearing in the interim. Other Members of the subcommittee are reminded that under subcommittee rules, opening statements may be submitted for the record.

I would like to welcome our witnesses. Our first witness, Dr. Sally Beatrice, is the assistant commissioner and director for the New York City Public Health Laboratory.

Our second witness is Dr. Bob Kadlec, former special assistant to the President for homeland security and senior director for biological defense policy. Currently, he is the vice president for the global public sector at PRTM. We commend him for his long military career.

Our third witness is Dr. Randy Murch, who holds a number of positions at Virginia Tech, including associate director for research program development. Dr. Murch had a long career, as a special agent in the FBI, Federal Bureau of Investigation, where among many programs, he created the Hazardous Materials Response Unit.

Our fourth witness, Dr. Julie Fischer, is a senior associate at the Henry L. Stimson Center, where she leads their global health security program.

We thank all of our witnesses for being here today. Without objection, the witnesses' full statements will be inserted in the record. I now ask each witness to summarize his or her statement for 5 minutes, beginning with Dr. Beatrice.

**STATEMENT OF SARA (SALLY) T. BEATRICE, ASSISTANT COMMISSIONER, PUBLIC HEALTH LABORATORY DIRECTOR, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

Dr. BEATRICE. Good afternoon, Chairperson Clarke, Mr. Lungren, Mr. Pascrell. I am Sara Beatrice, assistant commissioner of health and director of the New York City Public Health Laboratory.

The Public Health Lab is one player among many local, State, and Federal entities comprising the anti-terrorism preparedness and response efforts in New York City. It is our duty to provide the necessary surveillance and routine surge testing to support emergency preparedness and response for the city. We need the support of our Federal, State, and local partners to be able to do this.

As you know, New York City is a high-threat jurisdiction. Our approach to bioterrorism preparedness is not theoretical. We have been attacked. We are acutely aware that it could happen again, and we in the health department are fortunate to have a mayor who understands that public health is an integral part of biothreat preparedness and response.

I thank you for the opportunity to testify today, and I would like to share some of our challenges over the past decade that may be helpful as you consider legislation to improve the Federal structure in support of bioterrorism preparedness and response.

When the New York City Public Health Lab joined the Laboratory Response Network in 1999, the goal was to establish a laboratory that could detect a bio attack through clinical specimens from patients presenting at emergency departments. Instead, the anthrax attacks of 2001 revealed itself in both clinical and environmental samples.

We were prepared to receive a few specimens. We received thousands. Our Federal partners came to our aid with six tons of supplies and personnel to perform testing and to train our staff. Within a week the New York City laboratory was able to handle hundreds of environmental and clinical specimens a day.

An initial increase in Federal support in 2002 gave us the ability to build a highly robust biothreat response laboratory. Unfortunately, while the threat of another attack has not decreased, funding has been reduced with each fiscal year. Even with the added resources of the Urban Area Security Initiative funding, it is a challenge to maintain the level of excellence established by 2003. One-time and interment funding are helpful, but not sufficient to maintain our capability.

We strongly support section 2135 of the bill, which will provide funding for Laboratory Response Network activities, and we appreciate the bill's authors for recognizing this need. We urge you to consider the necessity for consistent and sustained funding for the long term.

BioWatch is an excellent example of a well-intentioned program that was implemented without sufficient funds to address the true needs of this program. Basic funding for technologists, reagents, and equipment was the extent of Federal funding for the laboratory. What wasn't funded was a comprehensive quality system to ensure the consistency of reagents and the training and competency of staff performing the testing, nor was there funding to ensure quality and consistent testing across jurisdictions, and nor was the cost to set up and maintain infrastructure of the local laboratory provided.

Also, clear roles and responsibilities for the Federal, local, and contracted entities involved in the BioWatch program need to be better defined, and jurisdictions need centralized Federal guidance for consequence management planning in the event of a BioWatch actionable result.

I am sure this committee is well aware of the consequences of unreliable BioWatch results, and I want to thank the office for recognizing the need for additional financial support in section 2132 of the bill.

I also have some concerns about section 2104, which redefines a set of Tier 1 agents that required enhanced security. Again, I cannot overemphasize the importance of appropriate and sustained funding to support the enhanced biosecurity that will be required of facilities that handle these agents.

An additional concern is intergovernmental information sharing. The public health community believes biodefense needs to address

both intentional and accidental releases of biological threat agents. Local and State public health agencies need to have access to detailed information related to the biological agents and biosafety programs at each laboratory regulated by the select agent program in their jurisdiction. At this time this information is not shared locally.

It is our hope that the information required by sections 2105 and 2107 will be shared with State and local health departments to mitigate and respond to select agent incidents in laboratories within the locale.

While I have limited my comments to issues related to the New York City Public Health Lab, the city would like the opportunity to both provide more detailed comments on the entire bill, reflecting the concerns of all of our key emergency response agencies. We stand ready to assist the committee to develop and implement these critical initiatives. Again, thank you for the opportunity of testifying here today.

[The statement of Dr. Beatrice follows:]

PREPARED STATEMENT OF SARA (SALLY) T. BEATRICE

JUNE 15, 2010

Good afternoon, Chairperson Clarke and subcommittee Members. I am Dr. Sara T. Beatrice, Assistant Commissioner of Health and Director of the New York City Public Health Laboratory (NYC PHL), a Bureau of the NYC Department of Health and Mental Hygiene (DOHMH). Thank you for the opportunity to testify on H.R. 5498, the "WMD Prevention and Preparedness Act of 2010."

The NYC PHL provides quality laboratory testing services that are needed by NYC DOHMH and its partner agencies, and our city's laboratory and health care community as they respond to clinical and environmental public health concerns. The NYC PHL has been a member of the Laboratory Response Network (LRN), an international network of laboratories able to respond quickly to public health threats and emergencies, since its inception in 1999. New York City has been a member of the BioWatch pathogen detection program since it was deployed in 2003, and is working with our Federal partners in the assessment of new technologies and quality systems for this program. I am going to describe some of our challenges and experiences of the past decade in the hopes that it may be helpful to you as you consider legislation to improve the Federal structure and support of bioterrorism preparedness and response.

New York City is a high-threat jurisdiction. Our approach to bioterrorism preparedness is not theoretical; we have been attacked several times, and we are acutely aware that the city is a likely repeat target for terrorists. There will always be a need for significant bioterror response laboratory capacity and capability in the city to ensure our ability to rapidly and effectively respond to an event caused by the dissemination of a biological threat agent. In 1999, the NYC PHL received its first Centers for Disease Control and Prevention (CDC) grant to establish a biothreat response laboratory (BTRL). The first BTRL consisted of a single room situated in the middle of routine testing laboratories. Security was basic; there were padlocks for the evidence locker and a punch-code door lock at the entry. Later, the room access was upgraded to swipe card control and video surveillance was added. Reagents and resources were minimal; formal training was limited to one CDC-funded person attending a course on methods of agent identification at the CDC. In short, the NYC BTRL was a one-room space staffed by two laboratorians trained in standard safety methods for routine bacteriology work. There was only basic supporting infrastructure—there was no secure specimen receiving area, no secure computer database, no dedicated sample accessioning system, no standard report functions. Samples were delivered directly to the BTRL by first responders and tested for a collection of agents, and hand-written reports were sent to describe the results of the microbiological testing. All procedures were manual. There was no capacity for high throughput or Polymerase Chain Reaction (PCR) testing at that time. When the laboratory first became operational, the FBI submitted only approximately one specimen per month.

In October, 2001, on the same day that the index case of cutaneous anthrax was confirmed, law enforcement delivered a Bacillus anthracis-contaminated letter received at NBC by Tom Brokaw's staff. The BTRL sample load rapidly multiplied from a baseline of 10 samples in the previous year to hundreds of samples per day. Within days, the BTRL was transformed. Six tons of supplies were flown in from the CDC. Staffing went from two to 75 laboratorians, including staff from CDC and the Department of Defense (DOD). Rapid, molecular testing was brought on board. Dedicated space was increased by almost twenty-fold and included 10 laboratories, evidence rooms, support and storage areas, and a command center. Databases and computers were brought in and standardized testing protocols were developed.

New York City has received funding from several sources for biothreat preparedness activities. CDC's Public Health Emergency Preparedness (PHEP) Cooperative Agreement provides funding to the NYC DOHMH, and a portion of this funding is allocated by the DOHMH to the PHL. However, PHEP funding is increasingly dedicated to specific initiatives, and is decreasing with each fiscal year. Public health agencies receiving PHEP funding were authorized to use this support to enhance responses not only to bioterrorism but to other intentional and unintentional incidents that could evolve into public health emergencies.

The Urban Areas Security Initiative (UASI) provides funding, through the Department of Homeland Security (DHS), to the city of New York. UASI funds are allocated annually by the city to programs, including the PHL. Procurement of an All-Hazards Receipt Facility (AHRF) was funded with $1.5 million from UASI. This facility was deployed to ensure that unknown samples could be screened for hazards (i.e.: chemical, radiological, etc.) before entering the laboratory. An AHRF is considered a safety necessity; however, many jurisdictions will not have adequate funding for this purpose.

PHEP, UASI and city funding has enabled the NYC BTRL to develop into its current iteration. The city is fortunate to have a mayor who understands that public health is an integral part of biothreat preparedness and response, and Mayor Bloomberg has provided significant city tax levy monies for laboratory infrastructure. NYC dedicated $20 million of city capital funds to renovate the BTRL and Mycobacteriology laboratories after we were unsuccessful in getting Federal capital funding for this essential project. This included a biosafety level 3 (BSL3) facility necessary for working with highly infectious organisms. Security upgrades were included as well. Physical barriers keep unauthorized vehicles from entering the PHL premises. There is 24-hour police presence in the building, which is enhanced when necessary, and extensive closed-circuit security system was installed in the building.

We believe that Federal mandates for biosecurity enhancements must be Federally funded. While the BTRL has moved far beyond a one-room operation, there are upgrades and required maintenance to facilities, equipment, and instrumentation that we struggle to finance because external funding falls short, and the city and State dollars used to make up the difference are becoming increasingly scarce as well.

Today, many of the samples received by the BTRL are suspicious substances, such as unknown powders, that are found in envelopes or other packages. The samples are submitted by local (NYPD) and Federal (FBI) law enforcement and originate from a variety of places. In 2009 and 2010 the laboratory has tested suspicious substances from many locations, including banks, financial businesses and organizations (37 percent), governmental organizations (courts, transit, law enforcement agencies, 26 percent), embassies, consulates, diplomatic missions and the United Nations (26 percent), and hospitals, media organizations, and other businesses (11 percent). New York City is unique in that considerable portions of the NYC PHL budget are utilized to test samples which are collected from locations such as diplomatic missions and consulates that are considered "foreign soil".

Our Federal and local partners, including in particular the NYPD, are responsible for responding to incidents involving suspicious substances and assigning a risk level to the event based on predetermined criteria. A decision is made whether testing is appropriate, and a priority is assigned to the sample. Many samples arrive at the PHL at the end of the work day and may require evening and weekend testing, and the overtime adds additional pressures on our budget. Maintaining a group of trained and competent on-call staff that can effectively respond 24/7 to a surge in sample volume is challenging.

If a suspicious substance were submitted and tested positive for the presence of a Select Agent, an immediate and significant environmental investigation would be launched, resulting in a surge of sample collection and confirmatory testing similar to that experienced during the 2001 anthrax event. We need to build and maintain a stable infrastructure of staffing, state-of-the-art testing methods, and a cache of reagents available to seamlessly move into a surge mode at any time. The NYC

DOHMH, and the PHL in particular, recently challenged and proved the soundness of our system during the H1N1 outbreak of 2009. However, without adequate, consistent funding for staff, training, instrumentation, and reagents, this capacity will not be sustainable. We strongly support section 2135 of H.R. 5498 which would provide funding for LRN activities, and we appreciate the bill's authors for recognizing this need.

NYC's involvement in the BioWatch program has been more substantial than in any other jurisdiction. Beginning in January 2003, NYC participated in the first deployment of BioWatch, a limited array of air collectors designed to detect the airborne release of select biological agents. The laboratory assays used in BioWatch were derived from those developed by Lawrence Livermore National Laboratory (LLNL) and CDC for the Biological Aerosol Sentry Information System (BASIS) program. During the initial BioWatch deployment in NYC, the BASIS mobile laboratory was deployed for approximately 2 weeks to NYC, assisting PHL staff to process and analyze BioWatch filters pending completion of the PHL BioWatch laboratory. When the BASIS laboratory staff left NYC, much of the testing equipment remained at the PHL to help initiate the establishment of this laboratory.

Soon thereafter, PHL recognized that additional support would be necessary for the BioWatch laboratory to become fully functional and self-sufficient. Instrumentation, reagents, informatics and staff, not accounted for when the program was established, would be needed. To assist PHL during this period, LLNL provided equipment and supplies directly from LLNL "push packs" (instrument and reagents required to do the testing) and dedicated staff were hired through the CDC.

PHL continued developing relationships with our Federal partners during the next 12 months and embarked on the first of many pilot programs to enhance the capability and capacity of the NYC BioWatch laboratory. In February of 2004, LLNL provided DHS with a cost analysis to expand the laboratory capability that included additional instrumentation, implementation of sample tracking system, high-throughput sample processing and modified reagent contracts and formats. In March 2004, NYC staff was trained at LLNL in these new procedures with the goal to have the high-throughput laboratory in-place for the 2004 Republican National Convention (RNC). Based on the success of these initial programs, NYC, LLNL, DHS and CDC initiated 3 additional pilot programs beginning in 2004 to address IT enhancements, autonomous detection systems (APDS) and an improved platform for high-throughput testing (Luminex). The goal was to then provide other jurisdictions with these enhanced capabilities.

PHL, LLNL, CDC and DHS maintained close working relationships from 2004–2009 during the development, deployment, and testing of the APDS program. In addition, BioWatch stakeholders throughout the city have been increasingly involved with DHS and CDC regarding the BioWatch mission, and we welcome continued involvement and collaboration. Efforts have been made in the past 6 months to improve communication and interaction between local, State, and Federal stakeholders who have invested much time and effort since 2003 in the BioWatch program.

One NYC experience illustrates the importance of improved communication. In 2003, NYC and Federal partners began planning for special biosurveillance to be conducted during the 2004 Republican National Convention (RNC). Routine BioWatch testing was to be conducted by PHL, and Federal partners were to collect National Security Special Event (NSSE) samples and test them at PHL. Weekly planning meetings with all partners were held for nearly a year to prepare for the event. The NYC DOHMH worked closely with local, State, and Federal law enforcement agencies to develop a series of temporary security enhancements and procedures to ensure the safety of our staff, visitors, and information during the RNC event. Analytes were coded per mandate to ensure security, and testing was to be performed under "secret" conditions. Less than 48 hours prior to the Convention's start, our Federal partners changed the reporting protocol. PHL was notified by the National Laboratory Program Manager that all NSSE data was to be reported directly to the National Laboratory Director. The National Laboratory Director was to notify the National Laboratory Program Manager. The National Laboratory Program Manager was to then report the results to our Federal partner. Despite nearly a year of planning that involved all local and Federal partners, the structure and processes were changed at the "eleventh hour". While the "new" reporting algorithm was not objectionable, the lack of communication and lack of transparency was counter-productive to the mission.

NYC's long involvement in the BioWatch program has resulted in some insight into the program. Based on our experience, we urge Congress to clearly define the roles and responsibilities of the entities involved—CDC, DHS, the contracting agent responsible for laboratory personnel, and the host laboratories. In addition, there is

a need for a central Federal entity to guide consequence management planning in the event of a BioWatch Actionable Result (BAR).

We are concerned that DHS have adequate resources to support the additional responsibilities provided in this legislation. DHS is relatively new, and currently appears to be under-resourced. For example, the BioWatch program suffers from underfunding. The program was deployed hastily, and without an apparent understanding of what the true program costs would be. It is not clear that the correct funding algorithm for this program has yet been developed. Testing personnel, instruments, and reagents are Federally funded. Local scientific and administrative oversight, laboratory support, security personnel and infrastructure, and overhead, such as space, waste disposal, equipment (e.g., autoclaves and biological safety cabinets), and office support are not Federally funded, and represent a significant burden on laboratory budgets. Resources to build a quality system for the program are urgently needed. I am sure this committee is well aware of the consequences of unreliable BioWatch results, and I want to thank the authors for recognizing this need in section 2132 of H.R. 5498, which would provide additional financial support.

In "The World at Risk," the Commission for the Prevention of WMD Proliferation and Terrorism also recommended new Government investments in biosafety and oversight of laboratories working with select agents. Comprehensive biodefense needs to address both intentional and accidental releases of biological threat agents. The NYC DOHMH is responsible for detecting and mitigating the impacts from any infectious disease outbreak that threatens public health, whether it is caused naturally, intentionally, or accidentally. However, the NYC DOHMH does not have access to information that would enable it to mitigate vulnerabilities in certain laboratories before an accident occurs, or to be confident that spills and other accidents in NYC laboratories working with select agents would be reported promptly to the NYC DOHMH. Academic research laboratories are not regulated by New York City or New York State government, and through the Select Agent Act, the Federal Government provides the only oversight of biosecurity and biosafety within these facilities. The CDC releases only contact information to local and State public health agencies for laboratories regulated by the Select Agent Act. It is possible, for example, that a researcher could be exposed to a select agent through a laboratory accident, become ill, and expose others outside that laboratory. A second, limited SARS outbreak in 2004 resulted from just such a breakdown in biosafety in a Chinese laboratory. In the proposed bill, we hope that sections 2105 and 2107 will provide for the sharing of information with public health departments that would be needed to mitigate and respond to select agent incidents in laboratories within their jurisdictions. As responsibility for Tier 1 and Select Agent Programs shifts from the Department of Health and Human Services to DHS, we encourage the Federal Government to take steps that address the public health requirements of jurisdictions within which select agent research takes place. Local and State public health agencies need to have access to detailed information related to the biological agents and biosafety programs at each laboratory regulated by the Select Agent Program.

The proposal in section 2104 of H.R. 5498, to redefine a set of select agents as Tier 1 agents that require enhanced security, makes sense. However, the concordant enhanced biosecurity that will be required of facilities that handle these agents needs to be resourced appropriately and annually. Additional requirements will necessitate additional personnel. Currently, the NYC PHL Select Agents program has a Responsible Official (RO) and an Alternate Responsible Official (ARO); both are senior-level laboratorians that manage the program as one of their regular duties. Over time, increased duties for the RO and ARO in the form of increased responsibility for inspections and oversight, added requirements for conducting drills of increasing complexity, and requirements for detailed after-action reports have significantly increased workloads. However, there has been no concomitant increase in funding. Proposed additional requirements for handling select agents and Tier 1 agents need to be accompanied by an increase in funding for affected laboratories, including allocations for high-level personnel to oversee the program. Enhanced biosecurity for Tier 1 agents proposed in the legislation will be costly.

Public health laboratories are subject to regulation from a number of agencies. In addition to the LRN, the NYC PHL is a member of the Food Emergency Response Network (FERN), the environmental Laboratory Response Network (eLRN), and the chemical Laboratory Response Network (LRN–c). The development of the Integrated Consortium of Laboratory Networks (ICLN), as provided in section 2136 of the proposed bill, promises to integrate and streamline regulations. We have yet to see benefits from the ICLN. We are still required at the public health laboratory level to input data into multiple, distinct data management systems, and the data is analyzed by each individual Federal agency. The public health laboratory community has advocated for several years the use of a single laboratory data information man-

agement system, but this has not yet come to fruition. We support the participation of public health laboratories in the ICLN and look forward to a more focused and determined approach to integration. Organization through the ICLN could result in increased efficiency of resource use.

The NYC PHL is one player among many local, State, and Federal entities comprising the antiterrorism preparedness and response efforts in NYC. It is our duty to be prepared to provide the necessary surveillance, routine, and surge testing to support the emergency preparedness and response effort of the city. We need the support of our Federal, State, and local partners to be able to do this. Preparedness means not only meeting the threats of today, but also anticipating the threats of tomorrow. The building housing the NYC PHL was designed in the late 1950s and was opened nearly 45 years ago. An updated and upgraded facility is badly needed, and we are developing plans for a state-of-the-art facility that incorporates needed biosecurity and containment measures, as well as the technologies needed to detect emerging and re-emerging pathogens. However, the city faces challenges in funding construction of the new facility, particularly in the current economic climate. To optimally prepare for the future, the city would welcome the collaboration of the Federal Government in planning, funding, and ensuring the further development of a state-of-the-art public health laboratory for highly-at-risk New Yorkers and for the Nation.

The New York City Department of Health and Mental Hygiene appreciates the opportunity to testify on the development and implementation of the important measures outlined within H.R. 5498, the "WMD Prevention and Preparedness Act of 2010." While I have limited my comments today to issues related to the NYC PHL, the city would like the opportunity to provide more detailed comments on the entire bill reflecting the concerns of all of our key emergency response agencies. The NYC DOHMH stands ready to assist the committee, and our Nation, in any way possible, to develop and implement these critical initiatives. Again, thank you for the opportunity to testify, and I look forward to answering any questions you may have.

Ms. CLARKE. We thank you, Dr. Beatrice, for your testimony.

I now recognize Dr. Murch to summarize his statement for 5 minutes.

**STATEMENT OF RANDALL S. MURCH, ASSOCIATE DIRECTOR, RESEARCH PROGRAM DEVELOPMENT, NATIONAL CAPITAL REGION, VIRGINIA POLYTECHNIC INSTITUTE**

Dr. MURCH. Thank you, Chairwoman Clarke and Members of the committee. I appreciate the opportunity to come before you today.

You know from the Chairwoman's comments on my background it is heavily involved in sciences technology intelligence operations involving counterterrorism and weapons of mass destruction terrorism. I will summarize my comments from that perspective.

I strongly support the development and coordination and implementation of a National intelligence strategy. I believe it is an important roadmap for the Nation. But while creating and vetting such a strategy is important, as with many endeavors and Government and public policy and programs, implementation requires plans, measures of progress, and accountability. There are plenty of good ideas that never go anywhere and good strategies and plans that go adrift for lack of focus or interest.

So in my view it is not important simply to state where we should be heading, but what we are going to do, when we are going to do it, who is responsible for what, and measure how well we are doing. It is also important for us to know how well we know how well we are doing.

These should come through clearly articulated goals and objectives, assignments, and responsibility requirements, expectations, and measures of success. I am very gratified to see that provisions have been made in the legislation for planning and reporting.

It is also important to have someone clearly in charge. When everyone is in charge, no one is in charge. I hope that the DNI would take that role. Congress, too, has an important responsibility for oversight in this legislation and beyond.

This is a very complex system that we are trying to address. For those who participate, priorities and assignments and responsibilities should be well matched to the department and agency authorities, responsibilities, and capacities. For example, the copy of the legislation that I saw noted that the director of national intelligence should develop and implement a strategy in consultation with the Secretary of homeland security and heads of other departments and agencies.

It is important that DHS be involved, clearly, but in my view it is absolutely necessary to raise the involvement of the other non-DHS Federal departments and agencies that have more direct front-line responsibilities and roles in domestic security, law enforcement, and intelligence as equal partners. Those latter agencies do indeed have many years of experience and expertise and committed resources in areas such as WMD intelligence and response.

Perhaps more better focused and more innovative and integrated initiatives are necessary to address these very substantial challenges and gaps we face with WMD intelligence, but we should acknowledge that DHS is a relative newcomer.

I would like to move on now to the National intelligence strategy for countering biological threats. Many of the points I made above are applicable here, but I think the key point that I would like to make with you is to tightly couple the strategy with the broader National intelligence strategy, that they are closely interrelated.

It is known in a number of quarters inside and outside the intelligence that bio-intelligence, that colloquial phrase that is often used, is very important. It is a fundamentally very hard problem, and it is going to take innovation, creativity, resources, planning, and commitment over many years. It is not going to happen overnight. It is probably not going to happen in a single budget year.

We can learn lessons again by going back to an Institute of Medicine study that was published in 2006 called "Globalization Biosecurity and the Future of the Life Sciences" to really teach us how complex life sciences and its misuse can be and how we might tackle it in a more effective way.

Unfortunately, the intelligence and law enforcement communities cannot focus only on that, so we need to be in the right place at the right time focused on the right people, the right processes, a very significant challenge.

In the aforementioned IOM study, it also addressed the problem of—or the opportunity of engaging biological experts outside of the Government. I actually offered that recommendation, and I think it was the only one that was taken up from that study. I support that. I think there are tools and programs that could be built on, such as the biological sciences experts group that was started by the National Counter Proliferation Center some years ago.

Now, we quickly move on to the bioterrorism risk assessment, section 2103, to make a quick point. These bioterrorism risk assessments have been on-going, and they will continue to deliver important contributions.

However, one point I wish to make is that in 2006 the Department of Homeland Security engaged the National Research Council for review of their methodology. As a result, the NRC committee actually came up with a very detailed, pointed, critical assessment of the bioterrorism risk assessment.

To my knowledge, and no one I have talked to knows whether or not DHS has accepted or rejected those recommendations, whether or not has anything been done, and whether or not the NRC committee got it right or wrong. I think it is important to reconcile that before going forward.

Moving on to the issue of attribution, one that is near and dear to my professional existence over the last 15 years since I created the National program, I think it is important that we focus properly on a National microbial forensics strategy which is bigger and broader than the R&D strategy that was just published, which is a very important contribution, but it is not enough. We need to go beyond and incorporate some of the other aspects of forensic science that need to be incorporated and a robust approach to a National microbial forensics repository.

Ms. CLARKE. Dr. Murch, can you just sort of summarize? We will probably get into some more of your findings through questions.

Dr. MURCH. Yes, ma'am.

So the National microbial forensics repository needs its own substrategy to effectively move forward.

A couple of quick points—law enforcement training for investigating biological threats. I would strongly recommend the Department of Homeland Security, if they are going to undertake this, be assigned this role, that they engage the FBI and the public health community, as they have been working on this for 15 years, and we don't want to compete or conflict with what is already on-going in the field and the broader community.

Then two other quick points here on response. Integrated plume modeling is mentioned in your legislation. I would encourage the Department of Homeland Security, if they go forward, that they work with the Department of Defense and Department of Energy, who has been working on these models for many years and spent many millions of dollars of taxpayers' funds, rather than duplicate.

Then last, I strongly encourage, having been involved in two National Academy studies involving forensic science, one of which was involved in nuclear forensics, that the academies be engaged by the Department to take on a broader study—not simply the role of forensic science in homeland security, but also outlining forensic science in DHS with where the rest of the enterprise is going.

Thank you.

[The statement of Dr. Murch follows:]

PREPARED STATEMENT OF RANDALL S. MURCH

JUNE 15, 2010

Chairwoman Clarke, Members of the subcommittee and committee staff, thank you for the invitation to present a statement before you today and have my comments entered into the record regarding this important and timely legislation before the Congress.

My name is Randall Murch. I am a faculty member at the Virginia Polytechnic Institute and State University, which is more commonly known as Virginia Tech. Prior to joining Virginia Tech, I had a 23-year career as a Special Agent with the

Federal Bureau of Investigation during which I was heavily involved in counterterrorism and weapons of mass destruction terrorism and counterterrorism from the operational, investigative, intelligence, planning, science and technology, and forensic perspectives. In my FBI career, I spent 10 years in the FBI Laboratory and over 8 years in the technical surveillance program and oversaw forensic investigative and technical investigative support efforts for a number of well-known domestic and international terrorist attacks. During this period, the Nation endured the attacks in Oklahoma City, Khobar Towers in Saudi Arabia, the U.S.S. Cole, the U.S. Embassies in East Africa and 9/11, among other events. I created our National WMD forensic program in the FBI Laboratory in 1996 and oversaw its early development in partnership with other U.S. Government agencies. In my career, I served not only in the FBI, but was also detailed from that agency to the Defense Threat Reduction Agency during the latter part of my career. Later, I was loaned to the Department of Homeland Security, Science and Technology Directorate from Virginia Tech for 1 year. Since 2000, I have participated in several National Academies and Department of Defense studies related to weapons of mass destruction or homeland security. I still work in relevant areas and provide pro bono advice to the Government in these areas, in addition to others.

Today, I will provide comments for your consideration to some specific sections of the proposed legislation.

TITLE 1: INTELLIGENCE MATTERS

*Section 101. National Intelligence Strategy for Countering the Threat from WMD*

I strongly support the development, coordination, and implementation of a National Intelligence Strategy for Countering the Threat from Weapons of Mass Destruction as recommended by the WMD Commission to be led by the Director of National Intelligence (DNI). While the creation and vetting of such a strategy is important to lay out a high-level roadmap, as with many other endeavors in Government, public policy, and programs, successful implementation through plans with measures of progress and accountability are crucial. There are plenty of good ideas that never go anywhere, or good strategies and plans that go adrift because focus or interest is lost.

In my view, it is not just important to state "where we should be heading" but also to state "what we are going to do" and "when are we going to do it" and "who is responsible for what", and "measure how well are we doing" and knowing "how well we know how we are doing". These should come through clearly articulated goals and objectives, assignments of responsibility, requirements or expectations, and measures of success. I am gratified to see that provisions have been made in the legislation for plans and reporting. Also someone has to be actively "in charge"; when every one is in charge, no one is in charge. My hope is that the DNI will fill that role and do so well. The enterprise should be held accountable, otherwise having a strategy and a plan is not particularly useful or meaningful. Course corrections can be made as needed. Congress certainly has a role here through its oversight responsibilities.

No one entity can put a strategy and such as this and the associated "complex system" into play. For those who participate, the priorities, assignments, and responsibilities should be well matched to what department and agency authorities, responsibilities, and capacities are or should be. For example, the copy of the proposed legislation I have notes that the Director of National Intelligence should develop and implement the strategy "in consultation with the Secretary of Homeland Security and the heads of other appropriate Departments and agencies". The Department of Homeland Security does have important coordination and consumer roles in the envisioned process and outcomes, some DHS agencies are "operational contributors and users".

However, in my view it is absolutely necessary to improving our capabilities and performance that those non-DHS Federal departments and agencies that have more direct front-line roles in domestic security, law enforcement, and intelligence must be fully and aggressively leveraged and involved as equal partners. Those latter agencies I am alluding to have many years of expertise, experience and committed resources, in some cases substantial in each category, devoted to WMD intelligence and response. Perhaps more, better, better focused, and more innovative and integrated initiatives and approaches are required to address the very substantial challenges and gaps we face with WMD intelligence, but we should acknowledge that DHS is a relative newcomer.

Also, during the planning process and before new initiatives and improvements are embraced, it may also be quite cost-effective and operationally beneficial for the

DNI to commission a comprehensive and rigorous "systems analysis" which would identify the specific and relevant capabilities that already exist and assess their effectiveness, and provide the prioritization for gaps, needs, and opportunities across the enterprise. This would be the informed and testable basis for designing and commissioning all initiatives going forward across the intelligence community.

*Section 102. National Intelligence Strategy for Countering Biological Threats*

Many of the points I noted above for the National WMD Intelligence Strategy could also be considered, if not embraced, for the next generation of the National Intelligence Strategy for Countering Biological Threats. The latter could, and even should, be clearly viewed and undertaken as being tightly connected to the former. They are not separate, competing, or mutually exclusive, but should be developed and implemented as being closely related, with many interrelationships and interdependencies.

Without spending more time on this strategy itself, permit me to briefly turn to two issues, one which is often stated as "the need for better 'bio-intelligence'" and the second which is stated in the proposed legislation as "expand efforts to create a national cadre of biological experts".

First, it has been well known for a number of years and in many quarters inside and outside the intelligence community that effective and timely intelligence on adversaries' or proliferators' intentions, capabilities, plans, and actions are crucial in order to prevent, anticipate, disrupt, interdict illicit events and activities or, if an event or transaction of interest occurs, to respond, attribute, or prevent subsequent activities of concern. This is not a new revelation. Those who call most vocally for more and better "bio-intelligence" are often fundamentally are unaware of how significantly different and challenging obtaining and leveraging the most precious, timely, and sought-after nuggets of "bio-intelligence" really is. This truly is a "hard problem". If we agree that "bio-intelligence" is a high priority and essentially an unaddressed gap, then we should begin by defining and "unpacking" it so that all concerned know what it is and what "it" entails. From my personal experience, the term "bio-intelligence" was first coined by Dr. George Whitesides of Harvard University approximately 10 years ago. Then, he knew what he meant and those of us working with him on studies for the Department of Defense knew what he meant. Today, I'm not sure there is a single, accepted definition of what "bio-intelligence" is. What it means depends on who one is talking to. If a universal definition and description of the component elements can be agreed to, i.e. "terms of reference", it may be a boon to harmonizing interagency and stakeholder communication, collaboration, and action on recognized priorities. The next edition of this Strategy could assist with this.

In 2006, the Institute of Medicine of the National Academies published an important study entitled *Globalization, Biosecurity and the Future of the Life Sciences,* that still helps us to frame the complexity and uncertainty of what we face with the future of life science knowledge and technology and their misuse. The reality is that we contend with is a complex, dynamic global ecosystem of rapidly advancing, diversifying, scalable, and accessible life science knowledge and applications. The vast majority of this endeavor is used for noble and beneficial purposes, and cannot be controlled. However, in this ecosystem are some who are embedded or hidden in, peripheral to, and protected who acquire, develop, test, and seek to use or profit from biotechnology and expertise for illicit and nefarious purposes. Intentional and actual misuse can occur by many ways and means, by many actors, from and in many places. The effects and impacts are scalable; one does not have to kill millions to cause significant impact. A little bioagent effectively deployed can make a big mess, as we experienced with the anthrax attacks in 2001.

Intelligence and law enforcement cannot be everywhere, know everything all of the time, and be solely focused on "bio-intelligence", either domestically or globally. Thus, either we accept the realities we face and limitations of the capabilities and resources we have, or we design, fund, and institute a sustained program that identifies the most important priorities to focus on, being at the right places, at the right times, focused on just the right people and process nodes, all of which takes advantage of the best available expertise here and with our allies. Advancing and applying new knowledge and understanding, policies and practices, technology, and leveraging innovation, creativity, and calculated risk-taking must be the foundation upon which this effort is built. This would apply to gathering and making sense of large amounts of open source technical information, new infectious disease surveillance approaches, better connecting public health with intelligence and law enforcement, as well as new methods and techniques in human intelligence. There is no "silver bullet" for better "bio-intelligence" and I'm not convinced that simply throwing money at the problem will get us any further down the road. If we agree that

a new or improved approach is necessary, we should be prepared to properly choose and resource our priorities and stay focused and committed. Success will not likely be achieved overnight or even in a single budget year.

With regard to better engagement of biological experts for intelligence, this, too, is not a new idea. In my estimation, this is a particularly useful goal which should provide useful outcomes. In the aforementioned IOM study, such a recommendation was made, which I authored. As far as I am aware, it was the only recommendation from that study that was acted on. Soon after the study was published, the National Counterproliferation Center (NCPC) created the Biological Sciences Experts Group, which reportedly has run well and meaningfully under strong leadership at NCPC since then. However, the pool of highly qualified and available experts is not limitless; it is difficult to hire and retain these experts as Federal employees. Some agencies, such as the Department of Defense, have long and effectively used external experts to study and report on "very hard" science and technology-based problems, including those related to biological weapons and biotechnology. Other key agencies, such as the FBI, are still primarily focused on outside experts for scientific research and development or episodic support to investigations or for liaison purposes, rather than to support their respective mission and responsibilities in intelligence. Perhaps working with the Congress, the DNI, and outside senior experts, those agencies that do not have sufficient access to outside experts can improve access to support their intelligence-related missions and help address "grand challenges", gaps, needs, and opportunities. This could occur through a single cadre available to the entire intelligence community, perhaps by expanding the BSEG and tailoring as needed, or creating similar groups for each agency that are modified. However, with agencies creating their own versions they could well run up against a shortage of knowledgeable, experienced experts. In reality there are only so many highly qualified experts to go around.

I now wish to address to five other sections in the proposed legislation.

TITLE II. HOMELAND SECURITY MATTERS

*Subtitle A—Prevention and Deterrence*

*Section 2103. Bioterrorism Risk Assessment*

This subsection "requires that the Secretary of Homeland Security, in coordination with the heads of other appropriate Federal departments and agencies, to produce biennial integrated Bioterrorism Risk Assessments to identify and assess evolving biological risks to the nation". It is well recognized in the community of interest that this activity makes critical contributions to risk management and risk reduction by supporting strategies, plans and programs, investment decisions, and public policy. When properly designed, conducted, and used, these assessments will continue to prove to be important to the future of our National counter-bioterrorism and biodefense enterprise. However, just as it is important to perform and provide these assessments, it is also important to conduct them in a rigorous, accurate, reliable, scientifically-sound, and defensible manner. The users of and stakeholders for these assessments should be able to rely on these assessments with confidence.

In 2006, at the request of the Department of Homeland Security, the National Research Council established a committee to provide a review of DHS' Bioterrorism Risk Assessment (BTRA) methodology. This study resulted in an interim report focused on near-term improvements and a final report which included recommendations for longer-term improvements. The latter was published in the open literature in 2008. The final report, which includes the interim report in an appendix, provided a detailed, pointed, critical assessment of DHS' Bioterrorism Risk Assessment methodology and provided a number of recommendations for improvement. To my knowledge and through queries in the community of interest including those in the Government, DHS has not substantively or publicly responded to this report. We do not know whether DHS agrees or disagrees with or has acted on any or all of the NRC's observations and recommendations. If they disagreed, we should know why this is justified. If they have addressed some or all of the NRC's concerns, this would provide us with greater confidence that the BTRA is on the right track. Concomitantly, we do not know whether there is a basis for concern that the NRC got it wrong all or in part. If that is the case, there should be pause with future studies coming out of the NRC, since the National Academies reputation is built on performance that is expected to embrace independence, objectivity, relevance, and quality.

Going forward, a point-by-point response by DHS to this particular NRC report is not an unrealistic or outlandish expectation. All that is being asked for is to come full circle on the BTRA peer-review process. Good science often leads to sound public policy, programs, and benefits and gives all concerned greater confidence. Some-

times peer review can be harsh; I know this first hand as one who helped lead the FBI Laboratory through a very difficult time in the mid-to-late 1990s in an intense period of scrutiny from many quarters resulting from allegations that the quality of its science and performers were sub-optimal. Further, sometimes peer reviewers are peer reviewed themselves with surprising results. But the process is universally accepted and is designed to make the science and its performers better. This situation should be treated no differently, especially because of its importance.

Given the importance of the BTRA and the observations, recommendations, and conclusions reported by our Nation's leading body of scientific, medical, and engineering experts, this should be resolved and done in a manner that gives all concerned confidence that future BTRAs will always be performed using the best possible methodology and provide the most useful and reliable assessments. This action should also inform the interagency task force that is called for in the legislation.

*Subtitle D—Attribution*

*Section 2141. Bioforensics Capability and Strategy*

Bioforensics is a discipline and National capability that has been near and dear to my heart and professional existence for the past 15 years. I initiated the latter from the FBI Laboratory in prior to the 1996 Olympic Games which gave birth to the former, and oversaw their early development and have been heavily involved various aspects ever since. I still do believe strongly that an effective, reliable, testable, defensible, credible forensic capability for biological agents, toxins, and associated traditional physical evidence is an important "tool" in our Nation's biosecurity "kit" specifically to support attribution decisions, legal prosecutions, policy decisions, and possibly significant follow-on actions. Though DHS is prominently mentioned in this legislation and previous policy documents and legislation, they are one of a family of agencies that have stakes in an encompassing and robust capability with the attributes I mentioned above.

We have made significant progress in a number of areas within microbial forensics over the past 15 years, but much remains to be done to bring our capability to full fruit so that can address likely events, predictable contingencies, and perhaps some exigencies with some surety. While good science exists to draw upon and many lessons have been learned from prior events, there are many gaps in the science and practice, unaddressed forensic requirements, infrastructure needs, and National assets that have yet to be established. One important contribution to moving forward was the recently-published *National Microbial Forensics R&D Strategy* led by The Office of Science and Technology Policy which is useful to harmonize the community and encourage collaboration and reduce duplication.

A broader, more overarching strategy document is needed which encompasses not only scientific advancements but also addresses common practices, standards, and shared infrastructure resources such as a National Microbial Forensics Repository, which is also mentioned in this section. Future legislative and policy documents not only need to mention what needs to be done, but also enable "the how" and "who" and what should the outcomes sought should be. These documents should do so to address and balance all appropriate needs and equities of key agencies, now and into the future.

Having a properly constructed, populated, operated, and maintained repository of known samples against which evidentiary samples can be compared is essential to the proper performance of forensic analyses and rendering conclusions, to include those that support attribution decisions. A repository of this nature can also provide important resources for research, method development, and testing. DHS is an important player and has been assigned a leading role in establishing the Repository, as alluded to in the legislation. However, it cannot and should not do this in a vacuum or without the cooperation, collaboration, participation, and shared value and risk of other Federal partners and other constituencies. For agencies to simply give samples to the National Bioforensics Analysis Center does not make a properly designed, functioning, and responsive National Microbial Forensics Repository, de facto. The call for a National Repository has been percolating in the microbial forensic (bioforensic) community for several years. There are differing views of experts as to how it should be designed and structured, what it should contain, how it should be organized and function, what standards should govern the science, and how best it can meet the needs, equities, and expectations of all prospective users and stakeholders.

As this effort would be very complex with many issues yet to be defined, I have recommended to my colleagues in this community that a well-constructed and conducted systems analysis could provide the proper foundation the desired capability. This would define the "what, why, where, when, who, and how" for future planning and execution.

*Section 2142. Law Enforcement Training to Investigate Biological Threats*

I must admit reading this section gave me some concerns, largely because DHS which is fundamentally not the lead involved in the law enforcement or public health investigations of biological threats is now being given a role in training those communities. At the Federal level, for nearly 15 years the responsibility for lead agency rests with the FBI and the Centers for Disease Control and Prevention which have been working closely together since 1996 to establish and improve investigative response and resolution. These two agencies, their parent departments and the communities they work with closely at the State and local levels have been doing this collaboratively for many years. Protocols, practices, and methods have been developed and are continually being refined. Many years of practical case experience resides with these agencies and the communities they work with.

More training may be needed but it should not be designed, planned, or provided so as to compete or conflict with what is being provided or the investigative processes and protocols that have been developed and used by the FBI and their field WMD Coordinators, the FBI Laboratory's Hazardous Materials Response Unit, FBI field office Hazardous Materials Response Teams, the FBI-led Joint Terrorism Task Forces, the CDC, State, and local public health and emergency services agencies, the Laboratory Response Network and others. To do otherwise could potentially threaten the health and safety of responders and integrity and success of bioterrorism investigations and prosecutions.

If DHS does provide this training now, or will be expected to, they should meet the requirements and expectations of the principal law enforcement and public health agencies that have the lead and who work most closely those who support these investigations. Close coordination with other appropriate agencies should be required; those agencies should monitor or participate in what DHS provides. Perhaps National standards should be developed, validated, and adhered to by all training providers to ensure the highest uniformity and quality.

*Subtitle E—Response*

*Section 2152. Integrated Plume Modeling for Collective Response*

This legislation calls for the Secretary (of Homeland Security) to "acquire, use and disseminate timely integrated plume models to enable rapid response activities following a chemical, biological, nuclear or radiological event."

Two key points with regard to this section: The Departments of Defense, including the Defense Threat Reduction Agency as well as others in DOD, and the Department of Energy in several of their National Laboratories, have spent many millions of taxpayers' dollars, have developed substantial expertise, and have produced usable plume models as a result of many years of effort. It is recommended that the Department of Homeland Security begin its search for, and assessment and acquisition of models in these Departments with leading experts. It is highly likely that it will be a massive and unwarranted waste of Federal funds for DHS to initiate its own de novo plume model research and development program.

With regard to the dissemination of plume models, I ask the questions "who are these models to be disseminated to?" and "if the recipients have no going-in capacity to effectively work with these technologies, who will provide training, seamless handoff, and reachback after the modeling technology has been provided?" In my opinion, even if well-intentioned, simply "throwing technology over the transom" will not be beneficial to those it is intended to help. If DHS will be in position to acquire, use and share DOD- and DOE-developed plume models, or from other sources that are recognized as "gold standard", then it should ensure that it has the requisite expertise to use them and provide effective training and reachback to those it provides the models to and expects to use them for improved planning, exercises, response, and recovery. I worry that this technology will be provided to the first responder community and just sit on the shelf and not be used or not be used effectively.

*Section 208. National Academy of Sciences Study of Forensic Sciences in Homeland Security*

I strongly support your legislative initiative for DHS to engage the National Academy of Sciences for a study on the role of forensic sciences in homeland security. This door was opened in the NAS study published in 2009 which was entitled *Strengthening Forensic Science in the United States: A Path Forward.* I was a member of the committee that produced this report and contributed to the section on forensic science and homeland security. This landmark study has been met with great interest and angst, and is beginning to change how forensic science will be funded, trained, performed, managed, scrutinized, and used in the courts, and is viewed by the media and public for years to come. This is very useful reading for how forensic

science should be advanced and improved. I am aware that the Senate Judiciary Committee is in the process of introducing legislations that acts on most of the recommendations of this report.

A forthcoming NAS study on the Nation's nuclear forensics capabilities, for which DHS' Domestic Nuclear Detection Office was one of three sponsors, will also provide valuable insights in this particular specialty of forensic science. I was a member of the committee that produced this report, as well. The NAS is also currently conducting a study for the FBI to assess the science that was developed and applied to the bioforensic evidence collected and analyzed to support the anthrax investigations which began in October 2001. DHS supported those investigations by scientific support from the National Bioforensic Analysis Centers and through others. Thus, the stage is certainly set to go forward with a new study by the NAS which focuses on forensic science and homeland security more broadly. Requiring a study by the NAS of forensic science for homeland security is a substantially good intention.

But, because of the legitimate concerns with forensic science and its use in our legal system, and the uncharted waters of forensic science being used to support policy decisions, I strongly recommend that the NAS study not only address the role of forensic science in homeland security but also be focused on the current state of forensic science in DHS as it is developed, validated, used and practiced, planned, managed, and intended in all of the agencies and components that have forensic science programs and capabilities of any sort or type. This aspect of the study should be comprehensive from traditional forensic science disciplines such as pattern evidence, DNA and chemistry and specialties such as bioforensics (microbial forensics), and nuclear forensics. Without this additional aspect, any NAS study on forensic science for homeland security would be incomplete, and be an opportunity missed. The Nation should demand that its forensic science enterprise will meet or exceed requirements and expectations and embrace best science and practice wherever it resides or for whatever mission it supports, including within DHS.

This concludes my testimony. I'll be pleased to try to answer your questions or address your comments. Thank you.

Ms. CLARKE. Thank you very much, Dr. Murch. Thank you for your testimony here today.

I now recognize Dr. Kadlec to summarize his statement for 5 minutes.

## STATEMENT OF ROBERT P. KADLEC, VICE PRESIDENT, GLOBAL PUBLIC SECTOR, PRTM MANAGEMENT CONSULTING

Dr. KADLEC. Thank you, Madam Chairwoman, Ranking Member Mr. Lungren and Mr. Pascrell. It is a great honor and privilege to be here today. I have dedicated most of my professional life in and out of uniform to address this issue of biological warfare and bioterrorism because of my deep conviction that the successful use of biological weapons can radically and forever change our Nation and our way of life.

I would like to applaud you and your colleagues for holding this hearing and congratulate you in particular, Representatives Pascrell and King and their staffs, Dr. George, for their newly drafted bill, H.R. 5498. I think it is a welcome addition to the other important pieces of legislation Congress has introduced and passed to address this serious problem.

During my tenure as special assistant to the President, I was able to basically provide him an analysis that indicated that if there were to be a successful attack with anthrax in a major metropolitan city, that that could result in several hundred thousand casualties and cost the Government $1.5 trillion in immediate direct costs.

It is clearly an issue that in these economic hard times that some people say we can't afford to do this to be fully prepared, but I suggest to you that we can't afford not to do it. With that, I would like

to just spend a couple of moments to highlight some of the great provisions that you have in your bill.

Clearly, your bill is comprehensive. Clearly, it is one that is going to take further study by a variety of experts and provide input to your staff. But I believe it is an important contribution to the overall dialogue and again I think results in the right form and tone in the sense of urgency that must be taken to address this issue.

First of all, subject to the issues of biosecurity and laboratory security, I welcome the notion that the select agent list is probably too long and too arduous and doesn't reflect the issues and agents that represent the greatest risk and potential impact to our country.

But I think it is worthwhile that the negotiated rulemaking that is identified in this bill includes the Department of Homeland Security as well as the secretaries of HHS and USDA to basically address that, as well as stakeholders from academia and the private and public communities, to make sure that they understand what they have to abide to as well as provide input into this and get the right balance.

I also want to strongly endorse the creation of the high containment biological security grants. I think you heard from the previous witness the costs that are associated with enhanced security. Sometimes this cost comes at the expense of conducting either vital scientific work or day-to-day activities in these research and public health institutions. Providing grants to offset the current and likely increases in security is essential to the success of this entire effort.

I also want to reiterate the importance of the work that you are doing in the area of protection and biological identification, particularly increasing the ability to understand and increase situational awareness. Obviously, the National Biosurveillance Integration Center is a matter of contention, and I welcome questions on that.

I also want to underscore the role that you have for the EPA and OSHA in the area of recovery and restoration. The costs that we could not necessarily calculate as a result of this analysis that was conducted by the Council of Economic Advisors to the President was the notion of how long it would take and how much it would cost to restore a metropolitan area once again so that normal livelihood and business could be conducted.

Another area that I think is closely linked to this recovery and restoration from a biological attack is an issue that you have identified under Title 3 of the public health matters, and that is a National Pre-Event Vaccination and Antimicrobial Distribution Policy Review. It is probably the most, I would say, urgent issue that needs to be addressed within your bill, primarily because the best way to ensure that our responders will do their jobs effectively and safely is for them and their families to be afforded the highest level of protection possible.

In light of that approach, pre-event vaccination and distribution of antibiotics not only makes sense, but is essential. I am deeply disturbed about our current approach—we have vaccines, such as an FDA-approved vaccine for anthrax, that is expiring on the shelves of the strategic National stockpile. Expired vaccines are

useless to everyone, but a vaccinated first responder is priceless to everyone.

I also hope that you will have the opportunity to ensure that families of first responders have the opportunity to have an FDA-approved med kit that can be pre-positioned at homes or places of work to ensure that their first responders' families can go about their business without worrying about their families. It is interesting to note that in many airports as part of the U.S. postal program, delivery program, that volunteer postal workers have in their possession antibiotics for themselves and their families in case of biological attack.

In closing, I want to again congratulate and endorse the work of this committee and the responsible members of its staff. This bill will go a long way to advance the status of preparedness of this country for a threat that is unthinkable, but likely. I very much appreciate the opportunity to appear before you and look forward to your questions. Thank you.

[The statement of Dr. Kadlec follows:]

PREPARED STATEMENT OF ROBERT P. KADLEC

JUNE 15, 2010

INTRODUCTION

Madam Chairwoman it is both a privilege and honor to appear before you and your colleagues to discuss this issue of great importance to America's National security. I have dedicated most of my professional life to address the issue of biological warfare and bioterrorism because of my deep conviction that the successful use of biological weapons can radically and forever change our Nation and our way of life. I note that Senators Graham and Talent made the risk from biological weapons their central theme of their 2008 report "World at Risk" and their 2010 report card. I too share their concern about the risk of complacency and false assumptions that currently affect our preparations for the consequences of this threat.

I would like to applaud you and your colleagues for holding this hearing and congratulate you and in particular Representatives Pascrell and King and their staffs for their newly drafted bill: H.R. 5498. As I will highlight in a few moments it represents a welcome addition to the other important pieces of legislation Congress has introduced and passed to address this serious problem.

HISTORICAL CONTEXT TO THE THREAT

I would like to start by briefly underscoring the central tenets that shape my words and indeed shaped my actions over the last two decades. Biological warfare and bioterrorism have largely remained a current hypothetical threat. We were fortunate in 2001 that the likely perpetrator of the anthrax letter attacks only intended to scare and not kill scores of Americans. We likely won't be that lucky next time. There are some who wrongly equate those attacks with the kind of threat we may confront in the future. This kind of wishful thinking is not only wrong but dangerous. Further, the notion that is now a frequent comment made by some equating natural threats like pandemics and emerging diseases to bioterrorism, noting that Mother Nature is a pretty good terrorist, is similarly wrong and also dangerous. Assuming that bioterrorism is equal or some kind of lesser included case of natural events like pandemics is irresponsible and demonstrates the lack of understanding of the nature of the threat.

Mother Nature is not a thinking enemy as Clausewitz noted in his seminal work on military strategy. Mother Nature is not trying to create pathogens in a 3–5 micron particle size aerosol that is optimum to infect and deliberately kill men, women, and children in a given city or geographic area for a political cause. Mother Nature does not deliberately create pathogens that circumvent our defenses such as antibiotics. She does so incidentally not because she chooses to but because we choose to use antibiotics in a way that makes it more likely. Mother Nature does not care about political boundaries. Terrorists and adversaries of the United States

would use biological weapons as part of a deliberate plan to exploit our vulnerabilities and attack innocents to destroy our country and way of life.

I don't make these comments based on personal opinion but on the basis of knowing the facts of what the United States demonstrated in the 1950's and 1960's. During the course of the U.S. offensive program that ended in 1969, actual field tests such as *Red Cloud Shady Grove* and many others using live agents demonstrated the equivalent lethality of biological weapons to our most potent nuclear weapons—hydrogen bombs.

President Nixon and his advisors understood that biological weapons were strategic weapons that worked too well. Their greatest value was not on the battlefield but in cities as weapons of terror that could kill civilian populations potentially directly or starving them by attacking animal and agricultural targets. Counting on the America's nuclear superiority in a bipolar world, Nixon chose to renounce these weapons unilaterally and supported a global ban prohibiting the development and use of the entire class of weapons. The historical context to this decision was the United States and the rest of the world stood at the cusp of the biotechnology revolution.

America's moral high road leadership did much to galvanize responsible nations to choose against biological weapons. We now know that the Soviet Union used the veil of biological arms control to pursue the most extensive and advanced biological weapons program known to man. They succeeded in ways that boggle the mind and tear at the heart: Weaponizing highly virulent strains of small pox at the time when the world was seeking to eradicate that scourge; creating strains of anthrax and plague that were resistant to multiple types of antibiotics; and seeking to create new pathogenic agents whose effects would confound medical diagnostics and have now treatments. The whereabouts of these weapons and more importantly the information and the people who made them is still in doubt. The recently published Pulitzer Prize-winning book "The Dead Hand" by David Hoffman offers glimpses into the Soviet's biological plans and programs and is an authoritative account of their deception and duplicity.

This is a history that many have forgotten. More recently during my tenure as Special Assistant to the President and Senior Director for Biodefense Policy for President Bush, analyses we sponsored revisited some of these lessons forgotten and provided a current context to the risk. A single attack by a terrorist organization or a group of disaffected individuals could threaten the lives of several hundred thousand and have a direct cost over $1.5 trillion. When critics argue we can't afford in today's economic hard times to prepare fully, I suggest that we cannot afford not to. I urge you Madam Chairwoman and your colleagues to revisit the lessons learned and regrettably forgotten from our former program to fully understand the great challenge that we are confronted with.

COMMENTS ON H.R. 5498

The bill that is the subject of today's hearing is a welcome and helpful significant step forward. It is comprehensive and highlights a number of areas where more progress is needed urgently.

I would like to comment on certain aspects of the bill that deserve special mention.

*Title II: Homeland Security Matters*

*Subtitle A: Prevention and Deterrence: Enhanced Biosecurity Measures*

First, the bill addresses the need to update and streamline the measures used to ensure that work with dangerous pathogens is both safe and secure. I know firsthand the challenges that exist trying to find the right kind of balance to permit important, no vital work with high-risk pathogens to ensure with have the necessary antibiotics, vaccines, and antidotes while ensure the risk of malicious diversion. I note that your language requires the Secretaries of Health and Human Services and Agriculture to work with the Secretary of Homeland Security using negotiated rulemaking.

The premise of this provision I think is the right one which is that the list of agents of concern should be for the biological or toxin agents of greatest risk. The current list of Select Agents is too long and not reflective of the agents that represent the greatest risk and potential impact. I think it is also essential and noted in your bill language that representatives from the academic, private, and public communities should have a seat at the table to ensure that the standards and practices set have been discussed and agreed to by the entities that will have to abide and implement such rules. In the end, I anticipate that the right balance of responsibility for safety and security and reasonableness will prevail.

I also note and strongly endorse that creation of High Containment Biological Security Grants. Up to this point, the costs of enhanced security have come at the expense of conducting the vital scientific work at these research institutions. Providing grants to offset the current and likely increases in security required is essential to the success of the entire effort.

Finally, I note that your Senate colleagues, Senators Lieberman and Collins have written similar provisions in their Bill Senate 1649. While there are differences between these two pieces of legislation, the opportunity to create a realistic and less onerous mechanism to oversee high-risk pathogens is a great one.

*Subtitle B: Preparedness: Detection of Biological Attack*

There is an important provision contained in your bill that I wholeheartedly endorse and wish to expound on.

The provision devoted to "Detection of Biological Attacks" is vitally important to fully implement. Unless we have more rapid environmental detection of biological attacks, we will not likely be able to mount an effective response to a large-scale bioterrorism attack. BioWatch as originally created was viewed as the best we could do 7 years ago. The system has performed admirably to date and has had the added benefit of compelling the public health and emergency response communities to address the opportunity that environmental detection offers by verifying the release of a biological agent before anyone becomes clinically ill.

As good as the system is now; it is too slow to mount the kind of response that will be necessary should an attack happen. Accelerating the development and deployment of automated biological detection in conjunction with advanced point of care diagnostics for the agents of greatest concern should be one of the highest priorities. I note with great confidence the role of the Under Secretary of DHS in both environmental detection and rapid biological threat detection and identification and her ability to successfully achieve these tasks.

*Subtitle F: Recovery: Recovery and Restoration From a Biological Attack or Incident Guidelines*

I strongly endorse the provision contained in this section of the bill. One of the major unknowns that we confront from the risks of a biological attack is the residual threat. While there are anecdotal experiences that indicate that there may be significant residual hazards from indoor and outdoor releases.

There is a great need to better understand and validate these potential risks. Furthermore, there is a need to promote the development of capabilities to address the possible consequences. I applaud your language that enlists the involvement of EPA and OSHA to reconcile before an event the standards that constitute safe and effective for the response community and general public.

*Title III: Public Health Matters National Pre-event Vaccination and Antimicrobial Distribution Policy Review*

A prepared response workforce is our best hedge against uncertainty. One of the best ways to ensure that our responders will do their jobs effectively and safely is for them and their families to be afforded the highest level of protection. In light of that approach pre-event vaccination and distribution of antibiotics not only makes sense but is essential.

What is deeply disturbing about our current approach we have vaccines such as FDA-Approved anthrax vaccine that is expiring on shelves in the Strategic National Stockpile when it could be offered voluntarily to first responders in areas where the risk of a biological attack is evaluated higher than others. Expired vaccines are useless to everyone, but a vaccinated first responder is priceless to everyone.

Furthermore, looking at the opportunity to ensure that the families of first responders are take care of opens the possibility of developing FDA-approved MEDKITS that can be pre-positioned at homes or places of work that ensure that first responders are not worried about taking care of their families. This has been shown to be invaluable in the case of postal workers in Minneapolis who have volunteered to be part of the U.S. Postal program. Antibiotics are prescribed for both the volunteer postal worker and his or her family. In case of a biological attack, the responder can go do his or her duty without worrying about their families.

There is one last subject I would like to mention subject to your bill and that is to emphasize the importance of situational awareness as it relates to the evolution of a biological attack. As we experienced most recently with the H1N1 pandemic and even during the on-going crisis in the Gulf with oil spill, situational awareness—knowing what is going on with a high degree of confidence—is essential. There have been several attempts to address this critical enabling element in our biodefense strategy. Again and again we have come up short. I note that your bill highlights that important function and I endorse the goal and the importance of it.

In closing, I want again to congratulate and endorse the work of this committee and the responsible Members and staff. This bill will go a long way to advance the status of preparedness of this country for a threat that is unthinkable but likely. I very much appreciate the opportunity to appear before you and look forward to your questions.

Ms. CLARKE. We thank you, Dr. Kadlec, for your testimony here today.

I now recognize Dr. Fischer to summarize her statement for 5 minutes.

**STATEMENT OF JULIE E. FISCHER, SENIOR ASSOCIATE, GLOBAL HEALTH SECURITY PROGRAM, HENRY L. STIMSON CENTER**

Dr. FISCHER. Thank you. Good afternoon, Madam Chairwoman, Mr. Lungren, Mr. Pascrell, distinguished Members of the subcommittee. Thank you very much for giving me the opportunity to offer comments on this important piece of legislation.

Following the anthrax assault of 2001, Congress hardened the regulations that governed access to the so-called select agents, those pathogens and toxins deemed a serious threat to public health and security. The Departments of Health and Human Services and Agriculture administered oversight of the laboratories that possessed, used, and transferred these pathogens.

Since the implementation of the regulations, they have negotiated a delicate balancing act—how to apply the regulations in a way that effectively promotes biosecurity without hindering absolutely critical research, which is all the more important, because this research builds the public health toolkit that offers us protections from infectious diseases, including those that might be biological weapons.

Although they are aimed primarily at U.S. laboratories, the select agent regulations and many of the measures here affect international collaborations—research has become a global enterprise, and talented researchers within emerging economies increasingly engage in collaborative investigations with their U.S. counterparts.

These professional relationships build trust. They build shared norms. They foster open scientific exchange during international public health crises. Ultimately, they protect health and safety at home and abroad.

Many of the pathogens on the select agent list cause natural disease outbreaks in Asia, Africa, Latin America. The U.S. and international researchers based in countries where the pathogens are prevalent benefit mutually from open partnerships that include sharing of knowledge, skills, and specimens. An unknown number of U.S. researchers severed such international collaborations following the implementation of the select agent regulations.

The costs and benefits of security measures that might further imperil such collaborations or obstruct cooperation during an international public health crisis must be considered carefully.

A common criticism of the select agent regulations has been the application of a one-size-fits-all security strategy, and the proposed legislation would require enhanced biosecurity measures for laboratories using Tier 1 material agents. This is a good start in recognizing that there are tiered levels of biological risks sensitive to the context as well as to the pathogens themselves. Greater emphasis

on risk-based security could allow stakeholders to set priorities more effectively.

The proposed legislation implies that this list will be smaller than the current select agent list, specifying only inclusion of bioterrorism risk assessments, as referenced by Dr. Murch, which suggests an evidence-based approach. But the criteria that would be used to distinguish these Tier 1 agents from select agents is not yet described in detail.

The legislation does not yet make clear how these new Tier 1 practices would be managed in relationship to the existing select agent regulations at the National institutional level, although those standards will be relaxed to those institutions possessing select agents newly categorized as lower risk.

While the awards to offset the increased security costs mentioned here at Tier 1 laboratories would be strongly welcomed, it is unclear how risk will be evaluated or whether the organizations that receive such funds could use them to help their overseas partners comply with any new controls on pathogen acquisition, storage, transfer, and use. It is difficult to say, pending that detail, whether these measures might further isolate U.S. researchers who are investigating Tier 1 pathogens from their international counterparts.

The proposed network that would emphasize enhanced customs and export regulation and enforcement under DHS emphasize this operational relationship to not new authorities, but the committee must be aware that in this context the emphasis could reinvigorate apprehensions among the research community at home and abroad about the open sharing of information resulting from unclassified scientific research.

Biosurveillance systems have now faced new demands to provide warning of extraordinary events. As the SARS outbreak demonstrated in 2003, the costs when one nation lacks the ability or will to report emerging infectious disease before it spreads across borders can be enormous. This outbreak helped catalyze the adoption of the revised international health regulations by the member states of the World Health Organization in 2005.

All 194 state parties are required to strengthen the capacity through public health surveillance and response and report any deliberate natural or accidental events that might affect health across national borders.

Unlike other global health initiatives to strengthen capacities, these are legally binding. They enjoy widespread international support and complement the objectives of the Biological and Toxin Weapons Convention and the recently revised U.S. National security strategy for countering biological threats.

The United States is also stuck with its efforts to integrate its fragmented surveillance from networks, including, as mentioned, the National Biosurveillance Integration System and the National Biosurveillance Integration Center, an effort slowed at its outset by logistical and management challenges.

In the mean time the Homeland Security Presidential Directive 21 charged HHS with developing a National biosurveillance strategy for human health HHS.

As the legislation points out, DHS could play a much stronger leadership role in leveraging the operationally useful health-related

data and information that comes from this surveillance framework and existing arbitrary networks, as there are monitoring programs for decision-makers across all levels of government.

Finally, I would just like to say that the situational awareness for biological risk depends on capabilities far beyond U.S. borders. No nation in an era of accelerated globalization, no matter how technologically advanced, can build tall enough walls to keep out infectious diseases. This legislation acknowledges the critical need for the United States to support capacity building in other nations. We already have an endorsement of principles under the National strategy for countering biological threats to support principles consistent with the IHR 2005.

Stressing validated data on biological attacks does not parallel the terminology of the IHR and could eventually undermine or jeopardize U.S. and National efforts to support implementation of the IHR as a common global platform for disease protection and response, including for common biological threats.

Ms. CLARKE. Dr. Fischer, would you summarize?

Dr. FISCHER. Yes, ma'am.

Ms. CLARKE. Thank you.

Dr. FISCHER. So I would just strongly encourage the committee, and I hope that the committee will consider implementing the language within this very necessary legislation whether any measures might undermine U.S. support for mitigating risks from natural, accidental, or deliberate disease outbreaks under the IHR 2005 framework and through our collaborations with international partners. Thank you.

[The statement of Dr. Fischer follows:]

PREPARED STATEMENT OF JULIE E. FISCHER

JUNE 16, 2010

Good afternoon, Chairwoman Clarke, Congressman Lungren, Congressman Pascrell, Congressman King, and distinguished Members of the subcommittee. Thank you very much for giving me the opportunity to offer comments on H.R. 5498, the proposed WMD Prevention and Preparedness Act of 2010.

National and international responses to biological threats have evolved dramatically in the past decade. Following the anthrax assaults of 2001, Congress created legislation to promote biosecurity in the Nation's research and clinical laboratories, and to strengthen National capacities to respond effectively to public health crises. Measures broadened the regulations that govern access to "Select Agents," pathogens and toxins deemed a serious threat to public health and security if released. The Department of Health and Human Services (HHS) administers oversight of laboratories that possess, use, or transfer human pathogens on the Select Agent list, and the U.S. Department of Agriculture (USDA) serves a parallel role for laboratories that study plant and animal pathogens. These two agencies, together with the Departments of Defense, State, and others, have also invested in disease detection and response capacities abroad, through jointly owned research programs as well as training, funding, and technical assistance.

Since the implementation of the Select Agent regulations, these agencies and the biomedical research community have sought a delicate balance: How to apply the regulations in a way that meaningfully enhances biosecurity, without hindering the ability of laboratories to conduct legitimate clinical testing and research. The latter is all the more significant in that the research under scrutiny ultimately builds the public health toolkit of diagnostics, vaccines, and treatments against infectious diseases, including those that might be used as biological weapons.

Although primarily aimed at U.S. clinical and biomedical research laboratories, the Select Agent regulations have affected international collaborations. Life sciences research has become a global enterprise, and talented researchers within emerging economies increasingly engage in collaborative investigations with their U.S. coun-

terparts. These professional relationships build trust and shared norms, foster open scientific exchange during international public health crises, and ultimately protect health and safety at home and abroad. Many pathogens on the Select Agent list cause natural disease outbreaks in Asia, Africa, and Latin America and the Caribbean. U.S. and international researchers based in countries where such pathogens are prevalent benefit mutually from partnerships that include sharing of knowledge, skills, and specimens. An unknown number of U.S. researchers severed international collaborations following implementation of the Select Agent regulations, impairing progress and reducing the influence of U.S. scientists within international communities of practice. The costs and benefits of security measures that might further imperil such collaborations, or obstruct cooperation during an international public health emergency, must be weighed carefully.

The legislation introduced by Congressmen Pascrell and King would address many of the lessons learned since 2001, including recommendations by the bipartisan Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. The proposed act recognizes gaps in our abilities to respond to events that could jeopardize public health and National security. Public and private sector stakeholders in the life sciences still struggle to balance cultures of responsibility and fear in addressing potential vulnerabilities. The proposed legislation confronts another balancing act: How to improve coordination and integration of the myriad programs that have evolved to tackle biological threats without creating new layers of oversight that might rob existing efforts of their momentum.

PREVENTION AND DETERRENCE

A common criticism of the Select Agent regulations has been the application of a "one size fits all" security strategy to all of the listed pathogens, even though the public health, scientific, and security communities recognize a gradient of risks. The proposed legislation would require enhanced biosecurity measures for laboratories that possess, use, and transfer "Tier 1 Material Threat Agents." This is a good start in recognizing tiered levels of biological risks that are sensitive to context as well as pathogen characteristics. Greater emphasis on risk-based security measures could allow stakeholders to set priorities more effectively, focusing their resources on the subset of laboratories where challenges are most evident.

The proposed legislation implies that the list of "Tier 1" agents would be smaller than the current Select Agent list. The mechanisms described would give broad latitude to the stakeholders in identifying "Tier 1" agents, specifying only the inclusion of Bioterrorism Risk Assessments, which suggests an evidence-based approach. However, the criteria that would be used to distinguish "Tier 1" agents from Select Agents are not described in detail. The legislation would designate the Department of Homeland Security (DHS) to lead an interagency rule-making process to develop the enhanced biosecurity measures, including laboratory practices. Although a laudable attempt to mandate inclusion of the broader stakeholder community, this could further complicate existing dual HHS and USDA oversight. The proposed legislation does not describe how these new "Tier 1" practices would be managed in relationship to the existing Select Agent regulations at the National or institutional level, or whether standards would be relaxed for institutions possessing Select Agents newly categorized as lower-risk.

The legislation would authorize awards to offset increased security costs at "Tier 1" laboratories, based on risk. While a welcome response, it is unclear how risk would be evaluated, or whether academic and non-profit organizations that receive such funds could use them to help overseas partners comply with any new controls on pathogen acquisition, storage, transfer, and use. In the absence of such assurance, and pending further detail on the Tier 1 Material Threat Agent determination process, it is difficult to say whether these measures might further isolate U.S. researchers investigating Tier 1 pathogens from their international counterparts.

The proposed network to coordinate customs and export regulation enforcement under DHS emphasizes enhanced operational relationships, rather than new authorities. However, in this context—particularly given the reference to "dual-use" technologies, a term that includes a broader swath of activities and materials in the life sciences than commonly applied to commodities with military applications—this emphasis could reinvigorate apprehensions at home and abroad about the open sharing of information resulting from unclassified research.

DETECTION

Biosurveillance systems face new demands to provide warning of extraordinary events. In response, stakeholders have expanded their capabilities to detect and

characterize public health events that could become National, or transnational, threats.

The 2003 SARS outbreak vividly demonstrated the costs when one nation lacks the ability or will to report an emerging infectious disease outbreak before it spills over borders. The human, political, and economic tolls helped catalyze adoption of the revised International Health Regulations by the World Health Organization's member states in 2005 [IHR (2005)]. The IHR (2005) require the 194 state parties to strengthen their capacities for public health surveillance and response, and to report any deliberate, natural, or accidental events that might affect health across national borders. The regulations also vested WHO with new authorities to collect and share information on such events. Unlike other global health initiatives that aim to strengthen capacities for disease detection, assessment, reporting, and response, the IHR (2005) are legally binding. They enjoy relatively widespread international support, and complement the objectives of both the Biological and Toxin Weapons Convention and the recently released U.S. National Strategy for Countering Biological Threats.

The United States has also stepped up its attempts to integrate its fragmented disease surveillance networks. Public Law 110–53 charged DHS with overseeing the development and operation of the National Biosurveillance Integration System (NBIS), including the National Biosurveillance Integration Center, an effort slowed at its outset by logistical and management challenges. Homeland Security Presidential Directive—21 delegated the task of establishing a National biosurveillance system for human health to HHS. With input from the interagency Federal Biosurveillance Work Group and other stakeholder committees, the U.S. Centers for Disease Control and Prevention (CDC) developed the National Biosurveillance Strategy for Human Health delivered in February 2010. This strategy outlines steps for improving the timely, multi-directional flow of health-related information among local, State, and Federal stakeholders and with global partners. As implied by the proposed legislation, DHS could play a stronger leadership role in leveraging operationally useful health-related data and information for decision-makers across all levels of Government. This should build upon the existing National biosurveillance strategy for human health, laboratory networks, and biomonitoring programs.

### ATTRIBUTION

The legislation would require public and private entities that have received Federal funding to provide samples of biological agents and toxins for a proposed National bioforensics repository collection. Others here today will doubtless comment more comprehensively on the tools for attributing biological attacks to likely perpetrators. I would like to highlight additional sensitivities in including organisms derived from international partnerships or collections.

Many emerging economies already perceive the motives of the U.S. and the international community in collecting specimens for legitimate public health interventions as less than transparent. The proposed repository would explicitly include international collections and implicitly encompass agents originally derived by U.S. researchers from international partnerships. Including agents that trace their origins to international collaborations, perhaps even to third-party countries, could inflame tensions that already endanger specimen sharing under the IHR (2005) and other global disease surveillance agreements. The potential effects on U.S. engagement in global health should be factored into the examination of access and participation issues laid out in the proposed legislation.

### INTERNATIONAL COLLABORATION AND ENGAGEMENT TO ENHANCE BIODEFENSE AND BIOSECURITY

As recognized by the legislation's authors and articulated in the recommendations of the Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, situational awareness for biological risks depends on capabilities far beyond U.S. borders. In an era of accelerated globalization, no nation, no matter how technologically advanced, can build tall enough walls to keep out infectious diseases and other public health risks.

This legislation acknowledges the critical need for the United States to support capacity-building in other nations. Many nations will require significant technical and financial assistance to strengthen mechanisms for detecting and reporting unusual events that could presage a deliberate, accidental, or natural infectious disease outbreak. A large number of Federal agencies and organizations already play key roles in U.S. global health security engagement. The proposed legislation effectively recognizes the unique role of the State Department's Biosecurity Engagement Program. However, other Federal agencies and divisions, including the Department

of Defense, HHS (including CDC and the National Institutes of Health), USDA, the U.S. Agency for International Development (USAID), and elements of the U.S. National laboratories, have significant presence and track records in promoting biosecurity engagement and information exchange abroad. Because these agencies have different institutional goals, they have not always pursued coordinated strategies for building comprehensive biorisk management. The endorsement of principles consistent with the IHR (2005) in the National Strategy for Countering Biological Threats offered a platform for stronger interagency coordination, using an operational framework already shared by international partners. The proposed legislation's focus on building capacity to report "validated data on biological attacks" to United Nations organizations does not parallel the terminology of the IHR (2005), which refer to detecting and reporting "public health emergencies of international concern." This might inadvertently jeopardize U.S. and international efforts to support implementation of the IHR (2005) as a common global platform for disease detection and response, including deliberate biological threats.

International collaboration is an important tool in building shared norms, and U.S.-supported capacity-building projects in the life sciences increasingly build long-term partnerships that promote trust, openness, and converging research priorities. The proposed legislation acknowledges the benefits of such engagement, directing the Secretary of State to support partner nations' efforts to enhance biosafety and biosecurity, taking their own priorities in comprehensive biorisk management into account. Language in the proposed provisions that would generally promote data-sharing among Federally supported programs abroad for biosecurity purposes might reinforce negative perceptions of U.S. transparency and motives.

### INTERAGENCY TASK FORCE ON BEST PRACTICES FOR GLOBAL BIOPREPAREDNESS

The last decade has witnessed a rapid growth of public health preparedness capabilities at home and abroad. Domestically, the United States has supported efforts to share lessons learned during events and exercises among first responders in an effort to strengthen all-hazards preparedness at the local, State, and Federal levels. Clearly, other nations face the same need to build response capabilities across levels of government, and many do so without the resources available in the United States and other high-income nations. Concerns about exposing homeland security vulnerabilities have limited open information-sharing about lessons learned in disaster response with first responders outside of the United States. The United States is certainly not the only Nation to hold the results of simulations and self-assessments in public health preparedness close.

Several recently developed mechanisms answer the need to help nations identify and implement best practices to prevent, detect, or respond to biological and other catastrophic threats. The IHR (2005), under the aegis of WHO, provide an international forum for assessing and strengthening the global architecture for public health preparedness. United Nations Security Council Resolution 1540, through the work of the 1540 Committee, provides an information clearinghouse and means for capacity building to prevent proliferation of weapons of mass destruction, including bioweapons. The United States plays a significant role in assisting partner nations with their obligations under these frameworks.

By authorizing a U.S. interagency task force on global biopreparedness architecture, the legislation would spark a discussion of new developments and persistent gaps among a broadly inclusive group of stakeholders. The result, if viewed as a map of needs, vulnerabilities, and potential partnerships, could help the United States develop a more targeted engagement strategy for building global pathogen surveillance and response capacities. It is unclear whether this task force would be charged with considering only the architecture for a deliberate biological event, or for natural outbreaks and accidental releases as well. It is possible that this task force could overlap substantially with activities currently being developed under the National Strategy for Countering Biological Threats. It is also possible that recommendations for a global preparedness architecture developed outside of any international forum in which the United States is a key stakeholder may not be adopted with wholesale enthusiasm by the international community.

### CONCLUSIONS

Overall, the proposed legislation would address many weaknesses in sharing and integration of health-related information domestically, particularly at the State and local level. The "customer base" for information on biological hazards has expanded dramatically in the past decade, creating new requirements for data analysis and dissemination. Stronger integration of public health expertise into the security and

intelligence communities could help make data on disease threats more relevant for strategic and tactical planning across all levels of government.

Many provisions in H.R. 5498 consider concerns of paramount importance to the public health and life sciences communities as well as the security and intelligence communities, and carefully recognize the very dynamic nature of the field. This is crucial to strengthening a foundation for biorisk management that supports other U.S. strategic goals in the long term, whether through a more nuanced response that conserves research resources at home, or a coordinated approach to priority-setting for biosecurity engagement abroad. After years of struggling to find a palatable framework for building truly global disease detection and response capabilities, the international community has finally begun to make progress under the IHR (2005). The National Strategy for Countering Biological Threats enshrined the U.S. commitment to the principles of the IHR (2005), a compact for reciprocal responsibility among nations whose success is not yet guaranteed. As the subcommittee moves forward with its deliberations on the proposed WMD Prevention and Preparedness Act of 2010, I hope that it will avoid any measures that might undermine U.S. support for mitigating risks from natural, accidental, and deliberate disease outbreaks under the IHR (2005) framework.

Ms. CLARKE. I thank you, too, Dr. Fischer.

I thank all of our witnesses for their testimony.

I will remind each Member that he or she will have 5 minutes to question the panel. I will now recognize myself for questions at this time.

This question is for the entire panel. We believe there is a need to create a top tier of agents in the select agent program that are thought to pose material threats to the Nation and therefore should be better secured. Tier 1 Material Threat Agents should be secured Tier 1 Material Threat Agents.

In addition to the material threat determination, what other criteria should be used to determine what agent is a Tier 1 Material Threat Agent?

We will start with Dr. Murch.

Dr. MURCH. I am afraid I don't have a deep knowledge of the processes, but I think one thing that would be important is to incorporate the viewpoints of the operational community, the intelligence community, as opposed to simply the scientific and medical community. It is very hard to measure these sorts of criteria that the intelligence and operational community use to measure threat, for example, but I think it is an important ingredient.

Dr. KADLEC. I would just highlight that one of the things mentioned in your bill is the biological threat risk assessment. That may be a very useful tool to again kind of factor in many of the issues that I think Dr. Murch alluded to, and that is the availability of appropriate FDA-approved countermeasures and a variety of other things that can modify your view of what the risk would be. Again, I think that is a notable inclusion in your bill on that account.

Ms. CLARKE. Does anyone want to add any other comment?

Dr. Fischer.

Dr. FISCHER. I do agree that the intelligence community has a strong strategic view. I welcome in this legislation the broader inclusion of the stakeholder community that does include the academic and nonprofit community explicitly, because there are elements of technical achievement and ease of cultivation that should be factored in in terms of the ability not only to grow and access these agents, but to convert them effectively into a weapon, recog-

nize that that is not always a set of skills at the fingertips of the average laboratorian.

Ms. CLARKE. I just want to say to Dr. Beatrice that it did not pass me when you discussed in your testimony the idea of we are going to raise a higher level of security for Tier 1 Material Threat Agents—there should be some commensurate support for those entities that would have these agents as part of their programs or as part of their environs, so that didn't pass me by.

Dr. Beatrice, we want to commend you and your colleagues on your participation in the BioWatch program, despite some frustration over the years. Can you talk to us about your experience with the BioWatch program and how well or how quickly has BioWatch data been shared with the New York City Public Health Lab?

Dr. BEATRICE. Certainly. I will say that my experience with the BioWatch program actually started with a phone call from Dr. Kadlec in 2003. It was an interesting experience in that the Public Health Laboratory was used to supporting environmental and clinical testing, and we were now introduced to the world of biothreat in a slightly different way.

Dr. Kadlec indicated that there was a desire to roll out a new program across the country to urban areas and that these were going to be secret laboratories that would be installed within public health labs. So a growing together of two cultures needed to occur, because the concept of the military or law enforcement approach to testing and public health were slightly different.

Our experience has been one in which New York City has had a very strong partnership with both the participants at DHS and also with our partners at CDC. The initial rollout of the BioWatch program was based on a team effort in which the scientists from the National labs at DHS and CDC and the New York City Public Health Lab worked very closely to ensure that the quality of the reagents, the testing, and the training of the individuals would be as good as possible. The communications back and forth between Federal and local partners was very good.

I would say that during 2008 and 2009, we entered into a time where transparency became almost nonexistent and changes in the program that resulted in quality of the reagents were not—we were not alerted to those, and what resulted was an increase in some challenges in the program.

It took New York City outreaching again to both DHS and to CDC, alerting them to the problems in the program, to really bring the process back to one of strong communication and teamwork. We are in the process of working through the difficulties in operations. There has been strong commitment on the part of our Federal partners to work through these difficulties, and we are very optimistic that we will get to a place that we were in previous years.

Ms. CLARKE. Thank you very much, Dr. Beatrice. My time has expired, but we will revisit this.

I would like to recognize the Ranking Member of the subcommittee, the gentleman from California, Mr. Lungren, for his questions at this time.

Mr. LUNGREN. Thank you very much, Madam Chairwoman.

Dr. Kadlec, I found your testimony—I found everybody's testimony—interesting, but I found yours particularly interesting about the historical record that President Nixon, his advisors, decided that we should not pursue biological weapons, that we should try and pursue an effort to unilaterally renounce these weapons and support a global ban, but the Soviet Union, under the veil of that, continued to press forward.

So in some ways we took the moral high ground, as we should have, but the Soviet Union took advantage of us in that respect and proceeded apace and probably had more knowledge about this, about the production and so forth. You go on to say in your testimony that we may not know where all of the whereabouts of these weapons are. More importantly, the information on the people who made them are still in doubt.

As part of our bill, we stress giving the DNI the responsibility for coming together with a comprehensive intelligence approach on this. How difficult do you think it will be for us to build that up, No. 1? No. 2, how successful do you think we can be with that? How immediate is the problem that we address it?

Dr. KADLEC. To sort of kind of take your answers all in one thing, I think a lot more can be done. We have showed a dismal record in our intelligence efforts against this problem over the many years—decades, if you will, if we had to look at the situation with the former Soviet Union. It was a great surprise until a couple of defectors came out in the late 1980s, early 1990s, that really gave us an understanding of how large and sophisticated that program was.

I think, similarly, we found ourselves in difficult straits when we had to deal with Iraq. Then most recently with al-Qaeda, it is interesting to note that even despite having a public fatwa by Osama bin Laden in 1998, and their efforts began in 1999 to include building a dedicated laboratory in Kandahar, Afghanistan, we were unaware of that effort—highly compartmented, parallel effort—until 2002, when we invaded Afghanistan and uncovered that lab and then evidence of those efforts.

So, quite frankly, we can do a lot better at it. The issue is what is it going to take? Well, I think it is going to take priority. It is going to take a unified voice between the President and Congress and the oversight of Congress to ensure that this issue gets the kind of attention and the resources that it deserves.

It has been a poor stepchild of the nuclear issue. Clearly, we have a lot of vivid imageries of the Nagasakis of the world and Hiroshimas. Unfortunately, we don't have one of a biological threat.

But I note that Henry Kissinger gave a testimony recently about the START Treaty and said, "Well, one day when they wake up and hear that, 500,000 people will have died." Then we know from the Graham and Talent commission that that likelihood is probably going to be a biological event.

So there is much more that we could do. I think it is going to take a joint effort between Congress and the administration to kind of keep the interest up, the focus on. Certainly, the oversight role of Congress is going to be essential for this.

Mr. LUNGREN. Dr. Murch.

Dr. MURCH. Yes, sir.

Mr. LUNGREN. In terms of the capability that we have in the intelligence community, where are we in that with respect to what Dr. Kadlec just talked about? Is there more that we can do in this legislation with respect to the intelligence side of things?

We have made a start, I think, with Title 1, but I happen to personally believe that unless we give the DNI the authority and the direction and that is accepted by the other agencies and departments, it is not going to work.

Dr. MURCH. I agree.

Mr. LUNGREN. Having seen some recent commentary about DNI position thus far, it bothers me. Generally speaking, do you disagree or agree with Dr. Kadlec about the urgency of the matter with respect to intelligence, No. 1?

No. 2, can you comment on what we have in this legislation and anything else you think might be important? Because I think all parts of this legislation are important, but frankly, if we don't have the intelligence, we cannot prevent and deter. That is the linchpin, it seems to me.

Dr. MURCH. It is indeed a linchpin, and where we should be headed is moving our activities to the left, meaning anticipation, prevention, interdiction, disruption and so forth, as opposed to the reaction, surprise, response, finger-pointing and beyond, way to the right, my time-risk continuum.

Clearly, the DNI has to have the authority. I believe it has to be done in a methodical and structured approach. One technique that is often used by the Department of Defense is to use what is called a systems analysis. Where are we? Where do we need to get to? How are we going to get there in a very rigorous, methodical way? I think that will be informative to the process.

I also think we need to think beyond simply state-sponsored programs or sub-state down to a single individual, a lone wolf, which is the hardest of the hard problems. How do we scale our intelligence capabilities in an integrated systems fashion, ranging from our external collection and analytic and special operations capabilities all the way down to the domestic as well?

It has to be completely seamless between—very hard, with the number of agencies involved and perspectives and cultures, but again, under single leadership and commitment by the administration and the Congress and the institutions themselves, and also pull upon external resources, because all of the good ideas are not in the Federal Government.

Mr. LUNGREN. Thank you very much.

Thank you, ma'am.

Ms. CLARKE. Thank you.

The Chairwoman now recognizes the gentleman from Ohio, Mr. Austria, for his questions at this time.

Mr. AUSTRIA. Thank you, Madam Chairwoman.

Thank you to the panel for your testimony today.

Let me just kind of go back a little bit. I think I was glad to hear the last, by Dr. Murch as far as you described moving to the left, from preventative standpoint, being prepared for this ahead of time, rather than the reactive, which I think is extremely important.

I guess to the entire panel, I would like to get your thoughts on why you think—I know this has been addressed in the past—and maybe identify some of the reasons why we haven't been successful in moving in this direction in the past, and why you think this legislation, which I think does a very good job and works towards correcting one of the major deficiencies by expanding the list of entities to which DHS disseminates information to the appropriate different levels, whether it be State, local, and Federal, which I think has been a problem in coordinating that communication, why you think it would be this—we can be successful this time, and identify maybe some of the hurdles that we faced in the past as to why we weren't successful doing this in the past.

I will open up that to any member of the panel that wants to take the start of that.

Dr. MURCH. I will go first. Certainly, the report by the WMD Commission highlights in a more coherent fashion. I think that is No. 1. It has been commented on by a number of different sources in the media, obviously, here in the Congress, the administration and so forth. So I think it is important.

The problem has been stated and the road ahead has been stated in a coherent fashion. Action has been taken quickly by the Congress. I think there is a time now when a unity of purpose can be engineered and be sustained, and I haven't seen it to this point in my time in the Government, which for me working on WMD terrorism goes back to the early 1980s when I was a young agent in Los Angeles, it turns out.

But I believe going forward, strategies and plans are important for agencies for better collaboration—not simple cooperation, but collaboration, not duplicating it, but staying in their lanes and doing it well. I think that will help.

Again, it is leadership. It is oversight. It is measurement of progress, which we don't seem to do very well. We don't stay focused very well on that. With all due respect, I am not a big believer in simply throwing money at a problem. It is coupling money with purpose and measuring effectiveness and holding people accountable. We don't seem to do that very well either.

Mr. AUSTRIA. Dr. Murch, let me follow up on that comment, because I think there are those that would argue that this legislation is actually going to grow DHS. There is going to be more bureaucracy. You know, then there is the argument of whether that would be less efficient, whether it be more wasteful spending or whether this would be able to work. I would like to get your comments on that, if I could.

Dr. MURCH. Sure. Well, you begin the legislation, I believe, at the right point. You start with the strategy. It is ready, aim, shoot, not shoot, ready, aim. Starting with a strategy and planning and reporting and authorities and responsibilities which are embedded in that is the right place to start.

There are clearly a number of other initiatives captured in the legislation, which fit underneath that, which are part of a broader strategy that is yet to be built. So my hope is is that you are on an intelligent strategy. As the Member from New Jersey pointed out, we don't have a comprehensive strategy yet. I think that yet has to be constructed and put in place. We are not done yet.

Mr. AUSTRIA. Dr. Fischer.

Dr. FISCHER. Thank you, sir. I think that the other part to complement that, as Dr. Murch pointed out, once you have got the information, once you have the tools in place, you also have to have the skills integrated to analyze that information and to present it in a form that is useful for decision-makers for both operational or tactical decision-making and strategic decision-making. The customer base for that kind of information has expanded at the local and State level in ways we would never have anticipated only a decade ago.

So I think one of the challenges that this legislation does address is expanding the public health intelligence presence at the State and local level through mechanisms such as the fusion centers, which were intended to do that in the first place. But there are operational barriers to that.

There are professional culture barriers to that that I think will not be solved very—you know, they are not going to be solved immediately by simply dictating that there should be that capacity. There are obstacles that I think should be explored within those communities.

I also believe that the proposal here to move NVIC, which has had its problems, back into the intel portion of the Department of Homeland Security, can more effectively move the stream of information there, but only if there are people with the appropriate expertise within that directorate to understand, process, analyze, and produce it in a way that is useful for operational decision-making. So it is not necessarily growing the agency, but moving the appropriate expertise into that particular division.

Mr. AUSTRIA. Yes?

Dr. KADLEC. Sir, very briefly, to answer your question about, you know, why we haven't made more progress. First, it is hard. This is not Mother Nature at work. This is a deliberate thing of the enemy. It is complicated. Subject to the success of a response to a biological event, it is going to be more dependent on people in Sally Beatrice's lab and the funding and the staffing that they have as it is whatever the Federal Government is going to do, because they are at the tip of the spear. It is expensive. Quite frankly, we have not embraced this as a National security issue for our country.

If we look at the—and again, not to dispute the issue of throwing money at the problem, but what we spend about annually $5 billion. If you ask yourselves what do we spend on nuclear security and nuclear defense and offense, it runs about $50 billion, of which is that $15 billion is for defensive purposes. If you look at what we are going to spend on cyber, it is approaching $30 billion and probably will be $50 billion before too long.

Somehow we need to recognize that this is not just an extension of public health. This is an extension of National security and subject to everything that Congress has done. Congress has done a lot, and in no other area that I know of that has Congress done more, and more needs to be done.

But we are subject to a political process, and this notion of imperfect incrementalism is the one we need and, you know, we live with. The notion that we will go through other due processes and learn by doing imperfectly and adjusting as we have, I think, is a

pretty extraordinary legacy that Congress has left in this area. Thank you.

Mr. AUSTRIA. Thank you, Madam Chairwoman. I know my time is up. Thank you.

Thank you to the panel.

Ms. CLARKE. The Chairwoman now recognizes the gentleman from New Jersey, the author of this legislation, Mr. Pascrell.

Mr. PASCRELL. Thank you.

I just want to bring something to Dr. Murch's attention, because I think you asked very pertinent questions or brought up important points about section 2103 in the legislation, which deals with the bioterrorism risk assessments. On page 16 under that particular section, there is a very specific requirement, which goes to the heart of one of the points you are making.

The Secretary shall convene an interagency task force of relevant subject matter experts to provide recommendations to the under secretary for science and technology as to the adequacy of the methodology—which is in parentheses, your point—used in the assessments and to establish requirements for the standards for those assessments. We believe that the National Academy of Sciences should be on the task force. I just wanted to make that clear.

Some questions for our panelists. I think we have come a long way in the last 5 months, 6 months, on this to bring the legislation forward. But I would like to ask Dr. Murch and Dr. Kadlec and Dr. Fischer, have we as a country or the world sufficiently criminalized acts of bioterrorism and/or biological warfare?

We have a provision, for instance, in section 402 that seeks to address the need to support other countries in criminalizing such acts. Would any of you care to respond to that?

Dr. MURCH. Well, I actually am familiar with that section, and I do appreciate that there will be activities in that regard. Clearly, in the United States—and I am speaking as a former FBI agent working under Federal law—and it seemed to me within the United States there is sufficient attention under the law to criminalization of bioterrorism and related acts.

However, it is a global problem. It is not simply a domestic problem, and we need to work very closely with those countries that we usually work with, but also those where we have some concerns over their commitment to criminalizing bioterrorism misuse of the life sciences.

Lots of different processes have been undertaken—coordination, conferences, discussions and so forth, bilaterals and so on—but we have moved all the way up to the Biological Weapons and Toxins Convention and the fact that even though it defines illicit behavior, there is no enforcement provision. That is something we have to contend with, in my mind.

Mr. PASCRELL. Can you envision any enforcement mechanism?

Dr. MURCH. Not off the top of my head, actually, sir. But I think with the proper discussions, we can probably do that. But obviously, it requires almost uniform international cooperation to get there, which has been the struggle.

Mr. PASCRELL. Let me ask you this question, then. We have seen the study of the National Academy of Sciences just last year. That

study was very explicit—noted that only 2 pages had been dedicated to forensics and homeland security.

Dr. MURCH. Yes, sir.

Mr. PASCRELL. I think we could use some more dedicated effort in that subject, forensics in homeland security. What do you think should be included in such a study? You know we have a provision in section 208 that attempts to deal with it. Maybe you feel it is adequate or inadequate.

Dr. MURCH. Yes, sir. I actually was on the committee that is strengthening forensic science in the United States, and I actually wrote the somewhat limited treatment of forensic science in homeland security. Really by design that study was limited to a very short section.

I believe very strongly—very strongly—that forensic science in homeland security—nay, the Department of Homeland Security—must be aligned with the directions and expectation that forensic science in general is having laid on it. Those provisions in the legislation by the Senate—that is being worked in the Senate Judiciary Committee right now, taking on the recommendations of the strengthening of forensic science—should be applied to homeland security. Homeland security is not special just because it is labeled homeland security. So I think an overlay of that kind of treatment would be helpful.

In addition, it has to extend to those special disciplines that are somewhat unique in homeland security—bioforensics, nuclear forensics. I actually was also on the committee at the National academies that has finished up a study on America's nuclear forensic capability, and that study should be out soon. So it is more embracing. It is more encompassing. It is not simply the role to include innovation, being creative, but also performance in the Department as it stands now.

Mr. PASCRELL. If I may, Madam Chairwoman?

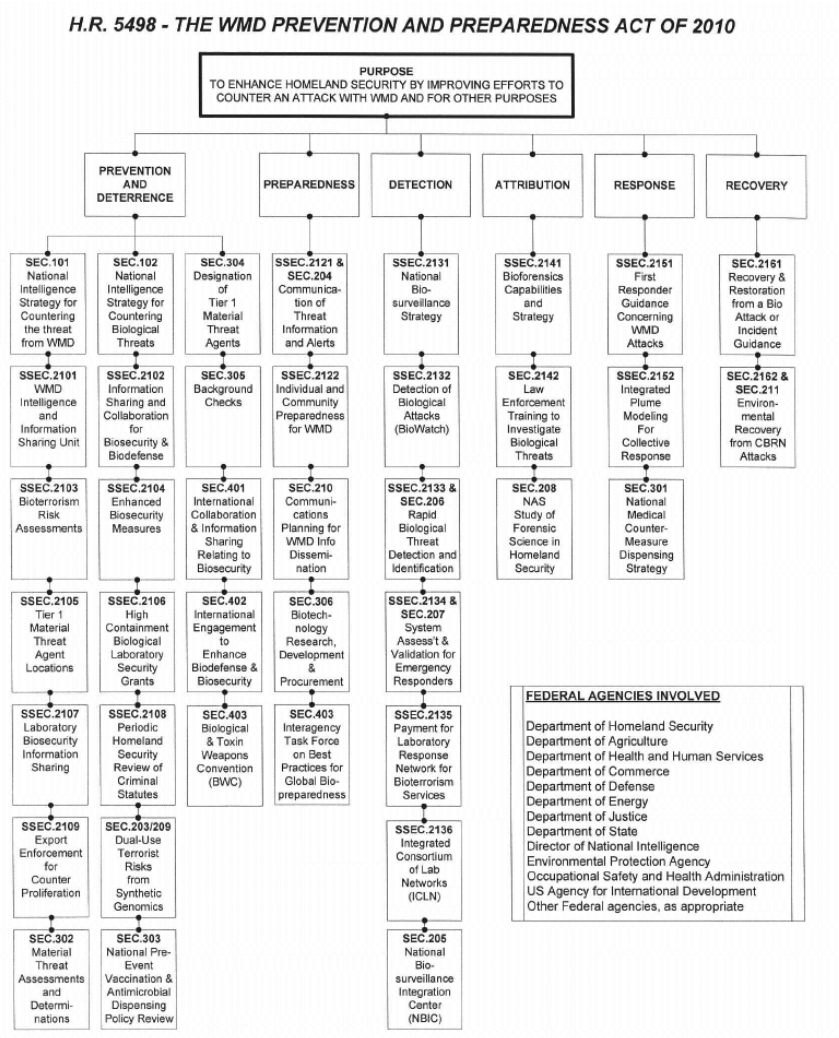
Have all of you seen the draft of how we broke down this legislation according to the 13 different departments that are affected? Have you all seen that and how each of those departments fall under those major areas, as Mr. Austria was pointing out the major emphasis on prevention and deterrence and preparedness?

This was a guideline for us to whenever we got off into the clouds, you know, to bring us back down to Earth, because you are dealing with multiple departments here. You are trying to get them coordinated, which is something new for us, you know. You know, in the words of George Kennan when he was talking about this great democracy, it needs its tail whacked once in a while so that there is movement and progress forward, rather than simply words and words and words.

I am very, very, very glad that we did this this way so that we have proper references to the specific 13 recommendations that were made by the WMD Commission. We are going—well, probably as the Chairwoman will say in a few moments, we will keep the record open for any, you know, direction that you folks want to give to us. I really want to thank the panel.

I want to thank the Chair of this committee. Thank you.

[The information follows:]




Ms. CLARKE. Thank you, Mr. Pascrell.

We have been joined by the Chairman of the full committee, Mr. Thompson, and without objection the Chairman's full statement will be submitted for the record.

[The statement of Chairman Thompson follows:]

PREPARED STATEMENT OF CHAIRMAN BENNIE G. THOMPSON

Today, our Nation is facing a number of different challenges—challenges which demand a great deal of attention. There are those who say that we should just concentrate on cleaning up the oil spill in the Gulf, or supporting our military efforts in Iraq and Afghanistan, or getting our economy back on track.

Even in the face of these seemingly overwhelming challenges, we cannot afford to turn a blind eye to the ever-present terrorist threat. The attempted Times Square and Christmas Day attacks certainly underscore the need to stay vigilant.

We also need to avoid the "failures in imagination" that the 9/11 Commission identified prior to that devastating attack. Now, more than ever, we have to address

emerging terrorist threats—because our enemies are constantly coming up with innovative ways to attack this Nation.

That's why H.R. 5498—the WMD Prevention and Preparedness Act of 2010—is so important. With this bipartisan bill, we are telling our enemies that we are taking steps right now to prevent, deter, prepare for, detect, attribute, respond to, and recover from a WMD attack.

By taking this comprehensive approach—addressing homeland security, intelligence, public health, and foreign affairs matters—H.R. 5498 puts us in better stead to counter the WMD threat before another attack occurs.

The bipartisan WMD Commission—with its reports and testimony before this committee—has warned us that unless we "act with great urgency," a WMD terrorist event will occur somewhere in the world by 2013, and that such an event would most likely be a biological attack.

In response, with H.R. 5498, we address the WMD threat in general and the biological threat specifically. The bill has the support of the WMD Commission, but we need more than that.

We need the cooperation of our colleagues on the Hill to help us swiftly pass this bill and deliver it to the President for his signature. As the WMD Commission has pointed out, we cannot afford to allow turf battles and fights over jurisdiction to keep us from doing the right thing by better securing our Nation against the threat of WMD.

Ms. CLARKE. The Chairwoman now recognizes the gentleman from Mississippi, the Chairman of the committee, Mr. Thompson, for questions.

Mr. THOMPSON. Thank you very much, Madame Chairwoman.

I would like to welcome our panel of witnesses.

I think that the two key points—first of all, Mr. Pascrell, I would like to thank you and Mr. King for your leadership on bringing this bill forward. It is the right thing to do. Everybody said it should have been done in the past, and we have not made it happen.

But there are a couple of comments, Dr. Beatrice. In your experience have you found that the Federal Government does a decent job of sharing the threat information to the State and locals? I understand Mr. Austria here talked a little bit about it. But I am trying to reinforce why this bill is so important that we really—if we have not done a good job, then this is an opportunity to do it. I would like your opinion again for the record.

Dr. BEATRICE. Unfortunately, I do not believe the Federal Government has done a good job in information sharing in this area. As I said in my testimony, there are times when it is very important for the public health infrastructure to be aware of what bioagents are in place, not only where bioagents are in place, but the quality of the biosafety programs that are available in both academic institutions and other institutions within the jurisdiction of the public health organizations so that we can outreach to them, ensure that the appropriate steps are in place, know what agents might be at risk.

We know that accidental exposure can result in a rather massive need for public health response, and yet we do not know how and where that response may be needed. Therefore, the public health community cannot prepare plans in advance and work with our partners in our locales. This information is available in the Federal Government and is not being shared.

Mr. THOMPSON. So basically, I think one of the provisions of this bill would mandate that. So clearly, from the initial sponsor of the bill, I am sure that was our intent, because so many times when situations happen, sometimes the State and locals are the first peo-

ple on the scene, and they need to have access to whatever information that is available.

Another aspect of this is that with the 9/11 Act, we authorized the National Biosurveillance Integration Center. Dr. Kadlec, can you give this committee your opinion as to whether or not there has been a real use of this entity?

Dr. KADLEC. Sir, I would just say briefly that it has been a great idea that has not lived up to the expectations. Quite frankly, I think that challenge has been to basically get the interagency to contribute to it, because in the end it really is the assimilation of all data, this integration that may exist in public health, that may exist in the medical community, may exist from environmental sampling, and may exist from a variety of sources that would be brought together and evaluated collectively.

Quite frankly, it has been a historical challenge to have the different agencies come to the table to do that.

Mr. THOMPSON. So as long as it is sort of a voluntary, come if you please effort, the participation is severely lacking.

Dr. KADLEC. That is correct, sir.

Mr. THOMPSON. So how would you suggest that Members of Congress fix that?

Dr. KADLEC. Well, sir, I think by mandating it, No. 1, mandating the entity and mandating the participation of the appropriate agencies to participate as part of it. In some ways it was what you said, sir—you know, come if you please.

This is such a critical issue, and I think the recent events, not only through the H1N1 pandemic, indicated that situational awareness is kind of like the fog of war. I mean, it really does affect the ability of senior policymakers and responders to act in a timely fashion, where even in the Gulf spill we know that we have suffered from the imperfect exchanging of information.

So as much as the information resides in the Federal Government, it does reside in the private sector and the public sector that really requires their participation as well.

Mr. THOMPSON. I thank you, because another one of the points in this bill is that we mandate that those agencies participate. So again, we are trying to fix the shortcomings of some things that clearly we thought would work voluntarily.

Last point on that—do you think that we should move that center out of the Office of Health Affairs at DHS, or have you looked at it in any——

Dr. KADLEC. Sir, I am somewhat agnostic to the idea. I think the fact of the matter is that need strong leadership. It needs to be in a place where the business is information sharing. I think in the case that you have identified within the area of DHS that does information sharing and intelligence analysis, that may be a better place.

Certainly, it has not lived up to what it was supposed to be in the past, so clearly, there is opportunity, I think, for a little bit of experimentation, but it really does require a fair bit of oversight. Obviously, it has your attention, sir, and that should go a long way.

Mr. THOMPSON. Good answer.

Ms. CLARKE. Thank you, Mr. Chairman.

I want to thank the witnesses for their valuable testimony and the Members for their questions. The Members of the subcommittee may have additional questions for you as witnesses, and we ask that you respond expeditiously in writing to those questions.

Hearing no further business, the subcommittee stands adjourned.

[Whereupon, at 2:20 p.m., the subcommittee was adjourned.]