ONE YEAR LATER—IMPLEMENTING THE BIO-SURVEILLANCE REQUIREMENTS OF THE 9/11 ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY

OF THE

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ONE YEAR LATER, IMPLEMENTING THE BIOSURVEILLANCE REQUIREMENTS OF THE 9/11 ACT

Wednesday, July 16, 2008

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 notice, at 2:19 p.m., in Room 311, Cannon House Office Building, Hon. James R. Langevin [Chairman of the subcommittee], presiding.

Present: Representatives Langevin, Christensen, Pascrell, and McCaul.

Mr. LANGEVIN. The subcommittee will come to order.

The subcommittee is meeting today to receive testimony on the current state and future course of the National Biosurveillance Integration Center, NBIC, and Project BioWatch.

Before I begin my opening statement, I wanted to mention to the witnesses that there is a committee rule that testimony is supposed to be in 48 hours in advance. We got the DHS testimony this morning. We can't do business like that, and I will caution you about ever doing it again. I don't want to have the testimony received by this subcommittee that late ever again. It is unacceptable. We just can't do business that way.

With that, good afternoon. I would like to thank my colleagues for their participation, and I welcome our witnesses here today.

As this committee is well aware, the threat of biological attack is real and potentially catastrophic. As the Chairman of the subcommittee, I have made it a priority to address the most glaring vulnerabilities facing our Nation, and this is certainly one of them. Of equal or greater concern, of course, is the possibility that a naturally occurring disease outbreak could grow to epidemic proportions. We have held numerous hearings on how better to protect against biological attack, and today we are continuing those efforts.

Today, our focus will be on determining whether the biosurveillance requirements included in the Implementing Recommendations of the 9/11 Act of 2007, which became law on August 3, 2007, have been properly implemented. The 9/11 Act included two key sections regarding our Nation's biosurveillance capabilities. Section 1101 authorized the National Biosurveillance Integration Center, or NBIC, and section 1102 requires the Government Accountability Office, GAO, to submit a report to Congress describing all Federal,

State, and local biosurveillance efforts. Each of these will help protect against biological threats, whether man-made or natural.

The key to stopping an outbreak from becoming an epidemic or an attack from becoming a catastrophe is early detection, identification, tracking, and response.

Now, the National Biosurveillance Integration Center, NBIC, and the BioWatch program, housed in the Department of Homeland Security, are critical to this mission. Each of these programs are designed to provide early detection of disease outbreaks, a critical role in preventing or containing their spread. The NBIC was created to fulfill the requirements of Homeland Security Presidential Directive 9, "Defense of U.S. Food and Agriculture," issued in January 2004, or better known as HSPD–9.

NBIC's mission is to develop robust, comprehensive, and fully coordinated surveillance and monitoring systems, including international information for animal disease, plant disease, wildlife disease, food, public health, and water quality that provides early detection and awareness of disease, pests, or poison agents. Section 1101 of the 9/11 Act authorized the NBIC and set a deadline of September 30, 2008, for full operation.

I am concerned that, although progress has been made, most estimates are that we are still 2 years away from having the full participation of Federal, State, local, tribal, private sector, and international partners that a robust biosurveillance capability requires. I am hopeful that our witnesses can shed some light on the current obstacles to getting the NBIC operational.

I also look forward to hearing, of course, from our witnesses on the status of the BioWatch program, which consists of two components, research and development activities on the next generation biodetectors, which are run by the DHS Science and Technology Directorate, while acquisition, operations, and management are now handled by the Office of Health Affairs.

Today, we will focus on the current state of both NBIC and BioWatch. While I am concerned that each of these programs has lingering problems, I am hopeful that this hearing will help provide a course to overcome current obstacles and move these programs forward.

With that, I do thank our witnesses for being here today.

The Chair now recognizes the Ranking Member of the subcommittee, my partner in these efforts, the gentleman from Texas, Mr. McCaul, for an opening statement.

Mr. MCCAUL. Let me thank the Chairman for holding this important hearing on the Nation's biosurveillance capabilities.

In May 2006, the subcommittee held a hearing on the Department of Homeland Security's development of the Nation's biosurveillance architecture. Now, 2 years later and a year after the passage of the 9/11 Act, this hearing presents the opportunity to once again assess the strength of our Nation's surveillance capabilities.

Detecting a bioterror attack or a naturally emergent disease is a critical first step to mounting an effective response. The sooner we detect an agent in the environment or in people, the better chance we have of mitigating its harmful consequences.

The National Biosurveillance Integration Center and BioWatch are two key elements to this enterprise. No one system has ever attempted to integrate all the streams of biosurveillance data collected by Federal, State, local, and private entities. The NBIC is an ambitious but a critical plan to create a one-stop shop for human, animal, and plant biosurveillance information.

The legislative origins of the NBIC can be found in the committee's 2006 authorization bill. Without question, the NBIC has its challenges, from technical hitches to interagency hurdles, but it has worked through many of these to become a more effective operating center. Most recently, it lent its expertise to provide surveillance data for the Nation-wide salmonella outbreak. I look forward to learning from our witnesses just how far along the Center has come.

I also take great interest in the Department's plan for BioWatch. This detection program provides an environmental monitoring system to cities around the Nation for early detection of airborne biological threat agents. Having been required to beef up their preparedness and response plans, many of those jurisdictions with sensors are now better prepared for a bio-event. DHS has lead the way in creating groundbreaking Federal planning guidance for dealing with intentional release of a bioterrorism agent, and BioWatch has helped bring Federal, State, and local governments together for a common purpose. We await the next generation of sensors, the new technology, with a particular interest in whether plans for a fully automated indoor system are truly viable in the near future. We cannot, however, expect the Office of Health Affairs to effectively complete this work if its requested fiscal year 2009 budget is cut by $27 million, as the House Appropriations Committee would have it.

In today's Washington Post, there was commentary on the hearing, this hearing and one in the Senate, regarding DNDO and also BioWatch. With respect to BioWatch, which is the focus of this hearing, they said in the Washington Post that: A 5-year-old program to detect the airborne release of biological warfare agents, such as anthrax, plague, and smallpox, in more than 30 major U.S. cities still lacks basic technical data to help medical officials determine how to respond to an alert triggered by the sensors. Congressional investigators and State and local officials will report to the House Homeland Security Committee.

I look forward to hearing from the four of you on this issue specifically, and how we can better integrate. We have our deadline coming up, as I understand, September. Can we reach that deadline? What technology is in the future to make this a better system?

With that, I yield back.

Thank you.

Mr. LANGEVIN. I thank the gentleman. Other Members of the subcommittee are reminded that, under the committee rules, opening statements may be submitted for the record.

I now want to welcome our first panel of witnesses.

Our first witness, Robert Hooks, serves as the Deputy Assistant Secretary for WMD and BioDefense in the Office of Health Affairs of the Department of Homeland Security. He is responsible for the

Department's early detection biodefense programs, including the National Biosurveillance Integration Center and BioWatch, two Homeland Security programs that address animal security, food defense, and biological threat mitigation efforts.

Our second witness, Eric Myers, is the director of the National Biosurveillance Integration Center, NBIC, starting in January 2008. His previous assignment was deputy director of NBIC, starting in September 2006.

Our third witness is William Jenkins, director of Homeland Security and Justice Issues at the Government Accountability Office. The GAO is conducting a study of national biosurveillance efforts pursuant to section 1102 of the 9/11 Act. Although the study is not yet complete, GAO has agreed to discuss their initial findings relevant to this hearing, and we do appreciate that.

Our fourth witness on this panel is James Wilson, chief executive officer and chief scientist of the Veratect Corporation. Prior to that, he was principal investigator at Project Argus and a member of the Department of Homeland Security's National Biosurveillance Integration System, NBIS, concept design review team, and the first chief of analytic operations at the National Biosurveillance Integration Center.

With that, and without objection, the witnesses' full statements will be inserted into the record.

I want to welcome each of you here today, and I now ask each witness to summarize their statement for 5 minutes, beginning with Mr. Hooks, who will read a joint statement from himself and Mr. Myers.

Welcome.

STATEMENT OF ROBERT HOOKS, DEPUTY ASSISTANT SECRETARY FOR WMD AND BIODEFENSE, OFFICE OF HEALTH AFFAIRS, DEPARTMENT OF HOMELAND SECURITY, ACCOMPANIED BY ERIC MYERS, DIRECTOR, NATIONAL BIOSURVEILLANCE INTEGRATION CENTER, OFFICE OF HEALTH AFFAIRS, DEPARTMENT OF HOMELAND SECURITY

Mr. HOOKS. Thank you, Mr. Chairman.

I have heard your words. I apologize that our testimony was in late, and I apologize sincerely for that.

Mr. Chairman, Ranking Member McCaul, and Members of the subcommittee, thank you for the opportunity to testify today on the Department of Homeland Security's biosurveillance efforts.

I serve as the Deputy Assistant Secretary for WMD and BioDefense, a division within the Office of Health Affairs.

Also with me is Eric Myers, the director, as you mentioned, of NBIC.

I appreciate your interest in this biosurveillance program and trust that my testimony today will provide valuable insight into the Department's biosurveillance initiatives to safeguard the Nation against a biological attack or other biological incidents that threaten the security of the homeland.

The Nation continues to face the risk of a major biological event that could cause catastrophic loss of human life, severe economic damages, and significant harm to our Nation's critical infrastructures and key resources. The challenges we face in assessing cur-

rent terrorist capabilities and identifying plots make it unlikely that we will receive actionable specific warning of an impending bioterrorist attack.

Furthermore, many of these deadly biologic agents are accessible in nature, relatively easy to procure, and can be developed and transported without an advanced background in the biological sciences. Unlike nuclear weapons, only a few people with advanced laboratory knowledge in the biological sciences are needed to weaponize many of these deadly pathogens. As such, it is incredibly difficult to predict and prevent a biological attack from taking place.

Having an early warning system capability against a biological threat is critical to reduce the potential loss of human life and prevent severe economic damages and other associated consequences.

Our first indication of a bioterrorist attack will likely be through an early detection and warning system, such as BioWatch and the NBIC. I will discuss BioWatch further during the next panel. In the event that a bioterrorism event occurs in the homeland, a comprehensive biosurveillance capability can minimize the impact and duration of the event via early detection and characterization, broad situational awareness, and by facilitating early intervention and mitigation.

Secretary Chertoff, in collaboration with other appropriate Federal departments and agencies, established a platform for information exchange between senior leaders and Federal partners to facilitate the early recognition of biologic events, including natural disease outbreaks, accidental or intentional use of biological agents, and emergent biohazards. This platform is known as the National Biosurveillance Integration System, NBIS.

NBIC, the Center located at DHS headquarters, seeks to provide information to interagency partners via the NBIS platform to allow early recognition of biological events of national concern, both natural and manmade, in order to make timely response possible. Currently, 12 Federal agencies exchange information on the NBIS platform. Eventually, this platform of information exchange will evolve to include State, local, and tribal entities, and potentially the private sector and international stakeholders as well.

We have established the NBIS Interagency Working Group, NIWG, which meets monthly to provide an open forum among Federal partners to enhance such information exchange. NBIC has developed a governance structure to provide senior level oversight of operations to ensure that the interagency goals and objectives are met. NBIC personnel analyze and monitor over 530 information feeds. During these information feeds, NBIC develops and shares the biological common operating picture, we refer to it as BCOP, with the NBIS interagency partners. The BCOP provides a comprehensive assessment of current biological events, data, and trends, and their potential impacts on the Nation's security.

In conclusion, developing an interagency biosurveillance capability focusing on biological threats in human health, animal, plant, food, and water is very difficult and a complicated task that has not been previously attempted. The challenge of detecting an impending bioterrorist plot and preventing an attack or an emergent of a naturally occurring pandemic outbreak is daunting. That is

why Homeland Security is enhancing early detection warning systems to build a comprehensive national biosurveillance capability to prevent a biological threat from becoming a catastrophic event.

Thank you for the opportunity to testify.

[The joint statement of Mr. Hooks, Mr. Myers and Dr. Stiefel follow:]

JOINT PREPARED STATEMENT OF ROBERT HOOKS, ERIC MYERS, AND JEFFREY STIEFEL

JULY 16, 2008

INTRODUCTION

Mr. Chairman, Ranking Member McCaul, and Members of the subcommittee, thank you for the opportunity to testify today on the Department of Homeland Security's (DHS) biosurveillance efforts. I serve as the Deputy Assistant Secretary for WMD and Biodefense, a division within the Department of Homeland Security's Office of Health Affairs (OHA). I appreciate your interest in our biosurveillance programs, and trust that my testimony today will provide valuable insight into the Department's biosurveillance initiatives to safeguard the Nation against a biological attack or other biological incidents that threaten the security of the homeland.

The Nation continues to face the risk of a major biological event that could cause catastrophic loss of human life, severe economic damages, and significant harm to our Nation's critical infrastructures and key resources. As you so vividly remember the Nation already experienced a form of bioterrorism in late 2001 with the deadly anthrax mailings that cost the lives of 5 individuals, injured 17, and caused severe disruptions to many of our Government activities, including operations of the U.S. Postal Service and numerous other functions.

The challenges we face in assessing current terrorist capabilities and identifying plots make it unlikely that we will receive actionable, specific warning of an impending bioterrorist attack. Furthermore, many of these deadly biological agents are accessible in nature, relatively easy to procure, develop and transport without an advanced background in the biological sciences. Unlike nuclear weapons, few people with advanced laboratory knowledge in the biological sciences are needed to weaponize many of these deadly pathogens. As such, it is incredibly difficult to predict and prevent a biological attack from taking place. The threat of bioterrorism has not subsided, and the impact of a large-scale bioterrorism event, such as the wide-spread dissemination of an aerosolized form of anthrax or other deadly biological pathogen, would have a serious effect on the health and security of the Nation.

A bioterrorist plot may not have detectable signals, thus, there may be little or no warning of an impending biological attack, presenting significant challenges to the identification, detection, and disruption of such plots. Our first indication of a bioterrorist attack will likely be through early detection and warning systems, such as BioWatch and the National Biosurveillance Integration Center (NBIC). Their detection capabilities will drive the subsequent response and significantly influence the number of individuals affected by an attack.

In the event that a threat does reach, or occur in, the homeland, a comprehensive biosurveillance capability can minimize the impact and duration of the event via early detection and characterization, broad situational awareness and by facilitating early intervention and mitigation.

BIOSURVEILLANCE

An integrated biosurveillance program is vital to help protect the homeland from bioterrorism: unintentional introductions (e.g. Foot-and-Mouth Disease); and naturally occurring biological events, such as pandemic influenza. Biosurveillance refers to monitoring for potential signs of biological events with the intent of early detection of that event to permit the timely response to mitigate consequences. Should an event occur, biosurveillance and detection allows the monitoring of an outbreak as it happens and provides accurate situational awareness to first responders. Biosurveillance is one of the critical components of our Nation's biodefense strategy, as outlined in Homeland Security Presidential Directive (HSPD) 10: Biodefense for the 21st Century.

Biosurveillance includes many different components that work in complementary fashion to achieve a comprehensive awareness. This takes the form of both traditional and novel methods of early event detection including environmental detection systems, clinical syndromic surveillance, reportable disease and laboratory-based surveillance, monitoring of agricultural and wildlife activity, testing of the food sup-

ply, and monitoring mail and open-source analysis to name a few. Each is a necessary and valuable component of a comprehensive biosurveillance strategy. I would like to discuss two biosurveillance programs that the Department is leading as part of the Federal Government's larger biosurveillance strategy: NBIC and the Biowatch Early Detection System.

NATIONAL BIOSURVEILLANCE INTEGRATION CENTER (NBIC)

Recognizing the need to create a new biological threat surveillance capability across multiple sectors and domains to provide early awareness and warning of emerging biological events, Secretary Chertoff, in collaboration with the other appropriate Federal Departments and agencies, established the National Biosurveillance Integration System (NBIS), which serves as the platform for information exchange between senior leaders and partners agencies and facilitates the early recognition of biological events, including natural disease outbreaks, accidental or intentional use of biological agents, and emergent biohazards.

Currently, twelve Federal Member Agencies comprise the NBIS community. Eventually, this community will evolve to include State, local and tribal entities, and potentially the private sector and, international stakeholders. The NBIS community provides situational awareness through the acquisition, integration, analysis and dissemination of information from existing human disease, food, agriculture, water, meteorological, and environmental surveillance systems and relevant threat and intelligence information.

In 2007, Congress passed and President Bush signed Pub. L. 110–53, The Implementing of the 9/11 Commission Recommendations Act of 2007 which formally authorized the establishment of the National Biosurveillance Integration Center (NBIC), which serves as the hub of operations and personnel to which the NBIS community contributes information. The NBIC is located in the DHS Nebraska Avenue Center and is charged with the primary mission to rapidly identify, characterize, localize, and track a biological event of national concern; integrate and analyze data relating to human health, animal, plant, food, water; and disseminate alerts and pertinent information. NBIC seeks to provide information to allow early recognition of biological events of national concern, both natural and man-made, in order to make a timely response possible. No other entity in Government serves to integrate this biological threat information from across the spectrum of public and private, domestic and international, open or protected sources.

As an operating center, the vital component parts of NBIC are:

- A corps of highly trained subject matter experts (SMEs) and analysts, including a 24-hour/7-day OHA Watch Desk within the DHS National Operations Center;
- Tailored customer products resulting from integrative analysis of biosurveillance information;
- A culture of cooperation, trust and mutual support across the Federal Government and other partners; and
- A robust information management system capable of handling large quantities of structured and unstructured information.

DEVELOPING AN INTERAGENCY INFORMATION SHARING CAPABILITY

Developing interagency cross-domain biosurveillance capability is a difficult and complicated task that has not been previously attempted. Coordination with our Federal partners to obtain data, personnel, and information-sharing agreements requires new processes and procedures. Additionally, building a new IT system to coordinate the information sharing, as well as creating new analytical tools to assist analysts in identifying trends, patterns, and anomalies quickly and accurately as is necessary for forward-looking and cueing capability has taken time. However, we are still scheduled to meet our full operational capability (FOC) goals by September 30, 2008.

NBIC has formalized its relationship with a number of Federal partners, and continues to make progress on obtaining formal agreements with the remaining relevant Federal Agencies in order to promote a robust interagency biosurveillance capability. MOUs are in place with Departments of Defense, State, Agriculture, Interior, Health and Human Services, and Transportation. We are also working closely with the Department of Veterans Affairs, FBI, Environmental Protection Agency, U.S. Postal Service, and the Department of Commerce and other components within DHS. While final details of some of these agreements are being resolved, these Departments and agencies are currently contributing to the NBIC mission and providing valuable information on current bio-events.

NBIC has established the NBIS Interagency Working Group (NIWG) which meets monthly to provide an open forum among NBIS members to discuss interagency col-

laboration, develop detailed operational procedures and offer recommendations to enhance the capability of NBIS. The NIWG representatives possess a detailed knowledge of their respective organization's biosurveillance-relevant capabilities, programs and activities that can contribute to the integrated effort. This collaboration has produced the first version of the NBIS Concept of Operations which lays out the details of how the mission of NBIS is being implemented and executed. This document is significant in that it describes the steps NBIS will take to accomplish the unprecedented task of biosurveillance cross-domain integration and analysis.

Further, NBIC has developed a governance structure to provide senior-level oversight of operations to ensure that interagency goals and objectives are met. The National Biosurveillance Integration System Interagency Oversight Council is made up of representatives at the assistant secretary level from each NBIS member agency and acts as the senior oversight body to provide guidance and direction for the efficient operation and evolution of NBIS.

NBIC INFORMATION INTEGRATION AND ANALYSIS

To accomplish the biosurveillance mission, the NBIC monitors over 530 information feeds. Monitoring of these information feeds is facilitated by the NBIS 2.0 IT system. These sources include interagency communications and 165 open-source sites. These open-source sites include 20 organizational sites, 14 Federal Government sites, 85 State, local, or territorial government health and agriculture sites, 35 foreign government sites, and 2 commercial sites.

Using its information feeds, NBIS develops and shares a Biosurveillance Common Operating Picture (BCOP) with the NBIS community. The BCOP is a comprehensive electronic picture with assessments of current biological events, trends and their potential impacts on the Nation's homeland security. The BCOP provides a secure platform for cross-domain information analysis by NBIS subject matter experts to learn more about and collectively evaluate current situations. An impact assessment of an event constitutes a major portion of the NBIS BCOP information dissemination.

As an example of the NBIC capability, several NBIS member agencies continue to work closely together to provide comprehensive situational awareness to Federal agencies on the current Salmonella stereotype Saintpaul event. NBIC remains thoroughly engaged in the tracking of this event, and regularly posts Situational Reports (SITREPs) on the BCOP. Thus far, NBIS has released 11 national SITREPs on this event.

NBIC FULL OPERATING CAPABILITY

NBIC has developed a set of goals to address the highest priority requirements to achieve FOC by September 30, 2008, which assumes the current reprogramming request before Congress. We continue to progress toward the following to achieve full operational capability:

- Install interagency staff and enhanced space resources for NBIC;
- Enhance IT Infrastructure for biosurveillance;
- Expand the NBIS Interagency Community;
- Further develop NBIC Intra-Agency Collaboration;
- Continue NBIC Collaborative Analysis and Production;
- Refine the NBIC Five-Year Strategic Plan with modified objectives; and
- Refine the NBIC Contingency Operations Plans with updated strategies.

BIOWATCH

I would also like to discuss the Department's BioWatch Program, which was established in January 2003, and is currently managed by OHA. The BioWatch mission is to deploy and maintain a national 24/7 early warning system capable of detecting the intentional release of select aerosolized biological agents in order to speed response and recovery efforts. The purpose of this early detection and warning capability is to mitigate the consequences of a catastrophic attack, which could affect tens of thousands of people if, for example, aerosolized anthrax were released.

The goals of the BioWatch Program include:

- Early detection and characterization of biological attacks against the Nation's cities, high value assets, and mass gatherings to allow for the rapid distribution of life-saving countermeasures;
- Cost-effectively improving bio-aerosol threat monitoring capability and increasing its capacity to cover a greater portion of the general population;
- Providing operational and consequence management guidance and assistance to Federal, State, local, and tribal entities; and

- Integrating BioWatch capabilities into a national bio-threat monitoring and response system.

BioWatch is part of a national biodefense strategy that includes intelligence, law enforcement, bio-monitoring, situational awareness, decision support, response, and recovery activities. Within this strategy, BioWatch is an essential component of bio-monitoring, along with astute clinicians, syndromic surveillance, food and agriculture monitoring, veterinary surveillance, and mailroom monitoring. BioWatch technical and operational capabilities are integrated with military capabilities at installations to the benefit of both the Department of Defense and DHS.

Bio-monitoring of infectious agents will enable earlier treatment of affected populations than would otherwise be possible, and contribute to the prevention of secondary transmission, thereby reducing morbidity, mortality, and the associated health care costs from a biological terrorist attack. Each component of bio-monitoring relies on different technologies and techniques that are optimized for their intended purpose. It is through situational awareness and decision support that bio-monitoring is linked with the public health and medical response communities that must respond in the event of a biological terrorist event.

CURRENT BIOWATCH CAPABILITY

The current generation BioWatch system, which is operating in over 30 of the Nation's largest metropolitan areas, is composed of aerosol collectors, secondary sampling kits, laboratories, guidance documents, concepts of operation, communications protocols, an internet-based information portal, subject matter experts, and a small number of early generation indoor detectors. System operation requires the integration and coordination of Federal, State, and local authorities whom all play an active role in the program. The system is tested routinely at each of the local jurisdictions where it is deployed.

The BioWatch program has established and strengthened existing local infrastructure. Laboratory procedures and field operations have been standardized and are reviewed periodically for quality assurance by the BioWatch program. Detailed environmental sampling plans have been developed that could be used to gather information about the viability and distribution of a bio-agent detected by the system.

BioWatch laboratories that analyze filters taken each day from the aerosol collectors are part of the Laboratory Response Network (LRN). Laboratory personnel follow strict protocols using laboratory assays that were developed jointly by the CDC and Lawrence Livermore National Laboratory to analyze the filters for the presence of biological threat agents. The BioWatch laboratories have been in continuous operation since 2003, having analyzed more than 7 million samples without a single laboratory false positive result.

If BioWatch detects the presence of a bio-agent of concern, it issues a signal known as a BioWatch Actionable Result (or BAR). Since the Program's inception, dozens of BARs have been reported by multiple BioWatch State and local jurisdictions. These valid laboratory findings have been attributed in all cases to naturally occurring environmental sources.

BioWatch operational readiness is essential for the system to be effective. Readiness involves planning, preparedness, detection, and initial response. Representatives from these agencies, along with State and local public health and response personnel, have created guidance documents for local jurisdictions to use in developing operational plans for BioWatch.

These guidance documents cover preparedness, response, environmental sampling, and indoor operations. They are reviewed and updated periodically by the Federal BioWatch Working Group to take advantage of lessons learned through training, exercises, and real-world execution of operational plans in response to positive laboratory results from environmental sources.

The operational response plans for each jurisdiction are triggered by a BAR and implemented by a local BioWatch Advisory Committee (or BAC). A BAR triggers a formal notification process whereby the local public health official notifies local, State and Federal partners. The public health official convenes the BAC via conference call to begin situational assessment; Federal and State partners join BAC members in a national teleconference within 2 hours of notification. The initial call may be followed by others as more pertinent information becomes known. Investigation and discussions continue until consensus is reached about the significance of the BAR, which is used to inform protective action decisions on the part of the local public health official.

Each environmental BAR has provided local, State, and Federal Government personnel an opportunity to exercise its preparedness plans and coordination activities that are fundamental to an effective response to a bioterrorism event or some other

incident of public health significance. These real world events have been a catalyst for collaboration among local, regional, State, and Federal authorities, resulting in greater integration of public health, medical, veterinary, laboratory, emergency response, and critical infrastructure personnel responsible for consequence management across the full spectrum of public health threats facing our Nation.

BioWatch technical and operational capabilities are also integrated with related military capabilities at installations around the country to the benefit of both DHS and the Department of Defense. It is through situational awareness and decision support that bio-monitoring is linked with the public health and medical response communities that must respond in the event of a biological terrorist event.

DEVELOPING FUTURE BIOWATCH CAPABILITY

The BioWatch system continues to evolve with new technologies, new partnerships with other bio-monitoring activities in the Government and private sector, and a refined national bio-monitoring architecture. We are striving to further the BioWatch system technologies and improve procedures to reduce the time-to-detect between biological agent release, detection and follow-on response. We are also working to increase the number of biological agents that are detected and to increase the population coverage in existing BioWatch jurisdictions, including in the highest risk indoor facilities.

We are striving to improve the detection capabilities of the system, while ensuring that appropriate testing and evaluation control processes are in place. We are working with DHS's Testing and Evaluation team on future technology developments to ensure the appropriate level of independent oversight to make informed decisions regarding deploying improved technologies and reducing risk of technological shortcomings.

One of our high-priority initiatives is to replace collectors—the filters of which require formal laboratory analysis—with automated detectors, wherein the analysis is performed within the unit itself. The primary objective of the Generation 3 system is the development of automated detectors that will significantly reduce the time to detect a biological agent from the current 10 to 34 hours down to between 4 and 6 hours which will potentially save thousands of lives for each day an attack, such as anthrax, is detected ahead of human syndromic surveillance and other public health indicators.

The BioWatch operational requirements (e.g., logistics, readiness and interoperability) stem from OHA's experience operating the system. Detailed requirements are captured in the Generation 3 Operational Requirements Document. That document is our guide for ensuring that the best automated detection system will be selected and fielded. The responsibilities for technical improvements and supporting R&D are jointly shared by DHS's Science and Technology (S&T) Directorate and OHA. Technologies under consideration must meet operational requirements for performance, operability, and reliability. As with any upgrade to a complex system, it is not as simple as plugging in a new component and assuming that the technology will work well and integrate properly with all other material and non-material elements of the system. To ensure new technology deployments are successful, candidate detectors need to be thoroughly tested under real-world operational conditions.

The operational test and evaluation of automated detectors under consideration for inclusion in the BioWatch Generation 3 system are scheduled to begin in April 2009. The tests will be conducted in two BioWatch jurisdictions over a period of 3 to 6 months. A procurement decision will then be made; the initial deployment of the BioWatch Generation 3 system is planned for fall 2010. The Generation 3 system will be operated along side Generation 2 systems for a period of 60 to 90 days to facilitate the transition to the enhanced system.

BioWatch deployment strategies are derived from risk-based analyses that account for threat, vulnerability, and consequences. Our plan is to continue increasing the population coverage in existing BioWatch jurisdictions, as well as expand coverage to new locations or facilities when the risk is determined to be high enough to warrant 24/7 environmental monitoring.

Given the current system's lag time between an attack and detection, DHS believes it is necessary to procure and deploy an interim automated system which we call Generation 2.5 designed to reduce notification times to as little as 4 to 6 hours. This interim system will be deployed in high-consequence indoor environments to provide coverage of the highest risk facilities before the Generation 3 system will be ready for deployment.

The BioWatch program will continue to reduce the risks associated with bioterrorism and continues to develop future technology options and best deployment op-

tions. This will provide increased safety to the American public through early detection of biological pathogens that threaten our public health.

CONCLUSION

Biological threats to the homeland continue to be of concern. We are facing persistent and evolving terrorist threats with potentially catastrophic consequences. A catastrophic biological event, such as a WMD terrorist attack, or a naturally occurring pandemic or emerging disease outbreak, could cause hundreds of thousands of casualties, damage our economy and the public's confidence, and threaten the security of our homeland. As I stated earlier, the challenge of detecting an invisible footprint of an impending bioterrorist plot and preventing an attack or the emergence of a pandemic is daunting. That is why DHS is taking the approach of enhancing early detection systems and building a national biosurveillance capability for situational awareness—to prevent a biological event from becoming a Nation-changing catastrophic event.

Our goal is to generate timely and comprehensive information about a biological event and put it into the hands of decisionmakers responsible for the continuity of society and Government. I have observed in today's vernacular that "time zero" when a response can be initiated is often referred to as the time an event is known to have occurred, not when the event actually occurred. The time lag between the true "time zero" when an event occurs and when it is recognized is critical in determining how successful a response will be in mitigating loss of life and suffering. DHS is committed to improving the Nation's biodetection and biosurveillance capabilities so that we can achieve a "time zero" as close to the true time of the actual event as possible.

I appreciate the opportunity to share the vision, status and direction of the NBIC and BioWatch biosurveillance programs with you and look forward to your comments and guidance on how to better shape the programs to protect the American public against intentional and natural biological events. Thank you for the opportunity to testify. I would be happy to provide answers to any questions that you may have.

Mr. LANGEVIN. I thank the witness.

The Chair now recognizes Mr. Jenkins to summarize his statement for 5 minutes.

Welcome.

STATEMENT OF WILLIAM O. JENKINS, JR., DIRECTOR, HOMELAND SECURITY AND JUSTICE ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE

Mr. JENKINS. Thank you. Chairman Langevin, Ranking Member McCaul, and Members of the subcommittee.

The 9/11 Commission Act mandated that GAO review biosurveillance efforts at the Federal, State, local, and tribal levels of Government. That review is ongoing.

I am pleased to be here today to discuss our preliminary operations on DHS's efforts to establish a fully operational National Biosurveillance Integration Center by the statutorily mandated September 30 deadline. DHS has not finalized the capabilities that the Center must have to be fully operational, nor has it clearly identified the capabilities it anticipates NBIC will have as of September 30 of this year.

The former acting director of NBIC testified last October that NBIC has three vital components of success: One, a robust information management system capable of handling large quantities of structured and unstructured information. Two, a core of highly trained subject matter experts and analysts. Three, a culture of cooperation, trust, and mutual support across the Federal Government and other partners.

DHS and NBIC leadership have taken steps in each of these areas, such as filling 26 of 37 authorized positions, hiring a perma-

nent staff director, acquiring facilities for NBIC that can accommodate classified data, creating a 24-hour watch center, and reaching out to 11 other agencies that DHS has identified as having analytical resources and data useful to NBIC's integration mission.

The success in achieving the first two objectives, a robust information management system and a core of subject matter experts to analyze data, are dependent upon obtaining the cooperation and substantive participation of agencies with relevant data and expertise. DHS has reached out to these agencies but had limited success to date in completing three types of agreements with each agency: First, memorandums of understanding, in which the agencies agree to participate as a member of NBIC. Six of the 11 agencies have signed MOUs with NBIC, Department of Defense, Agriculture, Health and Human Services, State, Interior, and Transportation. Five agencies have not yet signed MOUs, the FBI, Veterans Administration, Postal Service, EPA, and the National Oceanic and Atmospheric Administration.

Second, interagency agreements that describe the programmatic, financial, and staffing between NBIC and participating agencies. None of these agreements have yet been finalized. Only one agent, CDC, has provided a detailee to NBIC.

Third, interagency security agreements that formalize the types of data that agencies will share with NBIC's IT system and their access to that system. None of these agreements have been signed, either.

It is important to note that DHS cannot compel the participation of these 11 agencies. As in many other areas in which DHS is trying to develop cross-agency programs, the principle challenge is getting the full cooperation of agencies that have not historically cooperated and worked together in a fully integrated manner.

Finally, on April 1, 2008, a contractor delivered to NBIC an upgrade to its information technology system intended to enhance its data integration capabilities. However, DHS officials said that before this upgrade can be used effectively, NBIC will need to train its employees to use the system, training that it expects to complete in early 2009. In addition, NBIC will need to negotiate the previously mentioned interagency agreements to define the data participating agencies will provide for the system and their access to that system. It is not clear when that may be completed.

That concludes my statement, Mr. Chairman. I would be pleased to respond to any question you or other Members of the subcommittee may have.

[The statement of Mr. Jenkins follows:]

PREPARED STATEMENT OF WILLIAM O. JENKINS, JR.

JULY 16, 2008

GAO HIGHLIGHTS

Highlights of GAO–08–960T, a testimony before the Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives.

Why GAO Did This Study

The United States faces potentially dangerous biological threats that occur naturally or may be the result of a terrorist attack. The Department of Homeland Security (DHS) is developing two major initiatives to provide early detection and warn-

ing of biological threats: The National Biosurveillance Integration Center (NBIC), a center for integrating and coordinating information on biological events of national significance, and the BioWatch program that operates systems used to test the air for biological agents. The Implementing Recommendations of the 9/11 Commission Act of 2007 requires DHS to establish a fully operational NBIC by September 30, 2008. This statement discusses the status of DHS's efforts to: (1) Make NBIC fully operational by the mandated deadline, and (2) improve the BioWatch program's technology. GAO's preliminary observations of these two programs are based on our ongoing work mandated by the Implementing Recommendations of the 9/11 Commission Act of 2007 to review U.S. biosurveillance efforts. To conduct this work, GAO reviewed related statutes; Federal directives; and DHS planning, development, and implementation documents on these two initiatives. We also interviewed DHS program officials to obtain additional information about NBIC and BioWatch.

DHS reviewed a draft of this testimony and provided technical comments, which were incorporated as appropriate.

BIOSURVEILLANCE: PRELIMINARY OBSERVATIONS ON DEPARTMENT OF HOMELAND SECURITY'S BIOSURVEILLANCE INITIATIVES

What GAO Found

DHS has made progress making NBIC fully operational by September 30, 2008, as required by the Implementing Recommendations of the 9/11 Commission Act of 2007, but it is unclear what operations the center will be capable of carrying out at that point. DHS has acquired facilities and hired staff for the center but has not yet defined what capabilities the center will have in order to be considered fully operational. DHS has also started to coordinate biosurveillance efforts with other agencies, but DHS has not yet formalized some key agreements to fulfill NBIC's integration mission. For example, DHS has signed memoranda of understanding with 6 of 11 agencies DHS identified to support the operations of NBIC. However, DHS has not yet completed other key agreements to, for example, facilitate the technical exchange of information, such as data on human health, between NBIC and the agencies. In addition, a contractor DHS hired to enhance NBIC's information technology system delivered an upgrade to the system on April 1, 2008, intended to enhance data integration capabilities. However, before this upgrade can be used effectively, DHS officials said that NBIC will need to train its employees to use the system and negotiate interagency agreements to define the data that the agencies using the system will provide. DHS officials expect that NBIC will complete the training in early 2009.

DHS has two ongoing efforts to improve the detection technology used by the BioWatch program, which deploys detectors to collect data that are then analyzed to detect the presence of specific biological agents. First, the Directorate for Science and Technology (S&T) within DHS is developing next-generation detectors for the BioWatch program. DHS plans for this new technology to collect air samples and automatically test the samples for a broader range of biological agents than the current technology. Under the current system, samples are manually collected and taken to a laboratory for analysis. DHS plans to operationally test and evaluate the new automatic technology in April 2009 and to begin replacing its existing detection technology in 2010. Operational testing and evaluation of the new technology is planned to take place in April 2009, about 1 year later than DHS initially planned, because S&T officials received revised requirements for the new system about 4 months before S&T was scheduled to complete development of the system. Second, while S&T is completing its work on the new detection technology, DHS is developing an interim solution, managed by the Office of Health Affairs, to enhance its current detection technology. This interim solution is intended to automatically analyze air samples for the same number of biological agents currently monitored by the BioWatch program. Contingent on successful operational testing and evaluation that is to start in November 2008, DHS plans to decide whether to acquire over 100 of these enhanced detectors.

Mr. Chairman and Members of the committee: I am pleased to have the opportunity to be here today to discuss some issues associated with the Department of Homeland Security's (DHS) biosurveillance initiatives, specifically the National Biosurveillance Integration Center (NBIC) and the BioWatch program. The United States faces potentially dangerous biological threats that occur naturally or may be the result of a terrorist attack. New diseases, such as Avian Influenza, West Nile virus, and severe acute respiratory syndrome (SARS) have emerged in recent years. Infectious diseases have the potential to develop into widespread outbreaks and could have significant consequences, such as causing hundreds of thousands of casualties, disrupting and weakening our economy, damaging public morale and con-

fidence, and threatening our national security. In addition to naturally occurring infectious disease outbreaks, the United States faces the possibility that terrorists will use biological agents as weapons of mass destruction. Threats of bioterrorism, such as anthrax attacks and high-profile disease outbreaks, have drawn attention to the need for systems that provide early detection and warning about biological threats, known as biosurveillance systems. DHS, in cooperation with various other Federal agencies, is developing two major initiatives to provide early detection and warning about biological threats: NBIC, a center for integrating information on biological events of national significance, which the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) mandated DHS to establish and make fully operational by September 30, 2008,[1] and the BioWatch program, which operates systems to test the air for specific biological threats.

My remarks today will focus on the status of DHS's efforts to: (1) Make NBIC fully operational by the statutorily mandated deadline and (2) improve the technology used by the BioWatch program. Our preliminary observations of these two DHS programs are based on our ongoing review of U.S. biosurveillance efforts, as required by the 9/11 Commission Act.[2] The law mandates that GAO review U.S. biosurveillance efforts at the Federal, State, local, and tribal levels of government. Our preliminary observations on NBIC and the BioWatch program are based on reviews of DHS planning, development, and implementation documents concerning these initiatives; related statutes and Federal directives; and interviews with DHS officials. We interviewed officials from the Office of Health Affairs (OHA) responsible for establishing NBIC and managing the BioWatch program. We also interviewed officials from DHS's Directorate for Science and Technology (S&T), the primary research and development office responsible for developing next-generation detection technology for BioWatch. We conducted our work from February 2008 to July 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

SUMMARY

DHS has made progress making NBIC fully operational by September 30, 2008; however, it is unclear what operations the center will be capable of carrying out at that point. DHS has faced difficulties completing some key tasks, such as defining what capabilities the center will provide once fully operational, formalizing agreements to obtain interagency coordination, and completing work related to the new information technology (IT) system. For example, NBIC has made some progress in developing its capabilities to be fully operational by September 30, 2008, as mandated by the 9/11 Commission Act, but NBIC has not yet defined the capabilities the center will have in order to be considered fully operational. DHS, through NBIC, has also started to coordinate interagency biosurveillance efforts and finalized some, but not all, key interagency coordination documents. For example, DHS has yet to finalize interagency agreements with relevant agencies that describe programmatic, financial, and staffing arrangements between NBIC and these agencies. In addition, a contractor DHS hired to enhance NBIC's IT system delivered an upgrade to the system on April 1, 2008; however, NBIC officials stated that they need to complete additional work before granting other agencies full access to the new system. For example, NBIC is still in the process of training employees to use the system and negotiating agreement on the data that agencies will provide to NBIS.

DHS has two ongoing efforts to improve the detection technology used by the BioWatch program. First, S&T within DHS is developing new detectors for the BioWatch program, a program that deploys detectors to collect data that are then analyzed to detect the presence of specific biological agents. These new detectors, known as Generation 3.0, are intended to provide additional capabilities and replace the existing detection technology beginning in 2010. The new detector technology is designed to both collect and automatically test air samples for biological agents, unlike the current system in which samples must be manually collected and taken to a laboratory for analysis. DHS officials anticipate that the new technology will reduce the elapsed time between air sampling and detection of a biological threat by at least 4 hours and possibly as much as 30 hours. Additionally, the new technology is designed to detect more biological agents than the existing technology. Operational testing and evaluation of this technology is scheduled for April 2009, about

[1] Pub. L. No. 110–53, § 1101, 121 Stat. 266, 375–79 (2007).
[2] Id. at § 1102, 121 Stat. at 379.

a year later than initially planned because OHA provided S&T with revised requirements about 4 months before S&T was scheduled to complete the development of the new prototype detector. Second, while S&T completes its work on the new detection technology, OHA is developing an interim solution to enhance the existing detection technology so that it can automatically analyze air samples. Contingent on successful operational testing and evaluation that is to begin in November 2008, DHS plans to acquire over 100 of the enhanced detectors.

BACKGROUND

Since the attacks of September 11, 2001, there has been concern that another terrorist attack on U.S. soil could occur involving biological, chemical, radiological, or nuclear weapons. Concerns like these have prompted increased Federal attention to and investment in national emergency preparedness—that is, the Nation's ability to prevent, protect against, respond to, and recover from large-scale emergency events. Effective preparation for, detection of, and response to a major biological event requires effective pre- and post-disaster coordination and cooperation among different Federal agencies, levels of government, nongovernmental organizations, and the private sector. In the case of biological threats, detection of biological agents is a first step in an effective response to a natural, accidental, or intentional outbreak of a biologically caused disease.

In August 2007, the 9/11 Commission Act required DHS to establish NBIC to detect, as early as possible, a biological event of national concern that presents a risk to the United States, or the infrastructure or key assets of the United States. The 9/11 Commission Act provides that the mission of NBIC is to enhance the capability of the Federal Government to:

- rapidly identify, characterize, localize, and track a biological event of national concern;
- integrate and analyze data relating to human health, animal, plant, food, and environmental monitoring systems; and,
- disseminate alerts to member agencies, and State, local, and tribal governments.[3]

The 9/11 Commission Act also requires NBIC to be fully operational by September 30, 2008.

Prior to the passage of the 9/11 Commission Act, two Presidential directives charged Federal agencies to coordinate Federal efforts and create a new biological threat awareness capacity to enhance detection and characterization of a biological attack.[4] In response to these Presidential directives, DHS began the National Biosurveillance Integration System (NBIS) program in 2004 as a means of integrating information across Government agencies regarding biological events. The NBIS program developed an IT system, also known as NBIS, to bring together various data used for human, animal, and plant health surveillance; environmental monitoring data; and intelligence and threat analysis. Subsequently, the 9/11 Commission Act established NBIC as the entity responsible for, among other things, developing and running the IT system, still known as NBIS. Since it was created in March 2007, OHA has overseen NBIS and now the NBIC program office.

DHS, in cooperation with other Federal agencies, created the BioWatch program in 2003 to detect the release of airborne biological agents. The BioWatch program deploys detectors which collect data that, when analyzed, can be used to identify biological agents on the BioWatch threat list.[5] Current BioWatch detection technology contains filters that collect air samples, but the filters must be collected manually, and testing of the samples is carried out in State and local public health laboratories. Using this manual process, results are usually obtained within 10 to 34 hours of an agent's detection. BioWatch detectors are currently deployed in 30 cities, and

[3] According to the 9/11 Commission Act, the term "member agency" means any Federal department or agency that, at the discretion of the head of that department or agency, has entered a memorandum of understanding regarding participation in the NBIC. DHS is working with 11 other Federal agencies to establish NBIC: Department of Defense, Department of Agriculture, Department of Health and Human Services, Department of the Interior, Department of State, Veteran's Affairs, Department of Transportation, the Environmental Protection Agency, Postal Service, Department of Commerce, and Department of Justice.

[4] Homeland Security Presidential Directive (HSPD) 9, *Defense of United States Agriculture and Food* (Jan. 30, 2004), charges Federal agencies to create a new biological threat awareness capacity. Additionally, HSPD 10, *Biodefense for the 21st Century* (Apr. 28, 2004), calls for an integrated and comprehensive attack warning system that will assist in recognizing and responding to biological attacks on humans, animals, food, water, agriculture, and environmental resources.

[5] DHS has identified a list of specific biological agents that could pose a health threat if aerosolized and released to the environment.

local jurisdictions are responsible for the public health response to positive findings in the BioWatch program. OHA has responsibility for managing the operations of the BioWatch program. S&T, which is the primary research and development arm of DHS, is responsible for developing detectors for the BioWatch program.

DHS HAS MADE PROGRESS IN MAKING NBIC FULLY OPERATIONAL BY THE MANDATED SEPTEMBER DEADLINE, BUT FACES DIFFICULTIES COMPLETING KEY TASKS

DHS has made progress making NBIC fully operational by September 30, 2008, as required by the 9/11 Commission Act, but has faced difficulties completing some key tasks, such as defining what capabilities the center will provide once fully operational, formalizing agreements to obtain interagency coordination, and fully implementing its IT system. NBIC has not yet defined what capabilities the center should have in place in order to be fully operational. According to NBIC officials, NBIC has drafted, but not finalized, planning documents to define these capabilities. In addition, NBIC has initiated coordination with member agencies through memoranda of understanding (MOUs) and interagency working groups. NBIC is working to establish additional coordination efforts to enhance NBIC's integration capabilities. Further, a contractor DHS hired to enhance NBIC's IT system delivered an upgrade to the system on April 1, 2008, but more work remains to be done. For example, member agencies will not have full access to the IT system until NBIC employees have been trained to use the system. Additionally, NBIC reports that it continues to negotiate agreements with member agencies on the data they are to provide for the IT system.

Progress Has Been Made, But It Is Unclear What Capabilities NBIC Will Have by the September 30, 2008, Deadline

DHS has made progress making NBIC fully operational by the mandated September 30, 2008, deadline; however, it is unclear what operations the center will be capable of carrying out at that point. NBIC has acquired a facility that accommodates office space, a 24-hour watch center, as well as secure areas to handle classified materials. Additionally, in January 2008 NBIC hired a permanent Director to oversee NBIC operations. As of July 2008, NBIC has also filled 26 of 37, or 70 percent, of NBIC's available staff positions, and according to NBIC officials, NBIC is in the process of hiring four additional staff members, including a Deputy Director. NBIC officials are planning to use contractors to fill the remaining 7 positions. Furthermore, NBIC has also acquired one detailee from a member agency, the Department of Health and Human Services, and is working to acquire additional detailees. NBIC has drafted a concept of operations; a finalized version is pending comments from NBIC's member agencies. Officials have also drafted, but not finalized, standard operating procedures. In fiscal year 2008, $8 million were available to NBIC officials to establish the center; officials told us that they recently requested an additional $4.2 million in a reprogramming that DHS has not yet approved.

NBIC has not yet defined the capabilities the center should have in order to be considered fully operational. The 9/11 Commission Act does not define fully operational or what capabilities NBIC needs to have in place by the statutorily mandated September 30, 2008, deadline. NBIC officials told us that they are currently trying to define "fully operational" and are drafting detailed plans for the final 90 days of planning before the deadline. Officials told us that these documents describe the details of NBIC's expected operational capabilities and functions, such as the state of their IT system, personnel expectations, analytic capabilities, and include specific goals, objectives, milestones, and cost estimates. DHS did not provide us with these planning documents because the documents are in draft form.

NBIC Has Taken Steps to Coordinate With Federal Agencies, But Has Not Formalized Agreements to Obtain Their Cooperation

NBIC has initiated coordination efforts with 11 Federal agencies but faces difficulties completing formal agreements to obtain their cooperation. Since the new NBIC Director started in January 2008, NBIC has organized interagency working groups and has finalized MOUs with 6 of the 11 agencies that NBIC identified as important to the operational needs of the center. NBIC has an interagency working group consisting of these 11 agencies, in addition to DHS, that first met under the direction of the new Director in March 2008. As part of the interagency working group, DHS officials stated, NBIC has created a sub-working group that meets on a weekly basis to discuss issues such as the daily operations of NBIC, reporting requirements, and data-sharing issues. NBIC also organized an interagency oversight council, which includes representatives from member agencies, private-sector organizations, and academia, to provide technical oversight and guidance in the development and implementation of NBIC's operations. The oversight council plans to meet for the first

time in August 2008. NBIC has begun facilitating interagency coordination while continuing to implement additional elements of the program. For example, NBIC officials told us that they helped coordinate the Federal Government's efforts to deal with the recent national salmonella outbreak, while simultaneously continuing to work on making NBIC fully operational to meet the September 30, 2008, deadline.

As part of its efforts to establish interagency coordination, NBIC is seeking to formalize its relationship with Federal agencies through three types of documents: MOUs, interagency security agreements (ISAs), and interagency agreements (IAAs). First, DHS is asking Federal agencies to sign MOUs to confirm the agency or department's initial agreement to participate in NBIC as a member agency. Second, DHS is asking agencies to sign ISAs that formalize the technical exchange of information, such as data on human health, between NBIC and these agencies. Finally, DHS is asking agencies to sign IAAs that define programmatic, financial, and staffing arrangements between NBIC and these agencies. As part of the IAAs, agencies are to agree to provide detailees to work at NBIC. These detailees will provide subject-matter expertise and facilitate NBIC coordination with their respective home department or agency.

To date, NBIC and potential member agencies have finalized 6 of 11 MOUs; however, they have not finalized any ISAs or IAAs. DHS has signed MOUs with the Departments of Defense, Agriculture, Health and Human Services, Interior, State, and Transportation. DHS is still working to finalize MOUs with another 5 agencies to formalize their membership in NBIC.[6] NBIC does not have ISAs or IAAs in place with any of its current and potential member agencies. According to NBIC officials, one difficulty in finalizing the ISAs is due, in part, to defining the data-sharing arrangements with member agencies given the constraints on arrangements for sharing data imposed by the traditional roles of these agencies. For example, interagency coordination for the purposes of characterizing a biological event may require data that NBIC member agencies have not previously shared with other agencies. In addition, DHS faces difficulty finalizing IAAs, the formal mechanisms through which NBIC obtains detailees from Federal agencies. In the absence of IAAs, according to NBIC's draft concept of operations, the center cannot effectively perform its integration and analytical mission without the subject-matter knowledge from interagency detailees. As of July 2008, NBIC has been able to secure one detailee from a member agency. Officials were unable to predict how many additional MOUs, ISAs, IAAs, or detailees NBIC will have in place by September 30, 2008.

NBIC Recently Upgraded Its IT System, But Additional Work Remains

A contractor DHS hired to enhance NBIC's IT system delivered an upgrade to the system in April 2008; however, NBIC officials stated that they need to complete additional work before granting member agencies full access to the system. The system, known as NBIS, provides tools to enhance NBIC's data integration capabilities and collaboration with member agencies. Such tools include a worldwide geographical map displaying emergent and ongoing adverse health events, an assessment of the homeland security implications of those events, a library of all referenced data, and general disease and situational reports. NBIC officials told us that additional work needs to be done before giving member agencies full access to the system. For example, NBIC does not have interagency security agreements in place with member agencies that specify the data that agencies will share with the system. In addition, as NBIC officials work with the NBIS system, they are identifying additional improvements that need to be made to the system. Furthermore, while member agencies will have access to some of the individual tools that are a part of NBIS, until NBIC analysts have been trained to use NBIS, member agencies will not have full access to all of the system's interagency collaboration functions. Officials estimate that training will not be completed until at least early 2009.

DHS HAS TWO ONGOING EFFORTS TO IMPROVE THE BIOWATCH TECHNOLOGY, WHICH MAY DECREASE DETECTION TIME OR INCREASE THE NUMBER OF AGENTS THAT CAN BE IDENTIFIED

DHS has two ongoing efforts to improve the detection technology used by the BioWatch program. S&T is developing a new technology. OHA is developing an interim solution to enhance the detectors currently in use.

S&T is developing new detection technology known as Generation 3.0 which would replace the existing technology used by the BioWatch program. This new technology is to provide a fully automated detector which not only collects air sam-

[6] The five departments and agencies with pending MOUs include the Department of Commerce, the Environmental Protection Agency, Department of Justice, United States Postal Service, and Department of Veterans Affairs.

ples but also analyzes them for threats. The current technology collects air samples which are periodically manually removed from the equipment and taken to a laboratory for analysis, a process that could take 10 to 34 hours. Officials stated that automating analysis of air samples could reduce the elapsed time between air sampling and testing it for threats from the current 10 to 34 hours to 4 to 6 hours, reducing detection time by at least 4 hours and possibly as much as 30 hours. In addition to the automated detection capability, Generation 3.0 is to detect a broader range of identified biological agents to eventually cover all the biological agents on the BioWatch threat list—a list of specific biological agents that could pose a health threat if aerosolized and released to the environment. The estimated cost for acquiring these detectors is $80,000 to $90,000 per unit, with yearly operation and maintenance costs of $12,000 to $41,000 per unit.

Operational testing and evaluation of this technology is scheduled for April 2009, about a year later than initially planned because OHA provided S&T with revised functional requirements about 4 months before S&T was scheduled to complete the Generation 3.0 prototype detector. S&T developed the original requirements for the Generation 3.0 technology, which required the automatic detectors to, among other things, operate continuously, detect more biological threats, be less expensive to operate, and be deployed in both indoor and outdoor environments. S&T planned to complete the development of the hardware and software and conduct field tests of its prototype Generation 3.0 detectors by April 2008, at which point OHA was to take responsibility for final operational testing and evaluation of the detectors. However, OHA provided S&T with new requirements for the Generation 3.0 detector in January 2008, which delayed operational testing and evaluation by 1 year, from April 2008 to April 2009. The new requirements included additional requirements and provided additional details for some of the original requirements. For example, OHA's new requirements contain restrictions for the size and weight of the Generation 3.0 detector which were not specified in the original requirements. As a result of the 1-year delay, S&T also designed an additional field test for the Generation 3.0 prototypes, scheduled to begin in the first quarter of fiscal year 2009, which will occur in an urban environment and allow for the prototypes to be tested in real-world conditions. According to S&T and OHA officials, the Generation 3.0 detector will ultimately replace all current BioWatch detectors by 2013, with initial deployment beginning in 2010.

While S&T is completing is work on the Generation 3.0 detectors, OHA is developing an interim solution to enhance the detectors currently in use by adding the capability to automatically analyze air samples for some biological agents. OHA's interim technology, known as Generation 2.5, is intended to add the capability to automatically analyze air samples for the same number of biological agents currently monitored by the existing BioWatch detector technology. However, the enhanced detectors will not have the capability to identify additional biological agents listed on the BioWatch threat list. According to OHA officials, Generation 2.5 detectors will, like Generation 3.0 detectors, reduce the elapsed time between sampling the air and detecting a biological agent by at least 4 hours and possibly as much as 30 hours. Further, OHA officials stated that they plan to operationally test and evaluate new prototype detectors beginning in November 2008 and to acquire over 100 of these new detectors, contingent on successful completion of operational testing and evaluation. The estimated cost for acquiring and testing these detectors is $120,000 per unit, with yearly maintenance costs of $65,000 to $72,000 per unit. According to DHS officials, OHA plans to deploy these new detectors both indoors and outdoors; however, no procedural guidance exists for responding to positive results from detectors placed indoors. According to OHA officials, they plan to develop this guidance by October 2008 and apply it to all future BioWatch detectors deployed indoors.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the committee may have at this time.

Mr. LANGEVIN. Thank you, Mr. Jenkins.

The Chair now recognizes Mr. Wilson for 5 minutes.

STATEMENT OF JAMES M. WILSON, V, MD, CHIEF TECHNICAL OFFICER AND CHIEF SCIENTIST, VERATECT CORPORATION

Dr. WILSON. Thank you, sir.

Chairman Langevin, Ranking Member McCaul, and Members of the subcommittee, I appreciate the opportunity to testify today

about the Department of Homeland Security's National Biosurveillance Integration Center, NBIC.

My name is Dr. James Wilson, chief scientist and chief technical officer at Veratect Corporation, a privately funded company, with offices in Seattle, Chicago, and Alexandria, Virginia.

For more than 10 years now, I have been pursuing a mission of early disease detection and tracking. I have had the privilege of working with and for the World Health Organization, NASA, NOAA, the U.S. Army, DHS–NBIC, and several other Federal organizations, all with the intention of developing the art and science of timely, accurate, sensitive, and specific detection and warning for disease early enough to do something about it before it can spread via the global transportation and commerce grid.

Perhaps the most relevant points in my career for this discussion today are my role as the first chief of operations at NBIC, principal investigator of Project Argus, founding member of the Biosurveillance Indication and Analysis Community, BIWAC, and my current role at Veratect.

I am here today to speak about the national biosurveillance integration mission and what it would take to strengthen and hasten NBIC toward the successful completion of its congressional mandate to build and operate an integrated biological threat detection, tracking, and warning system.

I am also here as a physician and U.S. citizen with deep concerns about how to best meet the growing threat of global disease. The threat is real. The diversity of the threats is growing, and increasing globalization only heightens our risk. So what are we as a Nation doing about the threat?

NBIC is mandated to protect the United States from biological threats through effective early warning. Execution has fallen short, however, due to one basic point: Every warning system needs effective early detection. The earlier the better. Like hurricane, tornado, and tsunami warning systems, early, accurate, and specific warning of inbound disease is key to avoiding disaster.

I was fortunate to lead the team at Project Argus that represented the best available system at the time. Despite our best efforts, there were operational restrictions which prevented Argus from reaching its full potential. Most importantly, we were unable to analyze domestic data, leaving a tremendous blind spot in the system. In addition, we were unable to work with international partners in order to validate our findings. We were also unable to share vital information with the global health community. These restrictions were mission crippling.

Earlier this year, we set out to create from the ground up a more advanced methodology and operational framework that provides truly global reach, including domestic coverage, and allows us to work with private corporations and nonprofit organizations. This new approach is not trivial. Our ForeShadow engine and VeraSight interface have greatly expanded the number of information sources and the ability to detect and track emerging biological events in near realtime. Veratect's more open framework also allows for rapid ground verification to facilitate early warning and help initiate proactive response by working closely with both public and private resources around the world.

One of our key observations over the past 10 years is it is the critical importance of human analysis. Human-powered technology drives our ability to detect diseases earlier and more accurately than at any time in history.

The senior analytic team and I that I assembled at Argus is now at Veratect, where we now have more than 230 person years of international experience and nearly 100 person years within this new professional discipline. We currently monitor over 200 diseases that affect humans and animals, and our methodology has expanded to include monitoring for food safety. For the first time in history, we can now do more than simply deal with the aftermath of such disasters as HIV/AIDS, SARS, or the H3N2 vaccine drift this past winter, which is found in this commentary here in Nature this month. The team that is now at Veratect detected this new strain of influenza a full 6 weeks in advance of the WHO consultation on the composition of the influenza vaccine for the Northern Hemisphere in February 2007.

We stand at the threshold of a new era in public health, where we can detect and perhaps anticipate public health crises and disasters through Veratect's groundbreaking methodology and global partnerships. I am here not just as a professional of this new discipline but as a father and a husband who is worried about these emerging threats and the potential effect on my family. This is personal for all of us. Everyone in the world is a stakeholder in what we do here today.

Once again, I am grateful for this opportunity to testify, and I stand ready to answer any questions you might have. Thank you.

[The statement of Dr. Wilson follows:]

PREPARED STATEMENT OF JAMES M. WILSON, V

JULY 16, 2008

Chairman Langevin, Ranking Member McCaul and Members of the committee, I appreciate the opportunity to testify today about the Department of Homeland Security National Biosurveillance Integration Center (NBIC).

My name is Dr. James Wilson, Chief Scientist and Chief Technical Officer of Veratect Corporation, a privately funded company with offices in Seattle, Chicago and Alexandria, Virginia. For more than 10 years now, I have been pursuing a mission of early disease detection and tracking. I have had the privilege to have worked with and for the World Health Organization, NASA, NOAA, U.S. Army, DHS–NBIC and several other Federal organizations, all with the intention of developing the art and science of timely, accurate, sensitive and specific detection and warning for disease—early enough to do something about it before it enters the global transportation and commerce grid. Perhaps the most relevant points in my career, for this discussion today, are my role as the first Chief of Operations at NBIC, Principal Investigator of Project Argus, founding member of the Biosurveillance Indication and Warning Analysis Community (BIWAC) and my current role at Veratect.

Today I would like to cover five things:

(1) A quick review of biological threats past to present.

(2) What our Nation's response has been to date.

(3) Speak to NBIC's mandate as it stands today, and what will be required for it to succeed.

(4) Share with you the next generation in early detection methodologies that we have developed, and are improving at Veratect.

(5) Suggest how Veratect can support NBIC and the National Biosurveillance Integration Mission.

BRIEF HISTORY OF BIOLOGICAL THREATS, 1918 TO PRESENT

I would like to begin by sharing some historical context as we review past and present diseases. In the late 1990's, I worked with the World Health Organization

and NASA to examine environmental and climatic phenomena in Africa potentially associated with the emergence of the Ebola virus. This work led to the first model for rapid identification of "conditions favorable" for Ebola epidemics using satellite imagery. It was during this time period that WHO and its partners initiated the Global Outbreak Alert and Response Network (GOARN), the Canadians created the Global Public Health Intelligence Network (GPHIN), and ProMED was started; indeed it was the birth of what we would later refer to as a new professional discipline in monitoring publicly available global information.

In 2003, several colleagues and I applied this idea to West Nile virus, utilizing the concept of "graded alerting" married to "graded response", where clues of the emergence of a biological event sensitize a network of biosurveillance analysts to begin actively searching for more information that may ultimately yield a response action. That work evolved into the National Library of Medicine (NLM)-sponsored Project Sentinel, which examined the role of syndromic surveillance in biodefense. The most substantial realization of Project Sentinel was the possibility of connecting a global biosurveillance system seamlessly to hospitals in America using information technology so that patients would not be seen by American healthcare workers without access to immediate situational awareness of what that patient might have been exposed to while traveling overseas. This was a poignant note when considering the vulnerability of Toronto's hospitals in 2003 when they unknowingly admitted suspect and confirmed cases of SARS that prompted quarantine and closure of their facilities.

One of the things that history is teaching us now is that, in the context of influenza season, the impact on the medical grid is considered substantial, but brief. However, in the case of a pandemic, the possibility of a "medical blackout" becomes a serious consideration. America's hospitals are not linked to near real-time situational awareness, which is a serious issue given biological hazards can easily translocate undetected and un-forewarned in hours through the air traffic grid from Africa to New York and Asia to Los Angeles.

Clearly, globalization and more specifically the transportation grid (as it has become more developed) has heightened the risk of transnational spread of disease. Just last week we saw a case of Marburg hemorrhagic fever transferred by flight from Uganda to the Netherlands. Currently, the United States is experiencing the worst measles epidemic in 10 years, which has spread to 15 States thanks to foreign introduction by returning travelers to the United States. Of course, the Members are aware of the current national salmonella food contamination event that CDC and FDA are struggling to investigate, courtesy of our globalized commerce.

According to the U.S. Department of Transportation, the total bi-directional exchange of direct, non-stop air traffic between the United States and the rest of the world was 81.4 million passengers in 1990. By 2005, bi-directional air traffic between the United States and the rest of the world increased by 182 percent to 148.6 million. In 1990, bi-directional exchange between China and the United States was 84,308 passengers with 3 Chinese cities connecting to 7 U.S. cities. By 2005, this had increased to 1.5 million passengers, which is an increase of 1,819 percent with 9 Chinese cities connecting to 27 U.S. cities.

It is obvious that international air traffic to and from the United States is steadily increasing. However, translocation of disease by aircraft has been reported with community exposures. Historically, the influenza pandemics of 1918, 1957 and 1968 and the HIV/AIDS pandemic were brought to the United States through transoceanic ships and airplanes. Pathogens such as adenovirus, Chikungunya virus, the cholera bacterium, dengue virus, Ebola and Margburg hemorrhagic fever viruses, hepatitis A virus, human metapneumovirus, legionella bacterium, the malaria parasite, measles virus, mycoplasma bacterium, norovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus, salmonella bacterium, SARS-coronavirus, both seasonal and pandemic influenza virus, shigella bacterium, smallpox virus (historically), treatable tuberculosis as well as Multi-Drug Resistant (MDR–TB) and Extensively Drug Resistant (XDR–TB) forms of the bacteria, West Nile virus, and yellow fever virus have all been documented to have been vectored by aircraft.

But no historical review of disease threats would be complete without some understanding of the 1918 Spanish influenza–H1N1, which infected one-third of the world's 1.5 billion citizens and killed over 50 million of them. This pandemic took almost a year to spread from its origin to full global involvement. A contemporary 1918-like public health disaster could kill 1.9 million Americans and spread by passenger jets in as little as 3 to 4 weeks from source to global involvement. Our team has serious concerns that such an event may result in sustained "medical blackouts", critical infrastructure failures and acute, overwhelming socioeconomic social disruption. Further, economic research suggests a possible 8- to 10-year global economic depression in a multi-trillion cost to the world economy. Such a scenario

would have serious implications for our ability to project our military might, maintain our homeland security, and our national security, economy and society.

So where are we today—what have we done?

The United States stands at ever-present and increasing risk for further introductions of exotic infectious disease with potentially serious consequences to the Nation. From my perspective in a near real-time operations environment (which will be described below), we have hours or at most a few days to respond to an emergent threat. In other words, while consideration of intentional release or bioterrorism is important and key to national security, naturally occurring threats are more likely and have occurred regularly throughout history. Time-sensitive public health response is the best counter measure we have for both. Early detection is the key to early response and early containment.

My initial work to anticipate the emergence of Ebola, explore graded surveillance for West Nile Virus and connectivity to hospital-based disease surveillance made evident the significant limitations of situational awareness relating to emerging global biological threats among our medical, veterinary, public health, and homeland security communities. We concluded that, particularly with regard to highly communicable diseases, there was a critical need for identifying the earliest possible indications and warnings of foreign biological threats to enhance our ability to proactively implement effective countermeasures. Again, early detection coupled with early response means early control.

From 2004 to 2005, I volunteered my services as the Biodefense Technical Advisor of the U.S. Army Medical Research and Material Command's Telemedicine and Advanced Technology Research Center (USAMRMC–TATRC) to serve as a member of the National Biosurveillance Integration System (NBIS) Concept Design Review panel. In late 2005, I actively canvassed the Department of Homeland Security and the Homeland Security Council to assist with the operational activation of the National Biosurveillance Integration Center (NBIC). As its first Chief of Operations, and in conjunction with the talented people on the NBIC team, we drafted the first concept of operation.

Except for BioWatch, we did not have access to operationally relevant biosurveillance information, because it simply did not exist at that point. While at DHS–NBIC, I interacted with representatives of Customs and Border Patrol, Immigrations and Customs Enforcement, the Transportation Security Administration, and the U.S. Coast Guard who all told me stories of passengers and immigrants who presented with illness at the border. It was my impression that the coordination of situational awareness for these issues with CDC's Division of Quarantine and Population Migration would be a powerful adjunct within NBIC's mission of biosurveillance. It was in these early days we realized the need for a novel professional analytic discipline for integrated biosurveillance. With time, we came to understand that additional funding in a different setting was essential to develop the analytical methodology and discipline that would be so crucial to this historically unprecedented capability.

Up to this point, NBIC had configured itself operationally in the manner of a military operations center not unlike the North American Aerospace Defense Command (NORAD). This included mission analysis, concept of operations and an operations plan that was implemented using information feeds from sources such as BioWatch, BioSense, Argus (further addressed below) and other sources of information. This was a historically unique operations center in my opinion in that we were now beginning to function with integrated and prioritized reporting requirements across the Federal agencies. Unfortunately, the structure of the program was not optimal for its Federal partners because it needed to be established in a neutral environment that brought Federal agencies together as equals.

After my departure, NBIC focused heavily on building formal relationships with the Federal community. I did not see much support for detection subsystems nor substantive improvement in their early warning capability. I found there to be limited operational, routine, near real-time engagement between NBIC, their Federal partners and State and local authorities. However, NBIC's continued participation as a member of the Biosurveillance Indication and Warning Analysis Community (BIWAC) was an excellent step in the right direction. I will explain BIWAC in more detail below. It is my opinion the formal relationships needed for NBIC's success will take years to develop, meanwhile the threat space continues to increase in complexity.

RESPONSE TO DATE, THE CREATION OF THE ARGUS PROTOTYPE

Due in part to the emergence of SARS in southern China in 2002 and 2003 and the recent Highly Pathogenic Avian Influenza–H5N1 pandemic concern, DHS and

the Intelligence Technology Innovation Center (ITIC) supported the activation of Project Argus in late 2004. Project Argus was established as a prototype research effort to explore the use of indicators to detect and track biological events, crises and disasters. I served as the Principal Investigator while serving as a faculty member of the Division of Infectious Disease, Department of Pediatrics, Georgetown University Medical Center. It was during the research and development phase of Argus that I also volunteered by services to the NBIS Concept Design review and later as the first Chief of Operations of the NBIC. Therefore, the design of both NBIC and the Argus prototype became synergistic.

While at Georgetown University (we were housed at GU for convenience with little interaction with the rest of campus and no independent support from the university), we applied established proven methodologies to what would become a new analytic and professional discipline in biological event detection and tracking with a full time staff of cultural and linguistic and subject matter experts and analysts based upon state-of-the-art technology provided by the MITRE Corporation. The approach is based on one of the recommendations of the 9/11 Commission to collect, analyze and correlate data from the world wide web as a source for information about indicators of social disruption caused by illness and disease. Although simple in concept it was an extremely complex system. The sponsors of our work deserve the Nation's thanks for having the courage to back our idea—which in retrospect is one of the most powerful national security ideas to have emerged from the post-9/11 period. We benefited from the enthusiastic intellectual support of many parts of the U.S. Government including CDC, USDA, DoD combatant commands around the world, and many others.

In 2006, Congress supported activation of the Argus Research Operations Center, which was to be a prototype operations center for infectious disease event detection and tracking based on the methodology that we developed. Our mission was to monitor the world for the emergence and spread of H5N1 Avian Influenza. We later voluntarily expanded this mission to include 140 diseases the effect both animals and humans globally at no additional cost to the Federal Government.

At this point I became Chief of the Argus Research Operations Center (AROC), but remained in strong support of NBIC and the National Biosurveillance Integration mission. It was my opinion that NBIC would not be able to achieve its objectives without an adequate detection subsystem; therefore I chose to focus my efforts on Argus and support NBIC from Argus.

At our peak capacity, we estimated we were accessing over a million pieces of open source information daily covering every country in the world (except the United States) that resulted in the production of, on average, 200 reports per day. Using a disease event warning system modeled after NOAA's National Weather Service, we issued Warnings, Watches, and Advisories in accordance with guidelines agreed upon by our research partners in the Federal Government. On average, we maintained 15 Advisories, 5 Watches, and 2 Warnings active on our Watchboard at any given time, with 2,200 individual case files of socially disruptive biological events maintained and monitored daily in over 170 countries involving 130 disease entities affecting humans or animals. We reached a maximum load of 3,300 individual case files maintained and monitored daily during the winter of 2007.

This information, as provided to our mostly Federal user community, sensitized them to be vigilant for the most concerning biological events in the world; this vigilance occasionally resulted in proactive requests for more information by our partners such as CDC and USDA. This in turn, contributed to the United States' participation in the International Health Regulations through proactive information sharing with WHO and our international partners. Since the program had begun, we logged over 30,000 biological events in varying stages of social disruption throughout the world involving pathogens such as H5N1 avian influenza, other influenza strains, Ebola virus, cholera, and other exotic pathogens. Of note, while the majority of these events were naturally occurring, this capability identified several laboratory accidents and occasionally allegations of intentional use of biological agents.

Upon invitation by CDC, we presented the results of our efforts to the G8 Health Security Advisory Group in February 2008. To the best of our knowledge, our approach achieved unprecedented operational milestones in comparison to the leading global biological event detection and tracking systems such as ProMED, the Global Public Health Intelligence Network (GPHIN), HealthMap and MedISys. One of the key observations by the G8 members was a unanimous desire for there to be a human interface between the raw data and elicited warning information; there was strong support for nurturing a new professional discipline devoted to near real time operational biosurveillance.

The following examples highlight some of our achievements:

- The operations team at Argus, the majority of whom are now working for Veratect, served the country as the lead tactical global event detection team for H5N1 avian influenza and were the first group in the world to detect the expansion of H5N1 from southern China to Russia and then Eastern Europe. During the winter of 2007, we filed over 12,000 reports of events possibly related to H5N1 avian influenza.
- In late 2004 and early 2005, we participated in the tsunami response by providing daily situational awareness reports to humanitarian responders. In commenting on our operations, the U.S. Pacific Command wrote, "Information is power only when it's shared. The situational awareness that portions of Argus provided during tsunami relief efforts was an impressive attention step. We see some tremendous opportunities and value added for this capability within our area of operational responsibility, which literally covers half the globe. Thanks for keeping our situational awareness up during difficult times."
- On August 3, 2007, this team was the first to notify the U.S. Government of undiagnosed vesicular disease in cattle in Surrey, United Kingdom that later was diagnosed as hoof-and-mouth disease (FMD). Of additional interest, this event was later found to be the result of a laboratory accident, and intentional release was explored as a possible etiology but later discounted. The Members may recall the tremendous economic damage observed during the last epidemic of FMD in the United Kingdom in 2001.
- On August 27, 2007, we were the first to report indications of the Ebola epidemic in Kasai, Democratic Republic of the Congo. This information was made available immediately to CDC, and other members of the Federal user community. CDC's collaboration in rapid access to ground verification information through its partnership with WHO and other international partners was impressive, as it highlighted the potential reduction of the time between initial event detection to ground verification to hours and days as opposed to weeks or months. Again, early detection plus early response equals containment.

H3N2 VACCINE DRIFT

Influenza kills an estimated 250,000 to 500,000 people globally each year. While monitoring the current pandemic threat of H5N1 avian influenza, the team also monitored all influenza strains in support of global influenza disease monitoring. During the winter of 2006 and 2007, the team issued nearly 3,000 event reports across 128 countries and 27 languages, which included 181 Advisories, 58 Watches, and 38 Warnings. Our team identified hundreds of reports of a type A/H3N2 influenza virus that appeared to have drifted away from the current vaccine strain of H3N2 beginning in early January 2007 in Beijing, China, 6 weeks prior to the WHO Consultation on the Composition of Influenza Vaccine for the Northern Hemisphere. We later found similar reports in a multitude of countries and collaboratively worked with CDC to track this important finding. The value of this information was validated when the World Health Organization and its partners recommended a change in the southern hemisphere influenza vaccine to include an updated H3N2 strain.

The most important lesson from the H3N2 vaccine failure is not just the need for a robust comprehensive early detection system, but open and ongoing information exchange between Government agencies and other global health organizations. The lack of transparency to the vaccine development process has resulted in unnecessary deaths here in the United States.

During the subsequent 2007 and 2008 influenza season in the United States, the northern hemisphere vaccine for the type A/H3N2 virus provided suboptimal coverage at 58 percent effectiveness. This does not mean the vaccine was not helpful in terms of reducing the severity and burden of disease. However, although the vaccine achieved some degree of coverage, it was less effective than vaccines used in previous years due to the strain mismatch. The 2007 and 2008 influenza season was severe, with pneumonia and influenza-related mortality above epidemic threshold for 19 consecutive weeks compared to an 11 consecutive week maximum documented in the prior three seasons. This represents a 170 percent increase in seasonal deaths seen since the 2004 and 2005 season. Forty-nine States ultimately reported widespread transmission. In February, one physician commented in ProMED, "I have not seen in my 30 years of practice such a relatively large number of patients presenting with documented influenza vaccine 'failure'."

SHORTCOMINGS OF THE PROTOTYPE

Unfortunately, by operational design, the prototype was not able to monitor what occurred with that strain of influenza here within the United States. From CDC,

we learned that there had been an increase in H3N2 clustered initially around regions of the United States connected directly to China by international air flights. Later laboratory reports from CDC indicated this virus had drifted away from the existing vaccine strain. We noted that the very same week we became concerned about reports in Beijing of an unusual strain of H3N2, vaccine-drifted H3N2 isolates were reported in U.S. cities connected to Beijing by direct air traffic. We did the best we could do with the prototype, but it was not adequate. If precise surveillance of influenza "hot spots" was acted upon with vigorous sampling, we believe history might have been different.

Let's be clear here. As illustrated in the July 10, 2008 issue of Nature magazine, the northern hemisphere, including the United States, missed an opportunity for anticipating a bad season of influenza because: (1) Information was not used proactively to acquire influenza samples from suspicious event/areas in the world, and (2) our most mission critical surveillance was blinded at home. This was one of the biggest difficulties with the prior system as it was set up at Georgetown.

NBIC MANDATE AND THE BIWAC

For NBIC to successfully execute its mission, it needs to leverage the experience of its Federal partners. One of the early examples of this was the working relationship of NBIC and BIWAC.

To facilitate operational validation, my colleagues and I initiated the creation of the unofficial, Federal Biological Indication and Warning Analysis Community (BIWAC). As mentioned above, it was BIWAC that reviewed our reporting requirements with us on a quarterly basis to ensure proper product alignment with the user. BIWAC currently includes CDC's Global Disease Detection team; USDA's Centers for Epidemiology and Animal Health (CEAH); DHS' National Biosurveillance Integration Center; the Armed Forces Medical Intelligence Center; other Intelligence Community organizations; the Defense Threat Reduction Agency; and the U.S. Strategic Command Center for Combating Weapons of Mass Destruction.

The BIWAC created a central clearing base where each member contributed what he or she knew about emerging disease and to quickly determine coordinated next steps that included event verification and, in some cases, actual ground response. To enhance this process, we activated Project Wildfire, which was an experimental information sharing system that enabled near-real time, unclassified dialog among the BIWAC partners. Wildfire, although experimental, attracted a substantial amount of Federal use; for the first time, we saw the power of the National Biosurveillance Integration Mission in the daily activities of the BIWAC.

The success of BIWAC and the Wildfire experiment was tempered by the observation that ground verification of biological event information was severely limited both in terms of types of disease covered as well as geographic coverage. We realized that the actionability of the information was therefore impaired without near real-time interaction with such international partners as NGO's (who are often on the front lines as diseases emerge) and U.N. organizations. One key implication was a requirement for a near real-time functioning global network. Another implication was the realization that there will be times when we will be unable to verify warning information in the face of daily, nonstop air traffic. A recent example of this would be SARS in 2003, where by the time a global alert was issued, the disease was already present in eight countries, including the United States.

The committee is already familiar with the fact SARS was present in China many months before WHO awareness and the Global Alert was not issued until eight countries (including the United States) were already affected. It took 4 months to interrupt all chains of transmission that ultimately affected 27 countries on all continents except Antarctica. I would point out the same phenomena has occurred in the past including the 1957 and 1968 pandemics. Local authorities in Hong Kong reported unusual respiratory disease that inundated multiple urban sectors of their city nearly a month in advance of WHO's public acknowledgement of a global threat referred to as a "pandemic". By then the disease was already in the air traffic grid.

I will note here there was evidence in both pandemics that Mainland Chinese public reporting of unusual respiratory disease preceded reporting in Hong Kong by at least several weeks. In summary, the 1957 and 1968 pandemics and 2002–2003 SARS all were reported at the local level well in advance of national Ministries of Health and WHO awareness or the issuance of a warning to the world. Again, near-real time global disease detection and tracking is essential for our Nation.

VERATECT AND THE FUTURE OF BIOSURVEILLANCE

The Argus program, although a successful prototype, had two critical flaws. First, we were unable to extend our process to include domestic biological event detection

and tracking. Second, we were unable to build global partnerships with organizations whose missions could be greatly enhanced with this information. This was concerning as we realized other natural hazard warning systems such as tornado forecasting in the 1950's came under public scrutiny and criticism when it was discovered that a successful forecast of a deadly tornado was not shared by the military with the local community that received the onslaught of the storm. What was more important was not the high false-positive rate but that a successful forecast could have provided hours of lifesaving warning beforehand. We saw the Argus program coming under similar scrutiny some day; our team felt we had an ethical and moral responsibility to address this concern.

Because of these mission-crippling limitations, all the founding members and many of the most skilled analysts from the original Argus team decided to leave the prototype program and begin anew in a private industry environment, the Veratect Corporation.

Veratect's mission is to provide the earliest detection of threats to human, plant and animal life while empowering corporations, Government organizations, NGO's and global citizens with trusted and actionable information.

Our domestic capabilities and global partnerships, together with Veratect's new ForeShadow™ operating environment and VeraSight™ interface represent a significant step forward in the early detection and 24×7 tracking of biological events that empowers early warning and response from a broad range of private and public stakeholders that share these same risks. Our team of cultural and linguist interpreters with deep domain experience in recognizing pathogens at their earliest emergence represent 230+ person years of international experience and nearly 100 person years of experience in this new and proven professional discipline.

With nearly five times the sources of the prototype, we have an estimated coverage of 82 percent of the world's population now, in near real time. By the end of 2008, we will have expanded this coverage to more then 90 percent. Additionally, we are in discussions to have access to more than a quarter-million correspondents on the ground globally to support near real-time ground truth verification. We stand ready to not only meet the needs of DHS and other Federal agencies, but also local, tribal, and territorial governments in all 50 States. We currently monitor over 200 diseases that affect humans or animals, and our methodology is being expanded to include monitoring for biothreats to food security and crop disease.

For this approach to be successful, there is an absolute requirement for human analysts who serve as the intermediary between the raw data and the interface with those who may take further action like CDC or USDA. Having a close relationship with these users ensures we maintain a proper level of sensitivity and specificity, as well as conduct continual quality assurance and reviews of our standard operating procedures. This distinguishes our efforts from that of other systems that produce raw data outputs such as HealthMap. As mentioned earlier, the G8 Health Security Advisory Group, it was clear the G8 members were more interested in humans serving as an interface with the data versus being shown raw, unmediated data outputs.

VERATECT, NBIC AND THE GLOBAL MISSION

The team at Veratect has a unique perspective of what NBIC should do to meet the congressionally mandated mission objectives. Members of our team at Veratect have worked closely with DHS-NBIC from the very beginning. For the last 2 years, our team has been an important source of information for the entire Federal Government in the support of our Nation's biosecurity.

NBIC is chartered to collect and consolidate near-real time information on biological events using in part, resources within the Federal Government and make those consolidated resources available to the Federal user community charged with meeting biological threats.

We believe in this mission, and we look forward to working with DHS-NBIC again, and this time with far greater resources and capabilities. Veratect has offered to provide our analytical early warning system to NBIC and protect the United States from the threat of infectious disease, it should also be noted that this will also provide significant benefits to the rest of the world. Disease is the common enemy of every human on the planet.

NBIC's mission (as outlined in HSPD–7, –9, –10; NSPD–33; and Public Law 110–53), is a valid and critically needed function for both the United States and for the support of our international partners through the International Health Regulations, the World Animal Health Organization (OIE) Terrestrial Animal Health Code, the Biological Weapons Convention, and safety monitoring for biotechnology.

For the United States, a large number of biological crises and disasters are mostly imported events, as exemplified by the introductions of HIV/AIDS; West Nile virus; monkeypox; SARS and all four of the major influenza pandemics of the past 100 years. Influenza pandemics are generally believed to start outside the United States; the next pandemic will most likely come from a foreign location. Our best defense is based on early detection.

The current concern of an H5N1 influenza pandemic highlights this concern as well. As stated in the 2007 World Health Report, "It cannot be over-emphasized that a truly effective international preparedness and response coordination mechanism cannot be managed nationally. Global cooperation, collaboration, and investment are necessary to ensure a safer future. This means a multi-sectoral approach to managing the problem of global disease that includes governments, industry, public and private financiers, academia, international organizations and civil society, all of whom have responsibilities for building global public health security."

We can support the role of NBIC to protect our country by facilitating early recognition of biological events that may pose threats to our Nation's security, food production systems, and citizens' well being. The spirit of NBIC's mission may be seen across other public emergency warning systems. As with those systems, a critical requirement for NBIC is reliance on detection subsystems that include not only the information they provide but the subject matter expertise behind it.

Veratect is also able to support a turnkey portal for foreign and domestic biological event detection and tracking with extensive ground truth validation that can be shared with NBIC's Federal, State and local partners. The benefits of immediate access to this portal will include access for CDC, USDA, FDA, DOD and other Federal partners who can then engage in more effective coordination of disease surveillance and response.

By the nature of our business, we can assist NBIS by working in collaboration with other stakeholders in global health including transnational corporations, NGO's and friendly foreign governments. U.S. corporations are increasingly concerned about how emerging diseases might affect their own employees and indigenous workers, production partners and supply chains. Foreign corporations operate in areas of interest to the United States and include oil, mining, manufacturing and food production. Their partnership is key to NBIC's mission success.

We are prepared to support NBIC's implementation of its mission objectives by the end of August 2008. Our team and portal is available immediately and we stand ready to support a user community that is well known to us.

There is an opportunity for the United States to lead the world by example once again. The United States has been the one to lead that development of many other societal warning systems over the years. Here we can be the leader in supporting implementation of the new International Health Regulations along with our international partners. We can demonstrate to the world our moral and ethical strength by assisting NGO's in saving lives. We can support our domestic industry competing in the global marketplace. And most importantly, we can finally support our local city, county and State officials in biosurveillance. In the end, we are here to ensure the United States maintains technical supremacy in global biosurveillance in these uncertain times.

I have three closing comments that speak to where we go from here:

1. It is in the national and global interest for the NBIC charter to be implemented immediately. This envisioned system will help protect human, animal and plant life, the national food supply and critical infrastructure against the common enemy of disease. The first step is early detection. We are doing that today.
2. Veratect provides a superset of capabilities, resources and global relationships with private and non-profit organizations that can be of the greatest value to NBIC in meeting its mission. What we do is not reliant upon the NBIC system. We can provide NBIC with a fully operational early disease detection and tracking system today.
3. The disease risks are real and we are on borrowed time. We are fortunate that the SARS epidemic and this year's H3N2 vaccine mismatch were not more disruptive. And we remain very much exposed to an influenza pandemic. My colleagues and I at Veratect are eager and ready to support the national mission today.

I would like to thank the visionaries in the Federal Government and Congress who supported the research and development that led us to this point, the courageous men and women of the BIWAC for their partnership and the Veratect team for their hard work in operationalizing this critically important national asset. While none of us feel that we are, as a Nation, where we need to be in terms of

addressing the risks I have covered here today, I believe that Veratect can uniquely assist NBIC in rapidly achieving its goals.

Once again, I am grateful for this opportunity to testify, and I stand ready to answer any questions you might have.

Thank you.

Mr. LANGEVIN. Thank you, Mr. Wilson.

I want to thank all of the witnesses for their testimony, and I will remind each Member that they will have 5 minutes to question the panel.

Now I recognize myself for questions.

Before I do that, I am going to ask unanimous consent that the testimony for the record from Dr. David Hartley from the Global Argus Project be submitted for the record.

Without objection, so ordered.

[The statement of Dr. Hartley follows:]

PREPARED STATEMENT OF DAVID HARTLEY

JULY 18, 2008

Chairman Langevin, Ranking Member McCaul, and other Members of the subcommittee, please accept my thanks on behalf of the Global Argus team at Georgetown University Medical Center for this opportunity to update you on our work in the context of your hearing on the status of implementing bio-surveillance requirements of the 9/11 Act.

Project Argus is a prototype bio-surveillance system pioneered at Georgetown University which was initiated in 2004 with funding support from the Intelligence Technology Innovation Center (ITIC) and is today supported by the Defense Threat Reduction Agency (DTRA) and the Open Source Center (OSC) of the Office of the Director of National Intelligence (ODNI). Argus is designed to detect and track foreign biological events that may threaten human, plant, and animal health globally and in the United States by monitoring social disruption evident in local, native-language media reports around the world. Because of our funding source, the data collection focuses on sources outside our country.

By monitoring media sources—ranging from traditional print and electronic media outlets to internet-based newsletters in approximately 40 languages on every continent, save Antarctica—we have developed a solid prototype for gathering indications and warnings which serves an important cueing function. (A list of the languages covered by Argus as of last month is attached for your information.) It alerts users to events that may signal the initiation of outbreaks and show trajectories of events that may require additional investigation. To give you a sense of the kinds of reports that Argus generates, let me share two recent examples:

- On June 13, 2008, Argus reported on a child in Vietnam hospitalized with respiratory distress following eating duck form the family's farm. The illness was suggestive of H5N1 infection. The provision of this information by the CDC to the Vietnamese Ministry of Health proved to be very helpful to their epidemiology office.
- On July 7—just last week—Argus alerted a Federal user about a suspected case of H5N1 avian influenza in Egypt. This user alerted an AI response team on the ground, which was otherwise unaware of the situation.

Both of those instances and the manner in which they were handled recognize the fact that Argus cannot and does not purport to determine whether or what type of action should be taken. Instead, our activity serves to provide timely information to governmental officials to inform their decisionmaking. We are proud that Argus provides an important and unique data stream to the National Bio-surveillance Integration System (NBIS), complementing the reports of various Federal agencies with information gathered from open source media. We have been encouraged by the favorable comments from NBIS personnel about the value they find in the product generated by Argus.

In developing the Argus prototype, Georgetown University researchers have developed a taxonomy of direct and indirect indicators of outbreak activity based on:

- Environmental and ecological conditions;
- Reports of disease activity; and,
- Markers of social disruption such as school closings and infrastructure overloads.

Forty analysts fluent in the languages I referenced earlier are coupled with machine translation capabilities covering 13 languages to ensure a broad and deep scope to the media monitoring activities. Bayesian analysis tools are utilized for article selection and alerting. Approximately 1,000,000 articles are scanned daily with 25 percent of those being archived. Since the inception of the program, the Argus archive has grown to over 128,000,000 articles.

Over 40 Federal, State and local governmental entities use Argus on a daily basis including the Departments of Homeland Security, Health and Human Services, and State as well as the funding agencies. State and local governmental organizations in New York and Colorado as well as Colorado State, Kansas State, Syracuse, and Yale Universities are among the regular Argus Watchboard users.

Global Argus underwent a change in leadership in April of this year. Such transitions certainly present challenges, but they also offer opportunities for strengthening projects such as this. I am pleased to be able to report that we have effectively managed the transition, including some personnel changes, without disrupting the quality or timeliness of the reports generated by Argus. In fact, since the change in leadership, Argus has increased the number of languages covered by qualified analysts and is in the process of adding even greater language capabilities.

Having said that, working closely with the COTRs for the project, we are focusing on areas of focus designed to strengthen and perfect the prototype to ready it for eventual commercial utilization. I would emphasize that, while we are immensely proud of what has been achieved to date, we also share the interest of our current funding agencies in ensuring that Argus is fully ready to the task before it is scaled up. The areas on which we are actively engaged at present aim to validate taxonomies, methods and protocols including:

- Reliable statistical characterization of Argus system performance;
- Better documentation and validation of methodologies; and
- Defining operational procedures set out in manuals both for the operational team and for various types of users.

With Argus operational in its current configuration at Georgetown and with those validation and refinement efforts underway, I am confident that we, operating within an academic research institution with highly qualified scientific, medical and linguistic talent readily at hand, are ideally positioned to continue and broaden the project's ability to generate accurate and timely reports while also conducting the validation and refinement work to ensure that the system is commensurate to the task which we all want to have achieved. We have had the depth of experience of developing Argus to its current stage and managing its operations to date, and we now have the benefit of a strengthened team of analysts to address the improvements sought by the Government agencies who have become particularly familiar with the system.

On occasion, we have been asked about "next steps" for Argus, and the obvious need—beyond those referenced earlier—is to complement the international monitoring of these media-based indicators of social disruption with a similar capability domestically. As I referenced earlier, that is not possible given the current funding source, but, with appropriate funding, we stand ready to move on that front in a fashion that will benefit from the enhancements we are currently developing.

ARGUS FOREIGN LANGUAGE COVERAGE—JUNE, 2008

Team Europe

Albanian
Bosnian
Bulgarian
Croatian
Czech
French
German
Greek
Italian
Macedonian
Polish
Portuguese
Romanian
Serbian
Slovak
Spanish

Team Central Asia
Russian
Ukrainian
Belorussian
Mongolian
Georgian
Uzbek
Azeri
Turkish
Kyrgy

Team East Asia
Japanese
Chinese (Mandarin and Cantonese)
Korean

Team Southeast Asia
Thai
Malay
Vietnamese
Indonesian

Team Middle East
Arabic
Tajik
Farsi
Dari

Team Latin America
Spanish
Portuguese

Team Africa
Berber
Arabic
French

Mr. LANGEVIN. To Mr. Myers and Mr. Hooks, the 9/11 Act requires that the National Biosurveillance Integration Center, NBIC, under Section 316 of the Homeland Security Act be fully operational by not later than September 30, 2008.

Again, from our meetings with NBIC's staff, a fully functioning NBIC, including full participation by local authorities and private sector partners, are at least 2 years off. Is that accurate? Can you speak to how soon before it will be fully functional? It seems to us that right now really NBIC is running in a sort of test mode and is not really being used even by the perspective member agencies.

So can you give us a current status of NBIC, most especially how far off are we before it is in fact going to be fully functional? What are the problems? What is standing in the way of us getting to the point where it is fully functioning?

If we can start with Mr. Myers or Mr. Hooks.

Mr. HOOKS. Thank you, Mr. Chairman.

As you know, following the implementation of the 9/11 Act, which set clearly the vision and mission space forward for the NBIC, the NBIC started producing products last October into the interagency working group community. On 30 March of this year, we went live with the IT system, the NBIS 2.0, as well as the biological common operating picture, and at that point, we had an increased capability to share information in the interagency through that IT platform.

From that time, we have been operational. When we talk about being in a fully operational state by 30 September, we have identi-

fied, what are the different goals to reach that fully operational state? We have provided those seven different goals.

But to summarize and highlight that, that means that we have the key personnel in place on the Federal staff as well as 10 detailees on board from different interagency components; that we have the facilities in a condition that they are providing strong analytical support to our people; as well as an appropriate outyear funding profile for the NBIC operations, so it is very clear what the expectations and what are funding are as well.

Within the IT system, we have been identifying the functionality goals, specifically additional capability within that system to be able to share information, to improve the analytics, as well as a system backup capability and a contingency operations plan. We are making updates to the biological common operating picture and are providing improved situational reporting to the different interagency members.

Continuing on, in fact, with those goals, we are developing a more robust interagency community. We intend to have the memorandums of understanding in place, the interagency agreements in place for those detailees to strengthen. We will have held our NBIS interagency oversight council meeting this August, and we are on a path to have better cooperation and agreement with the government coordinating councils and sector coordinating councils that are run out of the Office of Infrastructure Protection.

We also are strengthening the interagency collaboration; that is one of our goals, to be at full operational capability within DHS. We will have a 5-year strategic plan developed by that point.

Those are our goals. There are huge challenges to reach those. The probably largest challenge is to create that trusted environment of information sharing within the Federal Government. In my previous position in Science and Technology Directorate, bringing together the 23 agencies to develop high-priority technology needs, I was able to do that in a 3-month period for the first draft of that and then ran that program for 2 years. That was easier than bringing the 12 member agencies together in a trusted information-sharing environment. We have seen that as a real challenge, but we have made progress as we have worked through the current tomato salmonella event that is ongoing. We will go into details of that as you would like.

Mr. LANGEVIN. Let me stop you there, Because in your testimony, in your answer just now, you talked about having 10 detailees by September 30. How exactly are you going to be able to accomplish that? Is that realistic, when I thought right now you only had one detailee from CDC? How realistic is bringing on the additional number and really completing that goal by September 30?

Mr. HOOKS. I think that is a realistic goal. Eric Myers and I have looked at that across the 12 member agencies and their commitment. On May 23, Secretary Chertoff issued a letter to his other Cabinet peers requesting they provide detailees to the NBIC operation. Eric has met with those different agencies. We have gauged the response from that. We are working the final efforts with some of those agencies now. In fact, recently one of the agencies said they wanted to bring over two of their stronger analytic people to

understand the NBIC operations so that they can work to understand what are the best complement of people in the long term.

Mr. LANGEVIN. We are going to follow up on that and hopefully can hold you to it.

Mr. Myers, since you are the program manager, would you comment on where we are? Do you have additional things to add to the testimony of Secretary Hooks?

Mr. MYERS. Thank you, sir.

Yes, just a couple of things to add to the spice. One is the sense that we are in fact operating. We sat down, using a previous study and also looking at the memberships. If you look at the 12 organizations, they are not only the traditional health and health-related organizations, but some that are not so related, Department of Commerce, Department of Transportation, Department of Interior, Postal System. So there are some very important partners in there who are trying to get into this culture.

We in fact have been operating and in fact started to go back into operational production last October, as was mentioned. We brought in a new cadre of U.S. Public Health Service officers to actually man up our watch to give us 24-hour-a-day sight and vision. This is in the midst of going ahead with the execution on two planes: One is the building of it to get members. The Department of Agriculture in the first week of August will have two members on board with us, which is the next two detailees, and they actually come in to start work with us, in addition to doing a turnover in the first detailee from HHS, which is the individual from CDC.

So, in addition to that, our interagency working group is a very vibrant group. There is a lot of analytic exchange. We do it on a daily basis. We formalize it in a routine production cycle. So that members, although they are not all signed on the dotted line on an MOU, are actually participating in any exchange. There has been very rigorous exchange on that. The salmonella and tomato risk happens to be one of those events.

In addition to that, it is not just the inward look, and my second point to you, of the NBIC, in the NBIS, into the group that we have identified. Of particular importance in there is that each of the agencies comes to the table needing to support basically two cadres of customers. One is the decision-makers, sort of the policymakers. But the other is that we all have are operating components. So, for example, DHS has seven operating components. So our products are going to those.

The other aspect that the NBIC brings that is very important is the taking of this health and health surveillance data that Dr. Wilson I think eloquently stated and superimposing that on top of how the Nation operates, the critical infrastructures. That becomes exceptionally important in terms of getting to early warning. It is not just the disease. It is not just a health issue. It is not just the population. But it is, what are the structures that that impacts, whether that be in food and agriculture, in health and finance, et cetera?

Mr. LANGEVIN. So what operations by September 30 will the NBIC center be capable of carrying out? Let's look at that. Then I am going to ask Mr. Jenkins to respond, if he would, to Mr. Hooks and Mr. Myers, to give your assessment in a point-counterpoint sort of way. Are they on track? Where are they perhaps being

overly optimistic? So if you can answer that question of the capabilities that are going to be capable to carry out.

Mr. HOOKS. So the capabilities that we will be able to carry out by September 30 are to continue to monitor worldwide different biosurveillance activity, looking for cueing opportunities and forward-looking opportunities by integrating information from the different partner agencies that they are bringing into the NBIC team. We expect to be able to provide quality analytical capability back out to our partner agencies, who are also feeding that information down into the State and local network, so that we will have a common picture that is available for the interagency community in the biosurveillance arena.

Mr. LANGEVIN. Mr. Jenkins or Mr. Myers, did you have anything to add for that?

Mr. MYERS. No, sir. For the sake of time, that is good.

Mr. LANGEVIN. Mr. Jenkins.

Mr. JENKINS. Well, I think with regard to the interagency agreements and the detailees, it is not quite clear. The current MOUs were signed in January 2007. So between 2007 and now, there haven't been any additional MOUs signed. So this is—either there is something breaking in the dam, or it is a fairly ambitious schedule in the sense that something is happening that will get these people to sign these agreement. But they also need to have these interagency agreements signed for those detailees, because that specifies whether or not they are going to be reimbursed, how they will come, what they will do, the staffing, the facilities. It is basically an operational agreement. The MOU is, "I agree to participate." An interagency agreement is much more an operational agreement, which is a little more difficult to negotiate simply because it has more details that have to be structured.

So I think, from our perspective, we wish them luck. I hope they are right. I hope they achieve it. But I think it may be a little bit optimistic.

Mr. LANGEVIN. Thank you, gentlemen, for your testimony and for your answers.

With that, I now recognize the Ranking Member for questions.

Mr. MCCAUL. Thank you, Mr. Chairman.

The Chairman brought up the point of the 9/11 Act being fully operational by September 30. It is not defined in the statute what "fully operational" means.

Mr. Hooks, what is your definition of "fully operational"?

Mr. HOOKS. Sir, my definition of "fully operational" are meeting the seven goals that we have laid out with the NBIC team and socialized into the interagency NBIC team to provide the capability necessary to conduct the mission as defined in the 9/11 Act.

Mr. MCCAUL. Do you feel confident you will meet that by September 30?

Mr. HOOKS. I feel confident that we can meet it if we can overcome some big challenges. I mentioned the one, which is the interagency cooperation in a trusted information-sharing environment.

I would also like to mention that there is a reprogramming request on the Hill right now for $2.2 million. That needs to be approved for us to be able to bring the detailees on board to provide the IT—to improve the IT system to the capability that it needs to

reach, as well as to make some space fitout improvements so that we can improve that analytical capability.

Mr. MCCAUL. So the interagency cooperation, which, granted, some of that is out of your control.

Mr. HOOKS. Yes, sir.

Mr. MCCAUL. And the appropriation you discussed.

Mr. HOOKS. Yes, sir.

Mr. MCCAUL. Mr. Jenkins, you referred to these MOUs that had been difficult to enter into. How many different agencies have now signed off on MOUs?

Mr. JENKINS. Six out of 11. There are 12 agencies participating, which one is DHS. So the 6 of 11 have signed off on them.

Mr. MCCAUL. What is the obstacle with the other five agencies?

Mr. JENKINS. Well, part of it, as mentioned by Mr. Myers, is that they are nontraditional in the sense that they are nontraditional sort of public health agency kind of things. So that is part of it. I think the other thing is, in terms of that, for example, with regard to the Postal Service, the Postal Service is not normally in this kind of environment, although they clearly have a very keen interest in early biological detection. They are the only Federal agency that has actually lost people as a result of a biological event, the anthrax attack of 2001. At the end, as I said, across the areas that we look at in DHS, there is a real difficulty in getting agencies to sort of come to the table.

There are concerns about privacy of data: Who controls the data? How will it get out? How will it be used? Who controls the use of it if there is a disagreement about something? As well as issues of, if there are disagreements, how will those be resolved? Those kinds of things tend to be the kinds of things that hold up these agreements, and they vary by different agencies as to what the specific issues are that are of concern to them.

Mr. MCCAUL. Did I understand your testimony correctly that this is more voluntary? That there is no specific requirement that they sign these?

Mr. JENKINS. That is correct.

Mr. MCCAUL. So nothing in the 9/11 Act, no act of Congress has mandated that this happen?

Mr. JENKINS. No. It is basically the ability to persuade, cajole, and negotiate.

Mr. MCCAUL. Would it be helpful if Congress enacted more of a mandatory law?

Mr. JENKINS. Perhaps it might be in the sense that it takes a long time. You can see how long it has taken here. There haven't been any new agreements signed since January 2007.

Mr. MCCAUL. Right.

Mr. JENKINS. That has certainly affected NBIC's ability to meet its operational goal.

Mr. MCCAUL. This is an area where waiting can be lethal.

Mr. JENKINS. Yes, sir.

Mr. MCCAUL. With respect to the salmonella response, what was DHS's role in that response?

Mr. HOOKS. Our role within the salmonella response—I should first mention that our role is not to replace the Food and Drug Administration's role in that mission space. They have the primary

authority for resolving that food contamination of that. But ours was initially to conduct the analysis, to understand the cascading effects of a food contamination event such as the salmonella event that we have seen. What are the economic impacts? What are the international ramifications? What other impacts can occur in the food sector, the public health sector that are not directly related to the salmonella event? Which is where FDA is working in that space.

Additionally, because of the NBIC structure and people who are involved in that daily production cycle, as Eric Myers mentioned, we were able to provide the first interagency information on the probable source of the contamination independent of the FDA trace-back efforts and to be able to share that in the interagency. Our mission is to be looking forward in a cueing sense, whereas FDA is looking in a confirmatory role and will not share that information in an ongoing investigation. But yet, we need to be looking forward for the Federal Government to minimize the impact of these events, and we were able to do that.

Additionally, we were able to bring other interagency members to the table, such as the Department of Defense, to help us better characterize the event. That is not a normal information flow that has been occurring. Additionally, we were able to bring State Department to the table in this NBIC construct to understand the implications if the source were with a foreign nation. We were able to bring specific information from Customs and Border Protection that is not normally brought into one of these food trace-back events, to be able to provide that to FDA to help them better characterize and improve their ability to do that. None of these efforts are replacing the effort of FDA; they are to augment and support.

An additional area is in the private sector. With regulatory agencies, the private sector frequently will not share information or chooses not to. They were willing to bring that into the NBIC forum anonymously so that we could use that to help in the trace-back.

Mr. MCCAUL. So you got a real-life case test, if you will, into what kind of response you are capable of dealing with. Will there be some sort of after-action report or lessons learned from this event?

Mr. HOOKS. Absolutely. That is our intent within the Department of Homeland Security. We have not broached that specifically with the Food and Drug Administration yet, but I think that will happen.

Mr. MCCAUL. Thank you, Mr. Chairman.

Mr. LANGEVIN. I thank the Ranking Member.

The Chair will now recognize Members for questions they may wish to ask of the witnesses. According to the committee rules of practice, I will recognize Members who were present at the start of the hearing based on seniority, so next is Ms. Christensen from the Virgin Islands for 5 minutes.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Thank you for holding this hearing, and I am looking forward to the one in Rhode Island next week.

I am going to ask a very basic question. First, you, Mr. Jenkins. We understand that you can't fully comment on the report until

you have gone through the internal review process, but several questions have been asked and answered here that you are most likely to have first-hand knowledge because of your work on the report. So my very basic question: First of all, does NBIC represent a needed and necessary function to improve biosurveillance capabilities in the United States, or is it self-redundant, in your opinion?

Mr. JENKINS. We are not in a position to say whether it is self-redundant or it isn't based on the work that we have done.

But I would say that, as Mr. Hooks has said, there is a real need in this international environment to have as early a warning system as you can that, and this is absolutely critical, but that it have data that is credible, reliable, and actionable. The sooner that you can have that data, the better off you are in terms of being able to reduce the impact of the event. You may not be able to prevent the event, but you could prevent the impact of it.

So whether it is NBIC or some other mechanism, there certainly needs to be something that provides the data from a variety of sources. There is no single source of data in the Government or in the private sector that is really going to get you there.

Mrs. CHRISTENSEN. Thank you.

Either Mr. Myers or Mr. Hooks, one of the most important things in biosurveillance is rapid validation, of course, of the initial indicators and outbreaks, for example, environmental conditions. Some local indicators may point toward the emergence of a certain disease, but this must be verified. So what mechanisms, if any, are available to the NBIC to obtain the ground truth, to verify what you may pick up in the biosurveillance?

Mr. MYERS. The process that we use is a very basic analytic process, which is to be in a constant screening mode and setting thresholds for the types of reporting that we want to do. So based on that, there is a constant screening review, a reach-out through the member agencies and an extensive network of data sources to be constantly canvassing.

When there is an event that starts to cue up that is more important or starts to really grow to a larger threshold, let me use salmonella and tomatoes, where you are now having to have a significant impact, the first thing that we do is just to simply establish a subgroup or a subcommittee that is working in an analytic product, and we do that in 24-hour cycles. So we pack the cycles together, because the need for reporting and the need for information usually grows exponentially. With that, you start to refine who has what data and what gaps there are, and so that while you are working a production environment, you are simultaneously also trying to go after the data that you don't have. You are trying to make that meet basically a 24-hour clock so that you are in a constant reporting.

What does that is refine your effort, refine your conditions and allow you to start working early cueing while the science community is going through laboratory and laboratory results, and there is a necessary time and space that must take place to get those results to verify what you have.

The marrying of this group of agencies and an NBIC, the importance is that you have a group and element in there that is the sci-

entific community that wants to have positive results and proven results, and another aspect of that same group that realizes that there is a high demand for information sooner, sooner, and sooner. So when we talk about any kind of a culture clash, that is the one unified floor, area, region, virtually and literally, where you can have those discussions and put out your situation reports and the types of reports that leadership need on a continuing basis.

Mrs. CHRISTENSEN. My time is almost running out.

One of the concerns that the committee and the subcommittees have had is the turnover in personnel and also transitioning as we move to a new administration.

I read recently that Dr. Runge is leaving. So are we anticipating that his leaving will impede the progress toward the NBIC becoming fully operational? Or are we deep and broad enough to sustain his leaving?

Mr. HOOKS. Ma'am, I believe we are deep and broad enough to be able to sustain. The reason I believe that is this has significant interest by Secretary Chertoff right now as well, and he receives regular updates on the tomato salmonella event and what the NBIC is doing. He is committed to it. The Homeland Security Council is committed to improving the interagency sharing of information and creating that trusted environment. I am committed to that. Eric Myers has done a great job pushing that forward. So I think we have the team in place to be able to continue to push that vision forward effectively for the Nation.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Mr. LANGEVIN. Thank you.

Mr. Wilson, did you want to respond to something that Mrs. Christensen had asked?

Dr. WILSON. Yes, sir. Thank you very much. I appreciate that.

The whole commentary about verification, that is a standard in outbreak detection and verification, and it was set by the World Health Organization and its partners about 10 years ago.

I would just draw the subcommittee's attention to the point that a lot of the points raised here today have been focused on domestic. We are heavily connected to the rest of the planet by the air traffic and commerce grid. Things come in here all the time. I have a wide variety of pathogens listed in my testimony, a quite astounding list, actually. Therefore, we have to monitor holistically. When we do that, we are getting, in a near real-time basis routinely, we are detecting things and vetting them with international partners on the ground as it happens. You can't make a choice as to whether or not you are going to choose Federal capabilities or NGO or U.N. partners or what have you, because no single organization has ground verification capability that is that comprehensive. Obviously, that implies a whole range of information sources and credibility and so forth that has to be vetted by analysts, but therein is the challenge.

Our ground verification network right now numbers 110,000 people globally. We need that kind of help for this mission. By the end of the year, we will definitely be pushing over a quarter million. This is unprecedented in history for this country and really for global health. So I would encourage the subcommittee to consider leveraging any and all available means to assist in that mission, because that step is critical to verification.

Mr. LANGEVIN. If I could, with the indulgence of the gentleman from New Jersey, I just wanted to follow up on something.

As you know, Global Argus is a biosurveillance system that compiles open-source information on foreign disease outbreaks. An outgrowth of Global Argus is the Veratect system, which was spun off from Georgetown University as a private company.

Can you explain the key differences between the two projects? Does the fact that Veratect is a private U.S. company remove the Title 50 problem associated with Global Argus? How would you compare the capability of Global Argus or the Veratect system to the current capability of NBIC?

Dr. WILSON. Yes, sir. Thank you for the question.

As the former principal investigator of Project Argus, now with the Veratect Corporation, we have the entire senior analytic pool from Global Argus now with our team at Veratect Corporation.

Currently, the system that we are utilizing has 36,000 sources that we are utilizing compared to Global Argus's approximate 9,000. That gives us coverage of 86 percent of the world's population through this medium.

There are two key differences that I am going to highlight here in a second between Argus and the current capability now available at Veratect Corporation. One is that we could not do domestic, which is what you were implying with the Title 50 restrictions. We can now do that at Veratect. That was a critical gap, when we were tracking the H3N2 vaccine drifted strain from Asia and watched it spread throughout the world but we could not follow it as it entered there United States and, as we all have seen now, created quite a bit of problems for our influenza season last year.

The second piece is, of course, as I mentioned before, the ground verification process, which is a critical step in our analysis. We must have that. We now have, as I mentioned before, we have 110 people around the world now as partners to help verify these events. We were unable to do that at Argus. Again, as I mentioned, we do do domestic, and Argus is unable to do that.

For biological agent tracking, my team and I, who are now at Veratect, we monitored about 60 pathogens in coordination with our Federal users. We have actually expanded this list now to 200 pathogens that affect humans, humans and animals, and animals only. So we have a range actually of human health and agricultural issues, and we do cover food safety issues as well.

We have research partners both in the national labs and transdisciplinary universities, so the bottom line here is, we started as a team designing a prototype, and now we have taken that to the next generation. We are now fully operational.

This is truly a world-class capability that is going to continue to grow exponentially as we work with our partners around the world.

Mr. LANGEVIN. I find that very interesting. We will be watching this closely as it unfolds.

With that, the Chair now recognizes the gentleman from New Jersey, Mr. Pascrell, for 5 minutes.

Mr. PASCRELL. Thank you, Mr. Chairman.

Just to follow up, Mr. Wilson, if DHS had simply offered to fund Argus, would we have a domestic biosurveillance capability today?

Dr. WILSON. No, sir. The nature of the funding at Argus prevented us from doing domestic analysis. Currently, at the Veratect Corporation, the team that was at Argus that worked with me, the entire senior staff, along with myself, now at the Veratect Corporation, we are able to do foreign and domestic analysis.

Mr. PASCRELL. Mr. Secretary Hooks, is it realistic to expect that the end game is to have sensors, biodetectors, as part of the surveillance systems in place throughout the United States of America? Is that the end game?

Mr. HOOKS. I think the end game needs to be based on what the risk is to the Nation.

Mr. PASCRELL. Well, what is the risk then, Mr.——

Mr. HOOKS. The risk is real for a biological attack or a naturally occurring biological event.

Mr. PASCRELL. Then let me ask this question to Mr. Jenkins.

Did you sense in the GAO's review of the work, that you summarized—I just quickly read through your total report—do you sense a—and I know this is a judgment call—a sense of urgency in what you reviewed, in the people that are being held responsible for giving us a program here?

Mr. JENKINS. I think they are very serious about it.

Mr. PASCRELL. I didn't ask you that question.

Mr. JENKINS. What I am saying is, I think they do have a sense of urgency because they do believe that the threat is real and that we have to have some way of trying to deal with it. So I do think they have a sense of urgency.

As I mentioned earlier, part of the problem in trying to get where we need to go is getting everybody fully on board and participating.

Mr. PASCRELL. I understand that. But it is 16 months. For instance, as an example, to your own report, 16 months before we have had another agreement, a mutual agreement. For you to sit there and provide a review—I have a tremendous amount of faith in GAO, as you well know—and not to go to the very heart of this issue, it would seem to me that if we can't get out of these eleven agencies some cooperation from five or six of them, there is a reason for that.

We all know the reason, understand the reason.

That doesn't help us secure a surveillance system that we can feel confident in. So my question to you again is do you sense a realistic view of urgency here?

Mr. JENKINS. Well, I think maybe I didn't make myself clear. I was really referring to the NBIC folks as to whether or not they feel a sense of urgency. I think, in some cases, it seems relatively clear that other agencies who have been asked to participate, at least by their actions, don't indicate that they feel a sense of urgency.

Mr. PASCRELL. Well, one of the problems is, we had to wait until 2007 to pass the 9/11 Commission Act and its recommendations. As you well know, one of the reasons, one of the main reasons why it took us so darn long is that the administration would not get out of our way. So we understand that this has been delayed down the road.

Let me ask you this question, Secretary Hooks. You have to prioritize in the business of defending the Nation. You are never

going to have a seamless defense; we understand that, we all understand that. We are fallible human beings; I hope we all understand that.

On a sense of priorities in terms of what you know and what we know and what those people who have inside intelligence about where we are in defending our neighbors and our children and our neighbors and the United States of America, where would you put a bioattack in regards to prioritizing what we need to be most prepared for at this moment in the history of mankind?

Would you be concerned about, for instance, nuclear attack? Would you be concerned about the bioattacks, the very pathogens that you were talking about just a few moments ago? How would you prioritize it?

Mr. HOOKS. I think that is a challenge obviously, integrating across the entire threat and risk space, considering the threat vulnerability and consequences.

I believe in the time that I have been working in the Office of Health Affairs and the information that I have learned that a biological attack or a naturally occurring event is a higher priority than I think it has been viewed at within the country.

Mr. PASCRELL. Yeah, I would tend to agree with you.

But if that is the case, if that is the case and we are waiting 16 months for the next mutual agreement, what does that tell you? How do you respond to that?

Mr. HOOKS. The way I respond to that is, that is where my sense of urgency comes from and the people that are working on this issue. Within that sense of urgency, we have brought the other agencies to the table in discussion. We have not finalized some of those memorandums of understanding that have been identified by Mr. Jenkins. But I think we are making significant progress in creating interagency collaboration and information sharing.

Mr. PASCRELL. You are waiting for a mere pittance, Mr. Chairman, relatively speaking—$2 million, $2.5 million you are waiting for.

Mr. HOOKS. Two-point-two million, sir.

Mr. PASCRELL. In this huge budget, and we can't get out of our own way in order to provide these guys and gals with the amount of resources that they need to do the job.

I would suggest to you, Mr. Chairman, that this is urgency by word and not by deed in this administration, and that we are at risk because of it—pure and simple.

I have no further questions. Thank you.

Mr. LANGEVIN. Well, I share the gentleman's sense of urgency and frustration that we are not moving along, if it is a lack of resources; and both the administration and the Congress has to press this issue to make sure we get the right resources in the right place. I, for one, believe that a biological attack or the biological threats that we face, whether it is man-made or naturally occurring, are very serious, very real.

The American people expect that we are going to get this right and we are going to protect the country. We are going to continue our rigorous oversight of this issue, and we will continue to partner with you in every way possible to make sure that we are closing the vulnerability of biological threats.

With that, I want to thank the witnesses for their testimony. There are votes on right now. So I am going to dismiss this panel.

We have the BioWatch hearing coming up as the second hearing to this overall effort today.

So, again, I want to thank the witnesses for their testimony. The Members of the subcommittee may have additional questions for the witnesses. We will ask that you respond expeditiously in writing to those questions.

With that, this panel is adjourned. The subcommittee now stands in recess.

[Recess.]

Mr. LANGEVIN. The subcommittee will come to order. First of all, let me apologize for the delay. As you have learned, unfortunately, around here our lives are not our own, and that was the longest 45 minutes I have ever had. I thought we would be done a lot quicker than that. Unfortunately, Members had other ideas.

So I do want to thank the panel sincerely for waiting around. Obviously, this is a very important issue, and something I am anxious to get to. So without any further hesitation, let me convene our second panel on BioWatch.

The first witness is Robert Hooks, who has testified on the first panel. Again we thank you for remaining for the second panel.

The next witness is Dr. Jeffrey Stiefel, Director of the Early Detection Division, and Program Executive of BioWatch, Office of Weapons of Mass Destruction, WMD, and Biodefense at the Office of Health Affairs, Department of Homeland Security. Thank you for joining us.

Remaining on the panel is William Jenkins of the GAO. We appreciate you, of course, remaining on the second panel to discuss BioWatch.

Finally, we welcome Dr. Frances Downes, who is the Administrator of the State Public Health Laboratory at the Michigan Department of Community Health. Her lab is a member of the Laboratory Response Network and participates in the BioWatch program.

Without objection, the witnesses' full statements will be inserted in the record. Again, I want to thank all of our panelists today, and I want to now ask each witness to summarize his or her statement for 5 minutes, beginning with Mr. Hooks, who will read a joint statement for himself and Dr. Stiefel.

Welcome.

STATEMENT OF ROBERT HOOKS, DEPUTY ASSISTANT SECRETARY FOR WMD AND BIODEFENSE, OFFICE OF HEALTH AFFAIRS, DEPARTMENT OF HOMELAND SECURITY

Mr. HOOKS. Thank you, Mr. Chairman and Representative Christensen. I appreciate your interest in biosurveillance programs and trust that my testimony today will provide valuable insight into the Department's biosurveillance initiative to safeguard the Nation against a biological attack or other biological incidents that threaten the security of the homeland.

The Nation continues to face the risk of a major biological event that could cause catastrophic loss of human life, severe economic damages, and significant harm to our Nation's critical infrastruc-

ture and key resources. Because of the challenges we face in assessing current terrorist capabilities and identifying plots, it is unlikely we will receive actionable, specific warning of an impending bioterrorist attack. Furthermore, many of these deadly biological agents are accessible in nature, relatively easy to procure, develop and transport without an advanced background in the biological sciences. Unlike nuclear weapons, few people with advanced laboratory knowledge in the biological sciences are needed to weaponize these deadly pathogens. As such, it is incredibly difficult to predict and prevent a biological attack from taking place.

Biosurveillance includes many different components that work in complementary fashion to achieve a comprehensive awareness. This takes the form of both traditional and novel methods of early event detection, including environmental detection systems, clinical syndromic surveillance, reportable disease and laboratory base surveillance, monitoring of agriculture and wildlife activity, testing of the food supply, and monitoring mail and open-source analysis to name a few. Each is a necessary and valuable component of a comprehensive biosurveillance strategy.

The BioWatch mission is to deploy and maintain a national 24/7 early warning system capable of detecting the intentional release of select, aerosolized biological agents in order to speed response and recovery efforts, primarily focused on aerosolized anthrax. The purpose of this early detection and warning capability is to mitigate the consequences of a catastrophic attack which could affect tens of thousands of people if, for example, aerosolized anthrax were released.

BioWatch is a part of a national biodefense strategy that includes intelligence, law enforcement, biomonitoring, situational awareness, decision support, response, and recovery activities. Within this strategy, BioWatch is an essential component of biomonitoring, along with astute clinicians, syndromic surveillance, food and agriculture monitoring, veterinary surveillance, and mail room monitoring. BioWatch is operating in over 30 of the Nation's largest metropolitan areas, and consists of aerosol collectors, secondary sampling kits, laboratories, guidance documents, concepts of operations, communications protocols, an Internet-based information portal, subject matter experts, and a small number of early-generation indoor detectors.

It is more than just detectors in the field. The BioWatch laboratories have been in continuous operation since 2003 and have analyzed more than 7 million samples without a single laboratory false positive result—an incredible feat.

The BioWatch operational readiness is essential for the system to be effective. Representatives from the agencies, along with State and local public health and response personnel have created guidance documents for local jurisdictions to use in developing operational plans for BioWatch. These guidance documents cover preparedness response, environmental sampling, and indoor operations.

The operational response plans for each jurisdiction are triggered by a BioWatch Actionable Result, and implemented by the local BioWatch Advisory Committee, or BAC. Investigations and discussions continue until consensus is reached about the significance of

the BioWatch Actionable Result, which is used to inform the protective action decisions on the part of the local public health officials.

One of our highest priority initiatives is to replace collectors, the filters that require formal laboratory analysis, with automated detectors wherein the analysis is performed within the unit itself. The primary objective of the Generation 3 system is to introduce technological advancements that will significantly reduce the time to detect a biological agent from the current 10 to 34 hours down to between 4 and 6 hours, which will potentially save thousands of lives for each day an attack, such as anthrax, is detected ahead of human syndromic surveillance and other public health indicators.

In conclusion, the challenge of detecting an invisible footprint of an impending bioterrorist plot and preventing an attack or the emergence of a pandemic is daunting. That is why DHS is taking the approach to enhance early detection systems and build a national biosurveillance capability for situational awareness.

Thank you for the opportunity to testify.

Mr. LANGEVIN. Thank you, Secretary Hooks.

[The joint statement of Mr. Hooks, Mr. Myers and Dr. Stiefel appeared previously in this document.]

Mr. LANGEVIN. I now turn to and recognize Mr. Jenkins to summarize his statement for 5 minutes.

STATEMENT OF WILLIAM O. JENKINS, JR., DIRECTOR, HOMELAND SECURITY AND JUSTICE ISSUES, GOVERNMENT ACCOUNTABILITY OFFICE

Mr. JENKINS. Thank you, Mr. Chairman, Ms. Christensen.

The United States faces potentially dangerous biological threats that may occur naturally or as a result of a terrorist attack. Concern about the dispersal of lethal biological agents or widespread infectious disease outbreaks focused attention on the need for systems that can provide reliably accurate early detection and warning.

BioWatch is intended to be such an early warning system. It deploys detectors to collect aerosol samples daily that are then analyzed to detect the presence of specific biological agents. The success of the program is dependent upon three things: accurate sampling, timely and accurate analysis that is actionable, and then actions based on that analysis. DHS has two ongoing efforts to improve the detection and analysis technology used by the BioWatch program, and the remainder of my statement today focuses on those issues alone.

Currently, BioWatch detector samples must be manually collected, then transported to a lab for analysis, a process that can take, as Mr. Hooks said, from 10 to 34 hours. The manual collection and analysis inherently adds to the time it takes to identify the presence of the agents that are being monitored.

BioWatch is developing two new types of detectors designed to reduce the time it takes to analyze samples. The first, Generation 2.5, which is designed as an interim measure, would automate the analysis of samples, but detect and analyze the same agents that are now being monitored. The second generation, 3.0, would also be capable of automatic sample analysis, but in addition would even-

tually have the capability to detect all biological agents on the threat list.

According to DHS officials, the ability of the detectors to automatically analyze the samples they collect on a regular or prescribed schedule could reduce the elapsed time between air sampling and detection from 10 to 34 hours to 4 to 6 hours. In addition, the deployment of Generation 2.5 and 3.0 detectors would expand the use of the detectors in indoor environments. Current detectors focus on exterior sampling primarily.

DHS officials say they plan to develop procedural guidance for responding to positive results from indoor detection by October 2008 and apply it to all detectors employed indoors. Currently, there is no procedural guidance for responding to indoor detection of biological agents.

DHS said that it plans to begin operational testing and evaluation of 2.5 Generation detectors in November 2008, and acquire about 100 of them if the testing is successful. Testing for Generation 3.0 detectors is scheduled for April 2009.

DHS plans to replace all detectors with Generation 3.0 by 2013, with initial deployment beginning in 2010. In addition, the Gen 3.0 detectors are expected to be less costly to both purchase and maintain than the 2.5 detectors—about 30,000 less to purchase, according to DHS, and 53,000 to 31,000 annually less to operate and maintain.

That concludes my statement, Mr. Chairman, and I would be pleased to respond to questions you or other Members may have.

Mr. LANGEVIN. Thank you, Mr. Jenkins.

[The statement of Mr. Jenkins appeared previously in this document.]

Mr. LANGEVIN. The Chair now recognizes Dr. Frances Downes for 5 minutes.

Welcome.

STATEMENT OF FRANCES POUCH DOWNES, STATE PUBLIC HEALTH LABORATORY DIRECTOR, DEPARTMENT OF COMMUNITY HEALTH, STATE OF MICHIGAN

Dr. DOWNES. Mr. Chairman and subcommittee Member Christensen, thank you for inviting me to testify today about the State and local government experience with the Department of Homeland Security's BioWatch Program. As I was introduced, I am Dr. Frances Downes, Director of the Michigan Public Health Laboratories.

State and local public health laboratories are an essential part of the Nation's preparedness infrastructure. Michigan is one of 24 public health labs that host the BioWatch program. I am also the current President of the Association of Public Health Laboratories, APHL, a national nonprofit that is dedicated to working with its members to strengthen governmental laboratories with a public health mandate.

In March 2003, Michigan became a host laboratory for the BioWatch program. The security climate in the United States was very different than it is today. Public health labs had just come off the testing demands of the 2001 anthrax exposures. Biological weapon caches were still a purported threat. DHS contacted secu-

rity officials in States with major urban centers and, together, determined that BioWatch testing would be a security asset.

When we in the public health laboratory community were asked to install BioWatch testing programs, we did what we always do to meet the challenges to protect the public's health. I was willing to take on the hosting program because it was clear that the response to a positive result would be primarily State and local. If I hosted testing, I could control the safety of the testing personnel and assure the quality of testing. Unfortunately, we have never hit this mark, and we are moving farther away from it.

At that time, verbal promises were made regarding support for the program. Did we get those promises in writing? No.

We are not contractors or vendors. Public health functions in a culture of partnership. Public health laboratories are part of a system that, for over a century, has been committed to providing services in the interests of our public health communities.

BioWatch space demands have grown at an unrestricted pace. The image you see on the monitors indicates the initial footprint of the BioWatch program in Michigan in 2003. The red space is exclusively for BioWatch use, and it cannot be used for public health priorities. The yellow space is shared between BioWatch and Michigan testing.

This next image shows the BioWatch footprint in 2008. You can see the significant growth in space that is utilized by BioWatch. These images are just from the first floor of the Michigan laboratory, but they are followed by images on the second floor over the same period. More equipment, dedicated sample receipt areas, servers, supply storage, the demands are limitless.

I have also brought along some photos that show how much of our space is used to store BioWatch supplies, equipment, and other material. All the items displayed in these photos are only for BioWatch use.

I would also like to briefly give voice to some of our major concerns about BioWatch that we have included in our correspondence to you.

DHS and its BioWatch contractor have no written agreement with, or contractual relationship, legal authority, regulatory or otherwise, with State and local public health labs, yet DHS is contractually obligated to their contractor to provide laboratory space. Because there is no agreement of any sort between public health labs and DHS or their contractors, there is no ability to require adherence to standard operating procedures and policies, even those related to laboratory safety.

DHS has distributed a draft memorandum of agreement to address this matter, but it is unlikely that the State and local governments will enter into an agreement soon. For starters, DHS has said they will not reimburse the use of laboratory space and storage space, an issue they say is nonnegotiable.

State and local public health labs have not received funding from DHS to support the expanding cost of testing programs, but other State agencies collecting the samples and transporting them to our laboratories daily are reimbursed for their expenses. To be blunt, this amounts to nothing less than a Federal Government demanding a match from State and local government to defray the cost of

a Federal program with no limits, no control on the direction of the program, but almost total responsibility for response. The lab absorbs the cost, including lab space with utilities, and removal of infectious waste materials, support services, training, IT infrastructure, telephones, cell phones, vaccinations, on-site scientific direction, and expertise.

The draft MOU, in fact, would increase the cost on labs by requiring them to pay for maintaining certification on lab equipment and information technology, costs currently covered by DHS. With State and Federal preparedness budgets shrinking at the same time, the burden of the costs incurred for hosting BioWatch will reach a critical mass in the near future. Although the lack of any written or contractual relationship or legal authority precludes BioWatch from being considered an unfunded Federal mandate, its effect on State and local obligations is the same.

Prior to January 2008, when a new contract was awarded, State and local labs were able to provide input on personnel matters, including having the final say on job offers, contributing to performance evaluations. Under the proposed MOA, these oversight roles are lost. Public health labs have other contract employees and Federal assignees working in our facilities and provide oversight without interfering with those employer rights and responsibilities.

The draft MOU provisions on cross-training BioWatch contract personnel to perform other preparedness and public health emergency testing is overly restrictive. Those provisions greatly reduce the ability of having BioWatch contract personnel trained for public health emergencies, such as the ongoing Nation-wide salmonella outbreak or helping out with testing related to the Midwest floods.

The State and local public health laboratories would prefer to work with the BioWatch program in a more constructive and direct manner, and my written testimony has several recommendations for DHS to consider. With funding and increased management oversight, public health lab directors would be able to improve work flow, promote cross-training among laboratorians to increase testing capacity for public health emergencies, and improve laboratory quality in BioWatch locations.

The BioWatch program has been variously described by my fellow State and local lab directors as a "parasite" to the public health laboratory and "squatters" in valuable laboratory space. I am hard pressed to disagree.

This concludes my testimony. Thank you again for inviting me to participate in this hearing.

[The statement of Dr. Downes follows:]

PREPARED STATEMENT OF FRANCES POUCH DOWNES

JULY 16, 2008

Mr. Chairman and Members of the subcommittee: Thank you for inviting me to testify about the State and local government experience with the Department of Homeland Security's BioWatch program. I am Dr. Frances Pouch Downes, the director of the State of Michigan public health laboratory—in the Michigan Department of Community Health. State and local public health laboratories are an essential infrastructure program that support testing for public health programs and serve as the reference laboratory to hospital and clinical laboratories Nation-wide. Michigan is one of 24 public health laboratories that host the BioWatch program. I am also the current President of the Association of Public Health Laboratories (APHL).

APHL is a national non-profit located in Silver Spring, Maryland, that is dedicated to working with its members to strengthen governmental laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure need to protect the health of U.S. residents and to prevent and control disease globally.

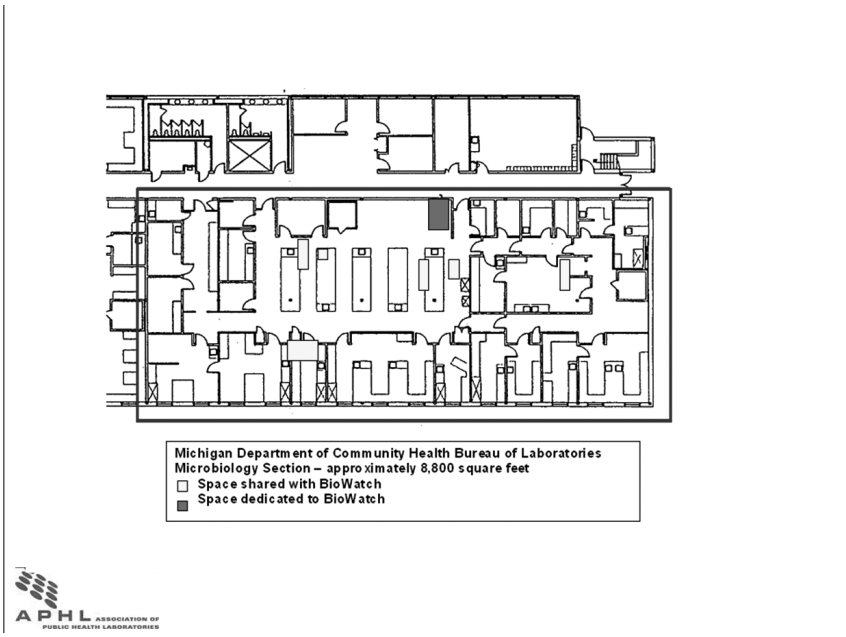
In March 2003, the Michigan Bureau of Laboratories became a host laboratory for the BioWatch program. The security climate in the United States was very different than it is today. Public health labs had just come off the intensive testing demands of the 2001 intentional anthrax exposures. Biological weapons caches were still a purported threat. DHS contacted State security officials in States with major urban centers and determined that the BioWatch testing program would be a security asset. When the public health laboratories were asked to install the BioWatch testing program, we did what we always do: Meet the challenges to protect the public's health, which in this instance meant devoting considerable resources to receiving and installing equipment and supplies, being trained, training the contractors who would perform the testing and participating in the development of response plans. The response plans made it clear that I would be responsible for result interpretation and initiating the cascade of events that ensue after a positive result. Therefore, I was willing to take on the burden of hosting the program, if I could control the safety of the testing personnel and assure quality of testing. I accepted the program with the caveats that the program did not divert us from other essential public health testing priorities and I controlled quality and safety of the testing program. Unfortunately, we have never hit this mark and are moving further away from it.

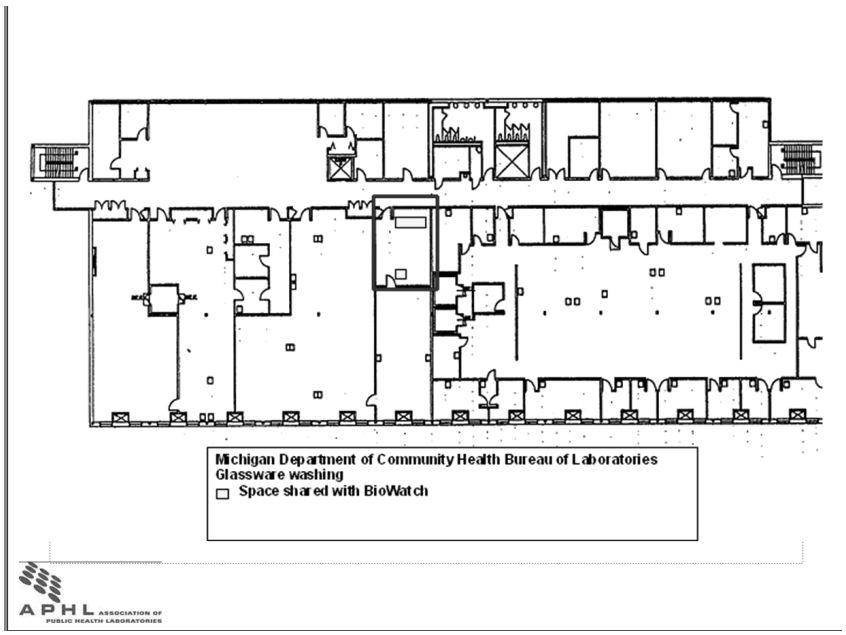
At that time verbal promises were made regarding support for hosting the program. Did we get these promises in writing? No. We are not contractors or vendors. We function in a culture of partnership. Public health laboratories are part of a system that for over a century has been committed to providing the services in the interest of the health of our communities.

The technology and the mechanisms for acquiring testing personnel have evolved since the inception of the BioWatch program but the contribution of the host laboratories has never been considered by DHS nor have the safety and quality responsibilities of the host laboratory.

First, space demands have grown at an unrestricted pace. The image you see on the monitors indicates the initial footprint of the BioWatch program in the Michigan lab in 2003. The red space is exclusively for BioWatch use and cannot be used for Michigan public health testing priorities; the yellow space is shared between BioWatch and Michigan public health testing. This next image shows the BioWatch footprint in 2008 and you can see the significant growth in the red space that is dedicated to BioWatch. These images from the first floor of the Michigan laboratory are followed by images that display the growth on the second floor over the same period of time. More equipment, dedicated sample receipt area, server, and supplies. The demands are limitless.

[The images follow:]





To give you a better visual perspective of the impact BioWatch has had on the Michigan laboratory, I've also brought along some pictures that show how much of our space is used to store BioWatch supplies, equipment and other materials. All of the items displayed in these pictures are only for use in the BioWatch program. None of these pictures show the actual equipment used to perform testing on BioWatch samples or the space that equipment occupies.

[The images follow:]

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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Mr. Chairman, APHL has provided you with correspondence that details the significant concerns related to the BioWatch program and its presence in public health laboratories. I would like to briefly give voice to some of our major concerns:

- *No agreed-upon roles and responsibilities between DHS, its contractor and Public Health Laboratories*.—At present, DHS and its BioWatch contractor have no contractual relationship or legal authority, regulatory or otherwise, with State and local public health laboratories for the operations of the BioWatch program. Yet, DHS is contractually obligated to the BioWatch contractor to provide laboratory space (Section 4.1 of Task Order No. HSHQDC–08–F–00016).

  Because there is no agreement of any sort between the State and local public health laboratory and DHS or BioWatch contractor, there is no ability to require adherence to site specific quality assurance practices, standard operating procedures and policies—even those that relate to laboratory safety. Furthermore the absence of any agreement has spurred State and local government legal offices into action because of their concern over the exposure to these governments, including unresolved liability and worker's compensation issues.

  DHS has distributed a draft Memorandum of Agreement (MOA) to address this matter, but the details included in the draft make it unlikely that State and local governments will enter into an agreement soon. For starters, DHS has said they will not reimburse for the use of laboratory and storage space—an issue they say is non-negotiable. Again, the draft MOA does not limit the space and administrative demands that the BioWatch program can place on a laboratory. Also, while DHS proposes one MOA that will be utilized nationally, the unique legal issues in each State and local government must be recognized and they demand individual resolution.
- *Uncompensated Laboratory Costs*.—State and local public health laboratories have not received funding from DHS to support the cost of housing and overseeing the BioWatch program whereas the State agencies collecting the samples and transporting to the public health laboratories daily are reimbursed for their expense. I have already mentioned the key non-negotiable element of reimbursement as it relates to the draft MOA. The message transmitting that draft MOA asserts: "DHS cannot enter into an arrangement to reimburse for space, due in part to funding limitations, and in large part to the Anti-deficiency Act, which precludes long term commitments without sufficient funds appropriated."

  To be blunt, this amounts to nothing less than the Federal Government demanding a match from State and local governments to defray the expenses of a Federal program with no limits, no control on the direction of the program

but almost total responsibility for response. The State and local public health laboratories absorb costs associated with administration, training, and safety for BioWatch-contracted personnel. These costs include laboratory space with utilities, removal of infectious waste material, support services, training, computers, telephones and cell phones, vaccinations, and on-site scientific direction and expertise on questionable results. As I've shown you, the BioWatch footprint continues to expand in the host laboratories, often taking up extensive space in multiple rooms.

For example, in one public health laboratory, the BioWatch program occupies 975 square feet of laboratory space in 8 rooms on 4 floors. In addition to the costs of providing space and administrative oversight, laboratories may need testing personnel to maintain daily testing or to support intensive testing that occurs during high profile special events (like political party conventions, sporting events). Two public health laboratories only have one BioWatch-contracted employee and must use State laboratory employees to complete BioWatch testing despite informing DHS of this work force shortage over a year ago. In plans to prepare for intensive testing or contract employee vacancy, the BioWatch contractor is to establish a contract and pay State employees to provide additional testing capacity. However, the contractor has been slow to sign, or has not signed these State employees on. Also, the contractor is on record of approving an insufficient amount of time for training and other quality assurance activities that will prepare the State employees for the situation when they are needed. Finally, these employees may not be available in the event of a bioterrorism emergency and great testing demand because their primary responsibility is to fulfill their role to the Laboratory Response Network (LRN). As the primary and career employer, the State laboratory director will determine the individuals assignment; not a contractor.

Further, the draft MOA would require that the State and local laboratories pay for the cost of maintaining certification on laboratory equipment used in BioWatch testing—costs that were previously covered by DHS.

Most alarming is the situation in one State where the current BioWatch contractor has been very reluctant to address any of the problems related to the daily operation of the BioWatch laboratory. When the new contract was awarded, payment for the internet connection service used by the BioWatch program was terminated. When the new contractor was informed of this problem, they suggested that the State laboratory pay for the service—an option the laboratory declined. This problem has yet to be resolved. With State and Federal preparedness budgets shrinking at the same time, the burden of the costs incurred for hosting BioWatch will reach critical mass in the near future.

Although the lack of any contractual relationship or legal authority precludes BioWatch from being considered an unfunded Federal mandate, its effect on State and local obligations is the same.

- *Management and Oversight of Contract Employees at the Local Level*.—In January 2008, DHS awarded the BioWatch staffing contract. In May 2008, public health laboratories hosting the BioWatch program received a communication from DHS (attached) explaining that the non-personal services nature of the BioWatch contract greatly restricts the roles of DHS and the public health laboratories in the management of the BioWatch-contracted personnel. I would call attention to this portion of the DHS explanation which compounds the challenges for State and local public health laboratories hosting the BioWatch program: "The current contract that the Department of Homeland Security (DHS) has with A-TEK, Inc. is a nonpersonal services contract. The following definition of a nonpersonal services contract comes from the FAR, Part 37.101: ''"Nonpersonal services contract" means a contract under which the *personnel rendering the services are not subject,* either by the contract's terms or by the manner of its administration, *to the supervision and control usually prevailing in relationships between the Government and its employees.*'" (Emphasis added.)

  The host laboratories are neither Federal Government nor employees of the Federal Government.

  Since the transition of BioWatch-contracted personnel to the new contractor, public health laboratory directors have struggled to maintain open lines of communications with the contractor, BioWatch-contracted personnel located in our labs and DHS. Communication has been constrained by contractor-issued directives that prohibit BioWatch-contracted personnel and supervisors from fully communicating with their public health laboratory counterparts and fail to understand how fully integrated BioWatch operations and personnel are with public health laboratory operations and employees.

Contract employees are instructed to contact the contractor in the event of quality control failures or positive results. There is no reason for this communication to occur since the contractor is not involved in response and CDC provides quality assurance consultation. It is imperative that lines of communication are seamless and totally unrestrained to assure the most efficient and effective laboratory operations. The advice and direction by the contractor will only confuse the response and is not welcome nor needed.

Prior to the issuance of the January 2008 BioWatch contract, the State and local laboratories were able to create salary parity between the BioWatch-contracted personnel and State laboratory employees based on prevailing local compensation; and they were able to have the final say on which interviewees received job offers, contribute to performance evaluations, and determine disciplinary actions to be taken by the contractor. Under the proposed MOA described previously, these oversight roles are lost. In fact the current contractor instructs their employees not to communicate with host laboratory personnel on many issues including wages. Public health labs have other contract employees and Federal assignees working in our facilities and provide oversight without interfering with employer rights and responsibilities. It is only this contract that has put us at odds with the contractor.

Public health laboratory directors are legally responsible under State and Federal law for the safety of all activities that occur within their laboratory, including all who work within their laboratory. This includes determinations on who has access to and is working in the laboratory (laboratory security), what analytical procedures are undertaken and how they are performed (laboratory safety and practice), and fair and equitable treatment and supervision among all laboratory staff (laboratory operations and employee morale), among others. BioWatch needs to run in parallel to the existing State and local public health laboratory infrastructure and it must not undermine that infrastructure with determinations on the internal operations of these laboratories, like whether the BioWatch-contracted personnel should be registered in the CDC's Select Agent program. The work location alone suggests Select Agent registration.

- *Science and Technology*.—To date, State and local public health laboratory directors have not been provided with the performance data (sensitivity, specificity, limits of detection) that are necessary for them to make the best judgment possible on any BioWatch Actionable Result (or BAR). In addition, many of these laboratories have expressed interest in providing input into the evaluation and implementation of new technologies as this has a direct impact on the use of laboratory space, personnel, and utilities as well as BAR response. New technologies have simply been foisted upon the laboratory without adequate preparation, including the performance data referenced above. Additionally, some public health laboratory scientists are concerned that there may be naturally occurring background levels of some pathogens in surveyed cities, such as Francisella tularensis in Houston, Texas, leading to positive findings in the BioWatch program which do not result from bioterrorism. Other than descriptive data from studies conducted in Houston, and Virginia, public health laboratories have not been privy to data depicting the background levels and types of organisms in the environment.
- *Other Issues*.—In the draft MOA, DHS continues the practice of asserting that BioWatch-contracted personnel do not have to go through the Department of Justice's Security Risk Assessment (SRA) clearance process. The SRA is required for any individuals who may have access to select biological agents and toxins. This is in direct conflict to the statement in the draft MOA that the contract employees may spend up to 25 percent of their time working on Category A and B agent testing. The biological select agents are all included in Category A. Due to the space demands of the BioWatch program, contract employees may be working in areas that provide them access to select agents. The draft MOA provisions on cross-training that restrict BioWatch-contracted personnel to only perform testing on environmental samples and not work on clinical specimens is overly restrictive. This greatly reduces the utility of having BioWatch-contracted personnel cross-trained for public health emergencies, such as the ongoing Nation-wide Salmonella outbreak.

State and local public health laboratories work closely with the CDC's Laboratory Response Network (LRN) to provide analytical support for the BioWatch program. Many of these laboratories have limited interactions with DHS. The public health laboratory personnel who perform LRN testing also would perform follow-up or Phase 1 Response testing on a BAR. It is important for both the staff of the public health laboratory and any BioWatch-contracted personnel to work closely together and fully understand all testing procedures.

The State and local public health laboratories would prefer to work with the BioWatch program in a more constructive and direct manner and recommend that DHS consider the following options for the BioWatch program:

I. Fund State and local public health laboratories through a DHS cooperative agreement mechanism to manage the BioWatch program. This mechanism could either be with APHL or directly with the jurisdictions. With direct funding to the State and local jurisdictions, the BioWatch-contracted personnel would become employees of the State or local laboratory and can be easily cross-trained and integrated into the public health laboratory. This would allow the public health laboratory director to fulfill their responsibilities to their jurisdictions (and comply with all applicable Federal and State regulations pertaining to the laboratory). A cooperative agreement would allow for significant programmatic involvement by DHS and collaboration by the public health laboratory.

II. Provide funding to States to via the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement—it is important to note that PHEP Cooperative Agreement funds are shrinking and State and local public health laboratories cannot take on additional activities, such as BioWatch without an adequate investment from DHS. Using the PHEP Cooperative Agreement mechanism, a designated sum of money can be set aside for each BioWatch host laboratory.

III. Remove the limitation on the ability of State and local public health laboratories to cross-train BioWatch-contracted personnel that limits them to testing environmental samples. Cross-training of BioWatch-contracted personnel should be more broadly applied to testing clinical specimens and environmental samples of public health significance, such as the work done under the CDC Public Health Emergency Preparedness cooperative agreements. This would allow for more effective and robust testing capacity in a surge situation and would increase employee morale as they would be integrated into the laboratory operations.

IV. Investigate the use of contractor incentives to foster integrated management of BioWatch-contracted personnel.

V. Until such time when an improved mechanism is in place, DHS must work directly with State and local public health laboratories and other vested partners to ensure that BioWatch-contracted personnel applicants and hires: (a) Meet minimum hiring qualifications equivalent to public health laboratorians performing the same work; (b) accept the hiring recommendation of the public health laboratory director or designee; (c) can interact effectively and productively with the public health laboratory staff; (d) are subject to public health laboratory policies and procedures, and (5) abide by all public health laboratory safety and security rules and policies. Further, DHS should require the BioWatch contractor to consult with the public health laboratory director when evaluating BioWatch-contracted personnel so that the public health laboratory directors can provide input into employees' evaluations with respect to laboratory productivity, safety, and security, and interaction with co-workers.

APHL members and staff met with the senior DHS BioWatch leadership in the Office of Health Affairs on November 19, 2007, to ensure they understood the role of State and local public health laboratories and APHL in homeland, including BioWatch and need for continued and enhanced communications. Once the BioWatch contract was awarded, APHL sent the attached January 17, 2008 letter to Dr. Runge outlining concerns about a number of personnel matters that developed with the award of the new contract and suggesting options for improvements. No reply has been received to this letter as of today's date.

Additionally, the association has documented our communication to DHS regarding the public health laboratory community's interest on communicating its recommendations concerning BioWatch. The process of developing memoranda of agreement with the public health laboratories may ultimately address these concerns; however because of the urgent need for some immediate solutions an interim approach is also needed.

APHL works to safeguard the public's health by strengthening public health laboratories in the United States and globally. We advance laboratory systems and practices, and promote policies that support healthy communities. APHL and its State and local public health laboratory membership are committed to working with DHS to assure that laboratories are adequately funded to support the BioWatch program and to improve the overall management of BioWatch-contracted personnel.

With funding and increased management oversight, public health laboratory directors would be able to improve workflow, promote cross-training among laboratorians to adequately utilize staff and improve quality laboratory practices by implementing standard quality control measures in all BioWatch locations.

The BioWatch program has been variously described by my fellow State and local laboratory directors as a parasite to the public health laboratory and squatters in valuable public health laboratory space. I am hard-pressed to disagree.

This concludes my testimony, and I thank you again for inviting me to participate in this hearing.

ATTACHMENT 1.—FAR 37 PERSONAL SERVICES CONTRACTS EXPLANATION

Federal Government agencies are required to adhere to Federal Acquisition Regulations (FAR) when purchasing goods or services. FAR Part 37 is the section that addresses "Service Contracting."

A service contract may be either a nonpersonal or personal services contract.

The current contract that the Department of Homeland Security (DHS) has with A-TEK, Inc. is a nonpersonal services contract. The following definition of a nonpersonal services contract comes from the FAR, Part 37.101: "'Nonpersonal services contract' means a contract under which the personnel rendering the services are not subject, either by the contract's terms or by the manner of its administration, to the supervision and control usually prevailing in relationships between the Government and its employees."

For reference, the definition of a personal services contract, as written in FAR Part 37.104, is as follows: "A personal services contract is characterized by the employer-employee relationship it creates between the Government and the contractor's personnel. The Government is normally required to obtain its employees by direct hire under competitive appointment or other procedures required by the civil service laws. Obtaining personal services by contract, rather than by direct hire, circumvents those laws unless Congress has specifically authorized acquisition of the services by contract." Here, the "Government" refers to DHS and not the local or State laboratory directors or their designees. The services acquired in this case do not constitute personal services because Congress has not specifically authorized the acquisition of personal services by contract.

Furthermore, Part 37.104 states that [Federal] "Agencies shall not award personal services contracts unless specifically authorized by statute to do so." DHS has no authorization for a personal services contract to support the BioWatch Program.

Since the DHS contract with A-TEK, Inc. (for the BioWatch Program) is a nonpersonal services contract, the following actions are prohibited:

- *Personnel hiring/firing actions*.—The Laboratory Directors (or their designees) cannot hire or fire a Contractor's employees. The Contractor is responsible for these employment actions, as these employees are their personnel. If there are any issues with Contractor employee conduct while hosted at the laboratory's facility, it is incumbent upon the Laboratory Director (or their designee) to inform DHS of these issues.
- *Contractor internal matters*.—The Laboratory Directors (or their designees) cannot interfere with a Contractor's internal matters (i.e., employee benefits, salaries, timesheet authorization, etc.), particularly those associated with the Contractor laboratory personnel. Under FAR regulations, DHS is also prohibited from interfering with Contractor internal matters.
- *Contractor operations*.—The Laboratory Directors (or their designees) cannot dictate to the Contractor how the Contractor should operate. Under FAR regulations, DHS is also prohibited from dictating Contractor operations.

Other matters:

- *Contract labor issues*.—The Laboratory Directors (or their designees) cannot attempt to solve, or engender labor irregularities. DHS' role is that of an impartial observer.
- *Contractor work efforts*.—The Laboratory Directors (or their designees) cannot delay, or cause to be delayed, the Contractor's work processes. Under FAR regulations, DHS is also prohibited from delaying the Contractor's work processes.
- *Contractor personnel behavior issues*.—In the event contractor personnel behavior constitutes an immediate danger to themselves, other personnel, or facilities, or create a workplace environment that is hostile (harassment) the Laboratory Director may take such actions as necessary to mitigate the risk, with subsequent notification to the contractor and DHS. The contractor will then conduct an investigation on the incident(s) and take such action as necessary.

Other notes: Justification for DHS obtaining a laboratory personnel services contract. DHS has a requirement for laboratory operations (including personnel) to ensure daily sample analysis is performed for the BioWatch Program. The performance of this work includes the operation of Government-owned equipment and systems.

Mr. LANGEVIN. Thank you, Dr. Downes, for your testimony.

I want to thank all the witnesses for their testimony. I remind Members that he or she will have 5 minutes to question the panel. Before I go to questions, I just want to make reference to the fact that my partner in this effort, the Ranking Member of the subcommittee, Mr. McCaul, unfortunately, due to the late hour that we returned, has a conflict with another meeting, and will not be able to return, but asked that we continue in his absence.

Let me begin with Mr. Hooks. This isn't the question I had intended to ask, but given Dr. Downes' testimony, it doesn't sound like BioWatch is being a very good partner in this case with the State and locals. Would you please respond to the testimony? How, if in this case the Michigan Department of Community Health in this case is not having a good experience, how are we going to expect other States and localities to want to participate if this is the way a, quote-unquote, partnership is working?

Please respond.

Mr. HOOKS. Yes, Mr. Chairman.

I point to some of Dr. Downes' testimony where she talked about a culture of partnership. I heartily agree that that is what the BioWatch program needs to be. It is a Federal-State-local partnership, including the local laboratories.

I am disappointed to be hearing the comments that she has provided. I am disappointed that I wasn't aware of the level of concern in the laboratory community since I have taken over this program. I am committed to resolving that.

I have already offered to go visit with her and other appropriate officials to ensure that we create that level of partnership because I think, ultimately, our goal is the same, that we want to provide an early detection capability for the Nation that benefits the Nation.

This isn't an issue of BioWatch, national program office, against the State, local community; and we need to look to create a value proposition that benefits both of our needs and our constraints.

Mr. LANGEVIN. Mr. Hooks, I know that you are relatively new in your current position, so I do want to turn to Dr. Stiefel as the program manager for BioWatch.

Have you heard the concerns that Dr. Downes has raised, or is this news to you?

Dr. STIEFEL. No, no, not at all, sir. There have been concerns.

One of the issues is, we just changed contractors. Whenever you change a contractor, there is always the—there is always turbulence when that occurs. We have heard about this. We have actually been taking actions with the contractor to try to ensure that the contractor performs up to the standards, talks to the lab directors about what has to happen.

There are certain issues, because it is a contract, that are contractor employee-based, and as such, a contractor has to hire and fire the employee. But that is done and should be done through the lab director's advice and guidance. That is what we are trying to ensure. That is the way it was done over the previous contractor, when those employees converted from a CDC term hire to a contract. So these aren't new issues in the sense that we have been addressing them through the contractor.

We also meet—have a conference call with the laboratory directors once a month, and these issues come up then. We haven't heard—we know there is concern out there, not to the extent that 28 laboratories have expressed that level of concern throughout the course of this contract revision.

Mr. LANGEVIN. What about the resource complaints, that we are not reimbursing for things that they consider to be priorities?

Mr. HOOKS. Sir, the current construct is the same as when the BioWatch program started. We expect to be paying for the personnel, the reagents, and the test equipment that are used to process BioWatch samples. We understand on the local laboratory side there are indirect costs associated with the space that is used for the BioWatch samples.

It should be pointed out that from 2003 to 2008 the number of collectors that were being used in the jurisdiction that this laboratory was supporting increased by a figure of two—or actually, a figure of three, and so that is going to cause more samples to be analyzed. We expect to be able to cover the costs, those direct costs of the people, the reagents, and the test equipment for the laboratory. We are not asking them to take on that burden.

So this clearly conveys that the communication needs to improve better with each of the laboratories so that they understand the position, where we have been. As appropriate, we need to revisit, is this the best relationship construct that is in place, since it is the same one that was put in place when the BioWatch system was stood up very quickly in a 90-day period back in 2003?

Mr. LANGEVIN. Given the seriousness of what I consider to be the biothreat and the fact that we need strong Federal, State, and local partners, I don't want to be doing this on the cheap. If we need to provide more resources, you have got to either provide them or speak up and say, you need more, and then the Congress has to do more in that area. But we can't obviously be doing this on the cheap, and then not having the State and locals feel that they aren't being supported and this isn't a good partnership.

Dr. Downes, let me turn to you again. Would you care to respond to any of the things that you have heard in response to your testimony?

Dr. DOWNES. One comment I would make is that the monthly calls with what DHS calls the "BioWatch lab director" is not someone in my role. It is not the person who is the administrator or the quality assurance regulatory lab director. They are more of what we call a section manager, or a smaller laboratory unit manager, and much more technical in nature. So they may not be conveying the resource issue as—because they are not responsible for the overall management of the laboratory the way that someone in my position is.

I think that is a separate dialog that we need to open, as opposed to the technical discussions that have been on a monthly basis.

Mr. LANGEVIN. Very well. We will continue to follow this.

Mr. Jenkins, do you care to respond to anything that you heard in the testimony?

Mr. JENKINS. No, sir. We haven't looked at this particular issue that has been raised here and discussed here.

Mr. LANGEVIN. Okay.

Let me just, before I turn to Ms. Christensen, I do have one question that I need to get to that is a priority. It is, currently the BioWatch system uses environmental sample collectors called Generation 1, Generation 2 detectors, as we have heard in testimony, that are collected once a day and analyzed in public health laboratories that are members of the Laboratory Response Network.

Generation 3 detectors, which are automated and do not require physical chemical analysis at an LRN lab, are supposed to replace them, but that deployment keeps slipping. Obviously, the Generation 1 and Generation 2 detectors require a lot of human interaction. There are several hours—actually, several days of delay before we actually have results. I think it goes anywhere from 24 to 36 hours before we actually have results. Obviously the Generation 3 detectors are near real time, with very little to no human interaction required to get the results back, which obviously are more preferable. That is why we want to move in that direction.

Clearly, we are not going fast enough as far as I am concerned. But the congressional justification for the fiscal year 2007 budget request submitted by the Science and Technology Directorate said that BioWatch would have fieldable prototypes in fiscal year 2007, and a Generation 3 BioWatch pilot in fiscal year 2008.

Now, the fiscal year 2008 congressional justification submitted by the Office of Health Affairs called for, "operational testing of Generation 3 BioWatch monitoring systems, which are planned to begin in fiscal year 2008." In fiscal year 2009, the congressional justification submitted by Office of Health Affairs changed to—and again I quote—"fiscal year 2009, which OHA plans a 6-month multicity operational test and evaluation of advanced automated technologies. This will allow Office of Health Affairs to advance to a full rate production procurement decision for advanced technology deployment in fiscal year 2010."

Now, finally, in testimony before the House Appropriations Committee on April 1, 2008, DHS Medical Officer Dr. Jeff Runge stated, quote again, that "our target for that is April of 2009 to do that head-to-head flyoff with whoever is ready, because we need to get technology ready, tested, thoroughly evaluated, boxes into the field, and to a large volume in 2010 and 2011."

So we slipped from deployment, a deployed pilot in 2008, back to operational testing in 2009, and maybe to deploy some units in 2010 or 2011. This concerns me. I want to know why the deployment has been continually delayed. Were the projections too optimistic? Are you running into severe technical difficulties? Are the companies underperforming?

We can start with those. Do you have, in fact, a drop-dead date where you either have a product ready or you rewrite your requirements and open the process?

I am going to ask for comments both from Mr. Hooks and Mr. Stiefel, and I am going to ask for Mr. Jenkins to comment.

Mr. HOOKS. Sir, as the BioWatch program has matured and moving to look to Generation 3 technology from the Generation 1 and 2 technology, as you discussed, getting into automated detection, technical requirements were written for that Generation 3 technology that were aggressive and probably appropriate requirements, trying to stretch the envelope of science and technology.

But there is always a risk in technological development that the science breakthroughs won't come as fast or as regular as we would like and desire in a technology deployment. I think, over the period of time, as we have managed the program, we have looked at optimistically being able to field a technology earlier than was actually realistic.

There is the balance point between—in the technology development that we ensure that we are looking far enough into the future of the technology we need to support the operations, so it is usable by the end-user community, such as the public health laboratory community, and at the same time managing the risk, to ensure we put the proper level of controls on that technology-development cycle—technical readiness assessments, test and evaluation procedures—at the same time trying to urgently get new technology out into the field. I think that has been the challenge, that some of the projections may have been over-optimistic.

I think, as we are getting closer to the deployment of a Generation 3 technology and the Generation 2.5 technology, the plan always becomes more clear, because you are further down the technical maturity cycle of the technology, so you can gauge more carefully. There are fewer scientific breakthroughs and discoveries that are necessary.

As you mentioned, Dr. Runge has said that the flyoff was scheduled for Generation 3 in April 2009. We are still on track for that. That is our plan, to fly off any technologies that meet the Generation 3 technologies, whether they have been developed within Science and Technology Directorate or are available on the commercial market. But it has already undergone a rigorous independent test and evaluation so we are not wasting time and money testing technologies that we know won't work.

Mr. LANGEVIN. Do you have a drop-dead date where you either have the product ready or you are going to rewrite the requirements and open the process?

Mr. HOOKS. Right now that is April 2009. I don't know that we would re-open the requirements process. We would look at that. It may be appropriate. If there is no technology that is ready to test as we are working through this cycle to Generation 3, then it would probably be more appropriate to delay, because we do need that level of automated technology.

We do have units, we do have prototype automated technology units in place in New York City, an earlier version of a potential Gen-3 solution. That may be the trade-off decision. The reason we want to get to Generation 3 is because of the significantly lower cost of procurement and operation, as well as improved specificity to identify the pathogens of concern, as Mr. Jenkins has mentioned.

That is important, and that is where we want to get. If we can't get there because our tests and evaluation and independent results convey that that is not possible, then we do need to look for an alternative interim solution to move forward and do the cost-benefit analysis on that.

Mr. LANGEVIN. Thank you.

Mr. Stiefel, I would like you to comment on this, as well.

Dr. STIEFEL. Yes, sir. Actually, what Mr. Hooks said is exactly right. But there is another important component to this that we

have to understand, and that is, whatever technology we field has to be good. It has to be trusted. It has to be public-health-actionable. So that when a signal comes in and it is considered a BioWatch-actionable result or a positive, that actions can be taken and the public health trusts that action.

As Dr. Downes can rightly tell you, the current assays that we have are CDC, public-health-actionable assays. The systems that are in our Gen 2.5 system are public-health-actionable assays. So we can't afford to put a system out there that is going to make a mistake, because the actions of that mistake are tremendous, especially in large airport or other large transit facilities.

So we need to get this right. Right now, April 2009, as Mr. Hooks says, is a good date. On the other hand, if technology didn't advance enough to be able to give us that system that we have full trust and confidence in that you would expect us to field, we potentially would have to slip. But at this point, we don't see that happening.

Mr. LANGEVIN. Thank you.

Mr. Jenkins, do you have anything to add?

Mr. JENKINS. I would make a couple of points here.

One is that if there are issues with 3.0, in terms of slippage or whatever the issue is, as to what extent does 2.5 help buy you time, the basic thing in 2.5 is that it detects the same number of agents that is currently being detected, it just automatically analyzes them.

If there are no new assay tests developed, then the 3.0, when it is deployed, will still only detect the same number of agents that are currently being detected. It has, as I said—I was very careful in the wording—potentially the capability to detect all of those on the list. But until there is, as I said, the proved CDC assay test for these, they can't add those to the system.

So, initially, it may be that the 3.0 only is detecting the same number the 2.0 is and 2.5 is. I think if there are issues here with regard to getting this right, the question is, what do I get in 2.5 and what do I not have that 3.0 will bring on? That is what we haven't really heard them talk about.

Mr. LANGEVIN. Mr. Stiefel, how would you respond to Mr. Jenkins on that point?

Dr. STIEFEL. What Generation 2.5 gives us today, because we are operational in New York City in a couple of venues, is getting that detection time down from 10 to 34 hours, because we collect for a 24-hour period of time, down to 4 to 6 hours. We actually collect every 2 hours, and then the assays run for 2 hours while we are collecting for the next 2 hours.

New York City will take full appropriate actions based on a positive from any one of those machines. That signal goes to the lab director. That is who makes that determination of a positive.

What Gen 2.5 will give us is essentially most of the requirements in Gen 2.3 but not all of them. It doesn't give us the 30-day cycle to put more reagents into the machine instead of seven. It can go up well beyond the six agents, the five agents that we currently screen for. But, as Mr. Jenkins says, they have to be public-health-actionable CDC-approved assays.

So 2.5 actually buys us significant time, but at the same cost, it is $40,000, $50,000, $60,000 more because we are making them in such limited numbers.

Mr. LANGEVIN. Thank you.

Well, with that, I am going to turn to Ms. Christensen for her questions. Thank you for bearing with us, as we drill down a little bit on this.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

One of my questions referred to the automatic pathogen detection system also. So you are saying that—my question would have been, is that use a wise use of resources and a good way to bridge? But you are saying, yes, it is, because it covers the things that you have assays for.

Mr. HOOKS. Yes, ma'am. Going to automated detection is critical for our biosurveillance efforts for several reasons. One is it does reduce the time of detection on average right now by about 24 hours, which is critical to be able to respond earlier following a biological attack, that it be identified.

Additionally, there are certain higher-risk venues, such as indoor facilities, where the current delay time on samples from an ability to detect in the 10 to 34 hours just does not work in the concept of operations. The cities have told us that they will not deploy the Generation 1 and 2 systems into those higher-risk venues, which are high through-put transportation environments such as subway systems or into airports and whatnot.

Mrs. CHRISTENSEN. From the time this committee was a select committee, we have always talked about having genetically altered or created pathogens. How far away are we from a point at which we can detect those kinds of pathogens that have never existed before or have been very much altered?

Mr. HOOKS. Genetically altered pathogens and other engineered threats are a concern to us. The technology is not there at this time to deploy into a BioWatch system. As we look forward to the future of a Generation 4 system, that is a key component that we need to be able to address in that.

It is not clear to me if it is optimistic or realistic at this point, but our best guess is that is probably 3 to 5 years out. But please don't hold me to that.

Mrs. CHRISTENSEN. No, you have gotten into enough trouble over dates and deadlines here today.

Mr. HOOKS. Yes, ma'am.

Mrs. CHRISTENSEN. Back to the lab for a minute. Why is it necessary to have a contractor, an in-between person between you and the laboratory? Wouldn't be it just easier to contract with the labs directly?

Mr. HOOKS. I am going to defer that one to Mr. Stiefel.

Dr. STIEFEL. Actually, when the program first started—and it started so quickly—CDC put emergency hires in place through CDC, converted them over to temporary hires, term hires. It came to a point when CDC wanted to back away from that, because that was a large expense and these people were given no benefits. So we talked to the lab directors, and through CDC the only possible venue for us to go to, at that point, was to turn to a contracting scenario to put these laboratory personnel into the laboratory.

We have also had requests from other labs and, for example, in Minnesota, where they have requested the possibility of putting State employees through a CDC grant or through some kind of grant. We have actually looked into that, and we have been looking into that for about a year. Many of the labs that I have spoken to would like that. The problem is that the States themselves are on hiring freezes, and even if we were to provide them money, they wouldn't have the ability to add these additional slots.

So we are looking at lots of different ways in order to compensate: one, through contracting. Another one is potentially public health officers from HHS that could go into these laboratories. Another venue would be, wherever possible, to try to hire State employees through a COTPER grant with HHS and CDC.

Mrs. CHRISTENSEN. Dr. Downes, you may want to follow up on that question and answer. But I was also wondering, are the State of Michigan employees in the laboratory put at any risk because of the limitations imposed on you by the DHS BioWatch contract?

Dr. DOWNES. We do treat those employees as if they are our own and require them to go through our safety training. Our concern is that, if we had somebody who was not performing to those standards, the fire safety program, that it would be—I have no mechanism at this point to dismiss that person immediately, for example. Or if the quality of their testing was not appropriate or they were disruptive in any sort of way within our facility, we would have no way to immediately take them out of the laboratory setting. So in that regard, they do potentially put our employees at risk.

In regard to the contracting, direct contracting issue, I don't recall having a discussion in which we were given the option of directly contracting with DHS. I recall that it was not put on the table as an option.

But, as Dr. Stiefel says, one contracting mechanism may not work in all States or local laboratories, and that having more of a portfolio of options would probably be the best and most direct way to accomplish achieving the through-put, as well as assuring quality and safety.

Mrs. CHRISTENSEN. Okay, thank you.

Either Mr. Hooks or Dr. Stiefel, the January 17, 2008, letter from the Association of Public Health Laboratories that was sent to Assistant Secretary Runge, do you know if it has been responded to?

It had outlined a number of concerns from member laboratories about personnel matters that developed with the award of the new BioWatch contract and suggested options for improvement.

Has that been responded to yet?

Mr. HOOKS. That letter was in response to a meeting that was held with Dr. Runge, the Principal Deputy Assistant Secretary, and my predecessor in my present position, along with Dr. Stiefel. The larger content of that letter from January 17 was to address discussing a variety of preparedness issues and whatnot.

There are, within there, paragraphs that mention that they were glad that they were able to discuss some of the issues that were on the table. From the reading of the letter, where it says, "Thank you very much for the meeting," in reading the letter the Office of Health Affairs did not feel that it needed a response. It was not

meant to be a snub of no response. The assumption was that the communication and dialog was continuing with a PHL.

So the sense was this was a closure letter to a meeting, not raising larger issues. It mentioned moving forward: "We reiterate our interest in working collaboratively." We completely concur and agree with that.

Mrs. CHRISTENSEN. Thank you.

My last question is more of a process: How do you work? There was a well-reported detection of tularemia bacteria in the District of Columbia a few years ago, and it was eventually decided that it was a naturally occurring bacteria rather than a biological attack.

I am a little more paranoid than most people. So everything to me, you know, all the food stuff, you know, I wonder.

But how does the Department decide whether a positive test came from a naturally occurring event rather than a deliberate release? What are some of the factors that influence how quickly that determination is made?

Mr. HOOKS. So when a BioWatch signal comes up and it is determined to be a BioWatch-actionable result because there is nucleic acid on that filter that indicates that there is a pathogen—not a pathogen, but that there is nucleic acid that could be from that pathogen—the decision is made at the local laboratory by the laboratory director, such as Dr. Downes.

In that case, there are procedures in place. At the national level, we have provided Federal guidance documents that discuss the preparedness, the response and the sampling for that event. There are very detailed procedures in place that have been put in place by each of the jurisdictions that we refer to as concept of operations.

Each of the jurisdictions has a BioWatch Advisory Committee, which is made up of different people in the local community, including the public health director or their representative. There will be representatives from the mayor's office or other city officials, from the FBI, locals, other public health officials that come together. They analyze what that BioWatch-actionable result says and what it does potentially mean.

They will look at a variety of different factors. The FBI will be looking: Is there intelligence information that would convey that we are at a higher risk of a potential attack? They will look at: Was it only detected on one collector or multiple collectors? That will give indication. They will look at the environmental conditions, as well. EPA is represented in this BioWatch Advisory Committee.

To ensure that this works effectively, there is a normal protocol. We have a BioWatch exercise and evaluation program that is done annually with each of the jurisdictions, where we send out people from the national office that evaluate the protocols and procedures that are ongoing in each of the local jurisdictions to ensure that they do meet a high quality. Because, as mentioned previously, there are potential high-regret actions that could be taken, and we don't want to ever get it wrong.

Also, there are tabletop exercises that are done either under the auspices of the national office or certain jurisdictions choose to do them on their own. We will send representatives to assist in that.

So this really is a partnership. We want to get it right every time.

There have been 37 environmental positives where there was actually a detection of nucleic acid since the program has begun. In each of those cases, the local jurisdictions have walked through the protocols that are in place, executed, and determined that it did not cause a public health risk.

We use those lessons learned from those events, from the tabletop exercises. Those are shared on a BioWatch portal to all of the jurisdictions so that we can learn from each other. They are briefed at the national conference every year to ensure that that information is passed, as well.

Part of that is looking: How can we improve those procedures to be more efficient and effective, but still maintain that high level of quality necessary on a program of this type?

Mrs. CHRISTENSEN. So it is probably the intelligence side that helps to really make that determination or—well, I heard a couple of factors. Thank you.

Thank you, Mr. Chairman.

Mr. LANGEVIN. I thank the gentlelady.

Before I conclude the hearing, let me just say that I would ask that we all redouble our efforts on this issue of being better prepared for prevention, detection and response to potential biological threats, whether they be emerging threats from naturally occurring things or from man-made potential biological attacks.

I take this issue very seriously. It truly concerns me. This subcommittee has jurisdiction over the Department's activities, and trying to prevent some of the scariest things, the things with the most devastating consequences that could face the country, whether dealing with a nuclear attack, preventing radiological attack, biological or chemical attack on the country.

Clearly, of all the things, a nuclear attack would be very likely the most devastating. But, thankfully, Mother Nature didn't make it easy for us or anyone to acquire weapons-grade plutonium or highly enriched uranium. The same is not the case for biological attacks, which could possibly be just as catastrophic in terms of loss of life.

The problem is, as experts have testified before this subcommittee before, someone with a basic degree in biology could cause a threat to public health. As technology proliferates and becomes more sophisticated and easy to acquire, especially those technologies that have dual-use technology, nebulizers and such, that are available on the open market, someone could cause real harm to the country through a biological attack and could cause massive loss of life. This keeps me up at night. We need to redouble our efforts to protect the country from these things.

Clearly, and if someone does develop that capability, what concerns me, unlike in the unlikely event of a nuclear attack, people would be able to do this biological attack again and again and again. We can't ever allow that to happen.

I want to thank our witnesses for their efforts and their testimony.

Again, I want to thank Ms. Christensen for her patience and staying through this second hearing, as well as our witnesses.

The Members of the subcommittee may have additional questions for the witnesses that we will ask that you respond expeditiously in writing.

Having no further business, the subcommittee now stands adjourned.

[Whereupon, at 6:06 p.m., the subcommittee was adjourned.]

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