IMPROVING THE DEPARTMENT OF HOMELAND SECURITY'S BIOLOGICAL DETECTION AND SURVEILLANCE PROGRAMS

HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGENCY PREPAREDNESS, RESPONSE, AND COMMUNICATIONS

OF THE

COMMITTEE ON HOMELAND SECURITY HOUSE OF REPRESENTATIVES

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Thursday, February 11, 2016

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

The subcommittee met, pursuant to call, at 2:13 p.m., in Room 311, Cannon House Office Building, Hon. Martha McSally [Chairwoman of the subcommittee] presiding.

Present: Representatives McSally, Payne, and Thompson.

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

The subcommittee is meeting today to receive testimony regarding the Department of Homeland Security's detection and surveillance programs to address the bioterrorism threat.

I now recognize myself for an opening statement.

The Subcommittee on Emergency Preparedness, Response, and Communications has a long history of oversight on the issue of bioterrorism. So far this Congress, we have held multiple hearings and a Classified briefing on this threat. The threat is real.

We know terrorist groups like ISIS have an interest in utilizing biological agents in their attacks. In fact, a little over a year ago, a laptop reportedly retrieved from an ISIS hideout in Syria contained plans for weaponizing bubonic plague, in a document discussing the advantages of using biological weapons. We now know ISIS is intent on conducting attacks in the United States.

In its 2016 World-wide Threat Assessment provided earlier this week, the director of national intelligence noted that weapons of mass destruction continue to be a major threat to U.S. security. He remarked that biological materials and technologies as well as personnel with the expertise to design and use them move easily in the economy.

The DNI also stated that infectious diseases continue to threaten our security, and that a more crowded and interconnected world is increasing the opportunities for human and animal diseases to emerge and spread globally, something we are seeing right now with the Zika virus.

A bio-attack could cause illness or death in hundreds of thousands of people, overwhelm our public health capabilities and have an economic impact of over $1 trillion per incident. Our Nation's

capability to mitigate the impacts of all types of biological events is a top National security priority.

But we know that our efforts leave room for improvement. The Blue Ribbon Study Panel on Biodefense's report, which was released October 2015, highlights shortcomings of the Department of Homeland Security's biological surveillance and detection efforts through the National Biosurveillance Integration System, or NBIS, and the BioWatch program.

In testimony before the full committee, Blue Ribbon co-chair and former Secretary of Homeland Security Tom Ridge stated: "DHS has made only limited progress with BioWatch and the National biosurveillance integration system—and at great expense."

Limited information sharing from Federal and industry partners has hampered the effectiveness of the National Biosurveillance Integration Center, or NBIC. BioWatch uses aging equipment, despite the fact that other agencies have fielded more advanced detection technology.

He recommended that: "Either we make these effective tools or we replace them."

The GAO also completed reviews of NBIC and BioWatch, containing a number of similar findings to the Blue Ribbon Study Panel.

With respect to BioWatch, the review found that DHS did not conduct sufficient testing to determine that the technology can effectively meet the program's objectives, which brings us to today's hearing.

In light of the threats that we face, the Department of Homeland Security must have biological detection and surveillance programs in place, which serve to enhance our security and provide a return on our investment. I am interested in hearing from Dr. Brinsfield on how the Office of Health Affairs, OHA, is working to address the findings of these reviews and chart an effective course for these programs.

I am also interested in learning more about collaborative efforts between OHA and the Science and Technology Directorate to determine the next steps for BioWatch.

With that in mind, the Ranking Member and I had a discussion with industry representatives on this very topic yesterday. We were concerned to hear that there has been limited engagement with the innovators who may have interim and long-term solutions to these problems. If you don't communicate your plans with industry, they can't plan for how they might be able to support you.

These are complex problems for sure, and we must work collaboratively at all levels of Government and with the private sector to address them.

With that, I welcome our witnesses. I look forward to hearing your testimony.

[The statement of Chairman McSally follows:]

STATEMENT OF CHAIRMAN MARTHA MCSALLY

The Subcommittee on Emergency Preparedness, Response, and Communications has a long history of oversight on the issue of bioterrorism. So far this Congress, we have held multiple hearings and a Classified briefing on this threat.

The threat is real. We know terrorist groups, like ISIS, have an interest in utilizing biological agents in their attacks. In fact, a little over a year ago, a laptop

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A bio attack could cause illness or death in hundreds of thousands of people, overwhelm our public health capabilities, and have an economic impact of over 1 trillion dollars per incident.

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The Government Accountability Office also completed reviews of NBIC and BioWatch, containing a number of similar findings to the Blue Ribbon Study Panel. With respect to BioWatch, the review found that DHS did not conduct sufficient testing to determine that the technology can effectively meet the program's objectives.

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These are complex problems and we must work collaboratively at all levels of Government and with our private-sector partners to address them.

With that, I welcome our witnesses. I look forward to your testimony.

Ms. MCSALLY. The Chair now recognizes the gentleman from Mississippi, the Ranking Member of the full committee, Mr. Thompson, for any opening statement he may have.

Mr. THOMPSON. Thank you very much, Madam Chair.

Let me say at the beginning that Ranking Member Payne is actually in the House physician's office and I am kind of pinch-hitting for him today.

Nonetheless, welcome, to our witnesses for this hearing.

I would like to also thank you for holding this hearing.

The Department of Homeland Security's signature programs in this mission space, BioWatch and the National Biosurveillance Integration Center, referred to commonly as NBIC, has historically struggled to meet Congress's expectations.

This committee has conducted exhaustive oversight of the BioWatch program since it was transferred to the Department and NBIC since it was authorized with the 9/11 Act.

Let me mention and I appreciate both Mr. Payne and Ms. McSally's efforts to continue those efforts.

That said, I have grown frustrated, like many, that we seem to be having the same hearings over and over again. At least once every Congress, we ask the Department to come to the committee to respond to the latest criticisms of BioWatch and NBIC.

In 2012, we asked about reports of false positives with the currently-deployed BioWatch system, a 2011 National Academy of Sciences report that found that current BioWatch technology would work in very limited circumstances, and acquisition challenges that ultimately proved to be Gen–3's demise.

At the time, we were assured that the currently-deployed BioWatch system did work and that the Office of Health Affairs would work closely with the Science and Technology Directorate to identify new technologies to address shortcomings of the archaic BioWatch system.

Two years after the Gen–3 acquisition was officially canceled, it is unclear whether we have made any concrete progress to identify new biodetection technology. Worse yet, last fall both the Blue Ribbon Study Panel on Biodefense and the Government Accountability Office released reports raising questions about what benefits the current BioWatch program provides.

The questions raised by the study panel and GAO were many of the same questions raised by our Members and the National Academy of Science years ago. Similarly, the GAO has raised questions about the value of NBIC since 2009.

While I commend the Office of Health Affairs for fully implementing the recommendations GAO made to improve the NBIC, it still appears that NBIC struggles to effectively collect, integrate, and analyze biosurveillance data from across the Federal Government to identify emerging threats.

Despite laudable efforts, GAO reports NBIC struggles to get access to the information it needs to do the job. Some stakeholders say the products NBIC produces are not timely or useful.

The Blue Ribbon Panel echoed these concerns particularly regarding stalled progress on identifying innovative data sources. These are many of the problems we heard about in 2009.

So, Madam Chair, in the interest of time, I think they get the point.

[Laughter.]

We would like to hear from our witnesses to help us out with this.

I yield back.

[The statement of Ranking Member Thompson follows:]

STATEMENT OF RANKING MEMBER BENNIE G. THOMPSON

The Department of Homeland Security's signature programs in this mission space—BioWatch and the National Biosurveillance Integration Center (NBIC)—have historically struggled to meet Congress' expectations. This committee has conducted exhaustive oversight of the BioWatch program since it was transferred to the Department and NBIC since it was authorized in the 9/11 Act. Let me also mention that I appreciate Mr. Payne and Ms. McSally's efforts to continue those efforts.

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While I commend the Office of Health Affairs for fully implementing the recommendations GAO made to improve the NBIC, it still appears that NBIC struggles to effectively collect, integrate, and analyze biosurveillance data from across the Federal Government to identify emerging threats.

Despite laudable efforts, GAO reports NBIC struggles to get access to the information it needs to do its job and some stakeholders say the produce NBIC produces are not timely or useful. The Blue Ribbon Panel echoed these concerns, particularly regarding stalled progress on identifying innovative data sources. These are many of the problems we heard about in 2009. I am frustrated that we are sitting here today having the same conversations we were having almost 4 years ago, and I want to understand what it will take to move the ball.

Today, I want to learn what challenges are undermining progress. Is it a question of insufficient resources for these programs? Is it a lack of centralized leadership on biodefense issues at the Federal level guiding prioritization, coordination, and investments? Is it time to rethink the mission of these programs so they are responsive to the current threat environment and capability gaps?

Help us understand the challenges you are facing, your vision for these programs, and what you need from Congress. I look forward to the testimony today, and I hope that we will hear a concrete strategy for making concrete improvement on programs that DHS has struggled with for too long.

Ms. MCSALLY. Thank you, Ranking Member Thompson.

The gentlemen yields back.

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

[The statement of Ranking Member Payne follows:]

STATEMENT OF RANKING MEMBER DONALD M. PAYNE, JR.

FEBRUARY 11, 2016

DHS has a critical role to play in the biodefense space. I am glad that Ms. McSally shares my commitment to ensuring that the Department's programs are responsive to the current threat environment and make meaningful contributions to help prevent and protect against a biological incident.

I joined this committee in January 2013, and have served as Ranking Member on this subcommittee ever since. At that time, the Office of Health Affairs was conducting the "Analysis of Alternatives" for the BioWatch Gen–3 "lab-in-a-box" and implementing its 2012 Strategic Plan for the National Biosurveillance Integration Center. The Gen–3 acquisition was ultimately canceled, questions about Gen–2 were on-going, and we took the "wait and see" approach with NBIC, hoping that with time and a new strategy, it would successfully achieve its mandate.

I find it remarkable that today I sit here with a new Subcommittee Chairman asking many of the same questions I was asking 3 years ago. I have met with both Dr. Brinsfield and Dr. Brothers privately, and expressed my concern about the lack of progress in identifying technology to replace the current BioWatch system.

Although I have been assured that progress is under way, the Chair and I have met with representatives from the private sector and they did not share that opti-

mism. Further, both the Blue Ribbon Study Panel on Biodefense and the Government Accountability Office have recently questioned the benefit of both NBIC and the deployed BioWatch technology. With respect to NBIC, the Blue Ribbon Panel acknowledged the challenges that OHA has experienced with respect to gaining access to information without an enforcement mechanism and urged OHA to innovate on identifying new data sources.

GAO raised similar concerns with respect to information access and suggested that NBIC could further clarify its mission to ensure that its work added to the National biosurveillance capability. That said, I do not know how OHA can address these challenges or clarify its mission under its current budget or the reduced resources sought under the President's fiscal year 2017 budget request. Together, the message from GAO and the Blue Ribbon Study Panel is that the NBIC cannot carry on with a "business as usual" mentality. I will be interested to learn how NBIC has internalized this message.

With respect to BioWatch, GAO recently found that DHS lacks a full understanding of the deployed system's detection capabilities. The Blue Ribbon Study Panel amplified the system's limitations by outlining a series of shortcomings, from relying on "winds blowing in optimal directions," to its inability to distinguish normal background bacteria from dangerous pathogens, to its inability to detect atypical threats.

Although the Department is adamant that BioWatch can achieve its operational objective—to detect a catastrophic biological event that would cause 10,000 casualties—I am not convinced that that objective is responsive to the current threat environment.

Before I yield back, I would be remiss if I did not note that the President's fiscal year 2017 budget request proposes devastating cuts to terrorism preparedness grants that first responders in my district rely on. The budget would cut $267 million from the State Homeland Security Grant Program, $270 million from the Urban Area Security Initiative, $15 million from Transit Grants, and $7 million from Port Grants. It is penny-wise and pound-foolish to make such cuts even to these effective programs. The Federal dollars we spend yield concrete capabilities at the State and local level.

Getting back to the subject at hand, I have to say that it is hard to justify funding for programs whose value is questioned year after year when essential first responder grants are being axed. I am committed to putting DHS's biodefense efforts on the right track, but I have a hard time going to bat for programs that appear to be stagnant, particularly in the current budget environment.

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

Dr. Kathy Brinsfield serves as assistant secretary of health affairs and chief medical officer for the Department of Homeland Security and leads the DHS Office of Health Affairs. Dr. Brinsfield is responsible for ensuring the DHS workforce and the Nation are prepared for the health impacts of all threats, including biological and chemical terrorism and emerging infectious diseases.

Prior to her appointment as assistant secretary and chief medical officer, she served on a detail to the National security staff as the director of medical preparedness policy. Before joining DHS, Dr. Brinsfield worked for various organizations, including Boston EMS, Boston Metropolitan Medical Response System, and the the del Valle Emergency Preparedness Training Institute.

Dr. Reggie Brothers serves as under secretary for science and technology at the U.S. Department of Homeland Security. Dr. Brothers is responsible for a science and technology portfolio that includes basic and applied research, development, demonstration, testing, and evaluation.

Prior to DHS, Dr. Brothers served as the deputy assistant secretary of defense for research at the Department of Defense where he was responsible for policy and oversight of the Department's science and technology programs, from basic research through advanced technology development.

Chris Currie is the director of GAO's Homeland Security and Justice Team where he leads the agency's work on emergency management and National preparedness issues. In this role, he and his team of GAO auditors evaluate Federal efforts and programs to prevent, plan for, and respond to natural and man-made disasters.

Prior to this, Mr. Currie was acting director in the GAO's Defense Capabilities and Management Team where he led reviews of DOD programs, including those related to military housing, aircraft, and the U.S. counter-piracy efforts. In the decade since DHS was created, Mr. Currie has led numerous audits and assessments of DHS programs, including those related to transportation security, research and development of new technologies, and the Department's effort to test and evaluate large acquisition programs and technologies.

The witnesses' full written statements will appear in the record. The Chair now recognizes Dr. Brinsfield, for 5 minutes.

STATEMENT OF KATHRYN BRINSFIELD, ASSISTANT SECRETARY, OFFICE OF HEALTH AFFAIRS, U.S. DEPARTMENT OF HOMELAND SECURITY

Dr. BRINSFIELD. Chairman McSally, Mr. Thompson and distinguished Members of the subcommittee, I appreciate the opportunity to speak to you today alongside my colleague, Dr. Brothers, and Mr. Currie from the Government Accountability Office.

Thank you for your continued oversight on this issue and your commitment to strengthening our Nation's biodefense.

I know you are familiar with the Office of Health Affairs and our mission and role in biodetection and biosurveillance, so I will focus my remarks on what we are doing to build better systems to detect and respond to biological events, whether man-made or naturally occurring.

We worry about biological attacks and other major biological incidents because of how wide-reaching the impacts can be. Within 24 hours, an individual infected with a virulent contagious pathogen, introduced naturally or intentionally, could land on our shores and spark an outbreak with far-reaching National or global consequences.

As noted by the Blue Ribbon Study Panel on Biodefense, our ability to defend the American public is a whole-of-Government issue because no single Government agency or even level of Government has the resources and the mission to handle this alone.

I continue to believe that this country must have a layered, early-warning capability for biodefense. Right now, our BioWatch program and National Biosurveillance Integration Center, or NBIC, serve to fill that need.

These capabilities aim to provide us with information that helps decision makers track trends and detect anomalies that may indicate that an attack has occurred, before sick people start flooding our hospitals and clinics.

BioWatch has worked over the last 7 years to reinforce the performance and capabilities of currently-deployed technologies. The deployed technologies have been tested many times and further verified through the quality assurance program. The early-warning capabilities that BioWatch provides allow responders and commu-

nities to make timely decisions and take actions to protect the American people and save lives.

Can our capabilities go further? Yes. We acknowledge that even our current BioWatch technology is labor-intensive and not suitable for every environment in which we need to detect an attack.

The Department also appreciates the work of the GAO on BioWatch. GAO clearly recognizes some of the unique challenges for this system which was rolled out with the best available technology in 2003 to respond to an urgent threat. So, in recognition of these challenges, we are looking at a suite of capabilities that will expand the venues into which BioWatch collectors can be deployed and provide more rapid detection, better situational awareness and improve our collective decision making in response to a bioterror attack.

Dr. Brothers and I share this goal because it is important. Together, including our interagency partners, such as Department of Defense, we are assessing various technologies to integrate into the BioWatch system.

In cooperation with DHS Science and Technology, we are exploring advanced detection technologies, such as improved DNA sequencing techniques intended to improve sensitivity and expand the range of agents of concern that BioWatch is able to detect.

The Department has a plan and proposed time line to implement the recommendations of the most recent report. Much of that effort is currently under way or already complete.

The same goes for biosurveillance. As part of our layered defense, the NBIC is the Nation's integrator of human health, animal health, and environmental data to develop a comprehensive understanding of the biological threat landscape and emerging incidents to ensure our Nation's decision makers have timely, accurate, and actionable information. This includes terrorist incidents and naturally-occurring biological threats.

For example, since April 2015, NBIC has provided updates to Federal, State, and local officials on the evolving nature of the current Zika virus outbreak.

We are cognizant the reports by GAO and the Blue Ribbon Panel have acknowledged that although NBIC has made progress in delivering daily situational awareness to our partners, we still have work to do to fully realize the vision of a comprehensive biosurveillance integration.

NBIC will continue to advance its capacity to conduct biosurveillance reporting and analysis by developing new collaboration tools, pursuing innovative data sources and methods and fostering greater stakeholder engagement. One such example is our work with the U.S. Departments of Veterans Affairs and Defense for data sharing and integration, which we hope to leverage as a model for future interagency collaborations.

I wish it was quick, easy, and cheap to improve our biosurveillance and biodetection capabilities. Unfortunately, it isn't. It is a constant balance to improve our capabilities in a fiscally responsible way.

At present, our programs provide and will continue to provide meaningful and actionable protections for the security of our home-

land. A key part of our system is our engagement with State and local partners.

In addition to our biodetection and early-warning support, we continue to seek ways to support our first-responder communities in their preparation and response to biological defense. By developing initiatives like the voluntary first-responder anthrax vaccine program, for which I thank this committee for its support, we improve our National preparedness.

We appreciate the legislative attention this committee has given to these issues.

Thank you.

[The joint prepared statement of Dr. Brinsfield and Dr. Brothers follows:]

JOINT PREPARED STATEMENT OF KATHRYN H. BRINSFIELD AND REGINALD BROTHERS

FEBRUARY 11, 2016

Chairman McSally, Ranking Member Payne, and distinguished Members of the subcommittee, thank you for inviting us to speak with you today. We appreciate the opportunity to testify on Department of Homeland Security's biological detection and surveillance programs. We want to thank you for your support and commitment to strengthen our Nation's biodefense.

THE CHANGING BIOLOGICAL THREAT

In the 15 years since the U.S. anthrax attacks, we have continued to face not only the threat of biological attacks but also naturally-occurring disease outbreaks (e.g., avian influenza, Ebola Virus, Zika Virus), a global pandemic (e.g., H1N1 influenza), and criminal acts using biological agents (e.g., ricin). The threats and risks posed by emerging and re-emerging infectious disease and the potential research, development, acquisition, and use of biological agents by international terrorist organizations, home-grown violent extremists, and rogue states will continue to challenge our ability to warn, prepare, and protect the homeland.

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

In the wake of these growing threats, the Department of Homeland Security (DHS) remains fully engaged and proactive in attempting to characterize the threat, providing warning of emerging and imminent threats, and coordinating whole-of-Government response. During the most recent Ebola Virus Disease outbreak in West Africa, DHS provided intelligence analysis to the interagency, State and local governments, and first responders, and it directed research to better characterize the threat and fill gaps in public health and operational responses. Additionally, DHS coordinated and implemented enhanced screening for more than 38,000 international passengers at 5 airports. The Department continues to work with State and local governments, intelligence community partners, and Federal partners to provide predictive analysis and early warning in addition to longer-term research and development (R&D) that strengthens preparedness and response capabilities and fosters resilient communities. We must remain vigilant and innovative as biological threats continue to evolve and new threats emerge.

DEPARTMENT OF HOMELAND SECURITY'S ROLE IN BIODEFENSE

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

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

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

BIOWATCH PROGRAM

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

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

The Department appreciates the Government Accountability Office (GAO) report and recommendations on the path forward for the BioWatch Program. GAO clearly recognizes the unique challenges for this system which was rolled out with the best available technology in 2003 to respond to an urgent threat. The relevant technical capabilities available to adversaries have only increased since then, as biotechnologies have continued their global development and dissemination. So the need for BioWatch persists. In the past 2 years, the capabilities of the system have been independently tested and validated. Four independent tests have been conducted over the last 6 years that have tested all components of the BioWatch system. This has included extensive testing of our identification assays (laboratory tests that detect selected biological agents), subsystem- and system-level testing in test chambers using actual threat agents, and open-air testing of simulated agents in as near an operational environment as possible. In addition, the BioWatch Quality Assurance Program has analyzed over 30,400 samples to monitor operations against performance benchmarks and requirements. The results of these tests reinforce confidence

in the system's ability to achieve its mission: Detecting a large-scale aerosol release of specific threat agents in our Nation's most populated areas.

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

The BioWatch Program is more than just an environmental detection system. BioWatch also helps strengthen jurisdictional preparedness in the event of a bioterrorism event through coordinating exercises and drills; providing training, guidance and assessments, and standardized methodologies for response; and by enabling a forum for all levels of government to share data and information. Over 500 State and local partners and stakeholders representing a broad cross-section of Government agencies have participated in BioWatch preparedness activities in the last year. BioWatch has also coordinated environmental assessment activities, including developing initial environmental sampling plans for jurisdictions to help characterize an attack. All of the program's key elements—including response—are supported by a number of Federal departments and agencies, such as the Department of Health and Human Services (HHS) including the Centers for Disease Control and Prevention (CDC), Department of Defense (DOD), Environmental Protection Agency, and Federal Bureau of Investigation. BioWatch also supports major events such as Super Bowls and National Special Security Events (e.g., 2015 papal visit to 3 U.S. cities).

Since 2014, BioWatch has been working with DHS S&T, DOD, and other Federal partners to identify technologies that would substantially improve BioWatch operations. These improvements are intended to advance the current "detect to treat" capability, which will enable us to deploy medical countermeasures before the affected population is symptomatic. Additionally, BioWatch and the National Biosurveillance Integration Center are working together to improve situational awareness at all levels of Government in the event of a biological attack.

NATIONAL BIOSURVEILLANCE INTEGRATION CENTER (NBIC)

Given the evolving threats that our Nation faces, both man-made and natural, greater coordination among Federal, State, local, Tribal, and territorial partners is required. NBIC is uniquely situated within DHS to provide a fusion of human health, animal health, and environmental data to develop a comprehensive understanding of the biological threat landscape and emerging incidents to ensure our Nation's decision makers have timely, accurate, and actionable information.

Established in 2004 and transitioned to OHA in 2007, the NBIC's mission is to enable early warning and shared situational awareness of acute biological events and support better decisions through rapid identification, characterization, localization, and tracking for biological events of National significance. To accomplish this, NBIC monitors thousands of data sources and leverages the expertise of 14 Federal departments and agencies, then integrates this array of information into reports on global and National biological incidents that could potentially cause economic damage, social disruption, or loss of life. Over 900 Federal and 1,500 State, local, Tribal, and territorial offices across this spectrum of human, animal, and environmental health and response have access to NBIC's reports and analysis.

We are cognizant that reports by the GAO and the Blue Ribbon Panel on Biodefense have acknowledged the progress that NBIC has made delivering daily situational awareness to our partners, but have pointed out that we still have work to do to fully realize the vision of comprehensive biosurveillance integration. Towards this end, NBIC is working with the Department of Veterans Affairs on a data initiative that will help to create an aggregated National view of disease trends, while also facilitating understanding of those trends in our veteran population. Similarly, NBIC is working with DOD's Defense Threat Reduction Agency to deploy new collaboration and analytic tools that will enable biosurveillance analysts from across the Government to collaboratively examine and report on emerging biological threats. NBIC's efforts are also focused on biosurveillance tools and reporting for local officials so that they can address the biological incidents emerging in their own communities, while strengthening National surveillance as a whole. NBIC will continue to advance its capacity to conduct biosurveillance reporting and analysis by

developing new collaboration tools, pursuing innovative data sources and methods, and fostering greater stakeholder engagement.

A COORDINATED R&D APPROACH FOR BIODEFENSE

S&T's Chemical and Biological Defense Division conducts R&D across 4 primary focus areas benefitting numerous interagency and intergovernmental biodefense stakeholders and end-users. Threat awareness R&D informs the Department of Health and Human Services' medical countermeasure acquisition programs for the Strategic National Stockpile. Surveillance R&D is examining capabilities that could support DHS OHA and the Department of Agriculture in improving the Nation's ability to quickly identify chemical and biological events threatening human and livestock animal populations. Detection and Diagnostics is supporting the CDC, Department of Agriculture, and DHS OHA on the development of new biological sensors for rapid detection of threat agent releases as well as bioassays for improved identification of pathogens in clinical and environmental settings. Finally, S&T's Response and Recovery programs help law enforcement to identify sources of chemical and biological attack events (forensics and attribution) and major metropolitan transit authorities and the Environmental Protection Agency to remediate and decontaminate after a biological attack.

Within S&T's biodefense portfolio, one reflection of R&D serving the Department's biodefense mission and specific language was last year's establishment of the Biosurveillance Apex project. Apex projects represent some of the S&T's most ambitious, strategically-urgent R&D investments, and the Biosurveillance Apex will spur short-, medium-, and long-term development and delivery of technology improvements to these essential operational programs. The R&D community within DHS maintains strong links to academia, National laboratories, and other R&D organizations to allow rapid transition of mature technologies and identification of further R&D to support promising new systems. S&T leverages that expertise to address technical gaps and needed enhancements by DHS components.

Last year, Secretary Johnson directed establishment of Integrated Product Teams (IPTs) calling for a central mechanism for the Department to identify and coordinate R&D. Specifically called for in the Secretary's memo was an IPT on Biological Threat to identify priority capability gaps in biodefense (e.g., needs for better predictive models and algorithms for response, decision support tools during events, better personnel protective equipment) and R&D efforts that address those gaps. The solutions developed will deliver new and improved capabilities, such as new bioassays for detection to our public health partners. The Biological Threat IPT is co-chaired by the Federal Emergency Management Agency and OHA and serves as a platform to jointly assess challenges and prioritize solutions, ultimately determining how we will conduct faster threat detection and response for a greater proportion of the population as well as predict the path and severity of emerging disease outbreaks.

STATE, LOCAL, AND FIRST RESPONDER ENGAGEMENT

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

OHA continues to seek ways to support the first-responder community in its preparation and response to biological events. One initiative we are developing is the First Responder Vaccine Initiative (FRVI), which is developing the infrastructure for an anthrax vaccination pilot to evaluate the feasibility of a voluntary pre-event anthrax vaccination program among first responders using anthrax vaccine scheduled to rotate out of the CDC's Strategic National Stockpile in at least 2 States. DHS is facilitating transfer of the vaccine from CDC to the States.

CONCLUSION

Since the stand-up of the Department, we have worked hard to strengthen our Nation's biodefense. We acknowledge and appreciate GAO's efforts to highlight areas for improvement in the Department's biodefense programs. We are committed to working with our partners and look forward to the subcommittee's continuing help building and refining these robust programs. We appreciate the subcommittee for keeping this issue at the forefront and for your continued support to biodefense and homeland security.

Ms. MCSALLY. Thank you, Dr. Brinsfield.

The Chair now recognizes Dr. Brothers, for 5 minutes.

STATEMENT OF REGINALD BROTHERS, UNDER SECRETARY FOR SCIENCE AND TECHNOLOGY, U.S. DEPARTMENT OF HOMELAND SECURITY

Mr. BROTHERS. Chair McSally, Ranking Member Thompson, distinguished Members of the subcommittee, good afternoon and thank you for this opportunity to discuss the role the Department of Homeland Security and Science and Technology Directorate in our Nation's biodefense.

I am grateful for the committee's long-standing interest in and support for the Department and directorate.

As the Blue Ribbon Study Panel on Biodefense's National blueprint for biodefense recently made clear, the risk of man-made and naturally-occurring biological events has not waned in the 15 years since the anthrax attacks. In that time, the Department has played a pivotal role in characterizing the biological threat, providing warning of emerging threats and coordinating Government response during events.

Still, while appreciative of progress made, the blueprint also emphasizes opportunities for improving and streamlining the Federal approach to biodefense. As with input from our colleagues in GAO, we welcome those recommendations and look forward to discussing them in further detail today.

The mission of the Science and Technology Directorate, or S&T, is deliver effective and innovative insight, methods, and solutions for the critical needs of the homeland security enterprise. As the research and development arm and technical center of gravity for the Department, S&T's portfolio extends across diverse homeland security mission areas, a few of which include borders and maritime, cyber, transportation, first responders, disaster resilience and, of course, biodefense.

We work hand-in-hand with our operators and end-users to identify capability gaps, connect them with the right innovators and solutions from laboratories, small and large businesses, universities, and international partners.

Last year, as part of a Unity of Effort initiative, the Secretary directed S&T to launch Departmental integrated product teams, or IPTs. These represent a formal mechanism for identifying technology capability gaps across the Department's mission areas. In the past 6 months, S&T and its operational partners have served 5 of these teams. Together, they have validated on-going research and development activities and prioritized project topics in IPT mission areas.

The ultimate result of the IPT process will be improved coordination of DHS research and development and assurance that identified technology solutions address component mission needs.

The biological threat IPT was 1 of 5 specifically called for by the Secretary and tasked with identifying priority capability gaps in biodefense as well as research and development efforts to address those gaps.

One of S&T's most important partners in this area is Dr. Brinsfield and the Office of Health Affairs. Our current collabora-

tion is on an enhancement effort for BioWatch. It will spur both near- and long-term development and delivery of technology improvements to essential BioWatch and National Biosurveillance Integration Center programs.

Another aspect worthy of recognition is demand for collaboration and cooperation in biodefense work.

Unlike many challenges the Federal Government faces that tend to isolate with a specific lead agency, biodefense is almost uniquely interagency and intergovernmental and involves an addition of State and local public health workers, the Departments of Agriculture, Defense, Health and Human Services, Homeland Security, and Justice.

While the agencies have specific equities, holistic success against biological threats requires a cooperative, collaborative environment.

Biodefense research and development by its nature also serves a broad group of stakeholders. In addition to co-managing a laboratory, S&T works with USDA on programs dedicated to the protection of livestock from foreign animal diseases.

In partnership with the intelligence community, we support acquisition of medical countermeasures by the Department of Health and Human Services as required by the Bioshield Act of 2004.

We partner with the Centers for Disease Control and Prevention on bioassay and diagnostic development, detection and rapid identification of bioagents during a biological attack.

We jointly run biological forensics programs with the FBI to enable surveillance, investigation, and prosecution of criminal elements seeking to harm citizens.

We work with several major city-level transit authorities and the EPA on remediation technology for public transportation systems in the event of a large-scale biological attack.

Homeland security in this area involves much more than DHS, as successful research and development is determined by how well we work with the entire community. DHS cannot and should not do this alone. Protecting our Nation from a biological attack is a joint effort. We are working across Government with partners like DOD to share information, build upon successes and lessons learned, and leverage resources whenever possible.

Although civilian and military missions are distinct, information gained and investment made in each informs and improves the other.

This rich union of effort, regardless of agency or level of Government, calls on mission owners to do their part to protect citizens from biological threats. That is where S&T is focused in all of our research and development projects in this area.

Thank you for your time time today and I look forward to your questions.

Ms. MCSALLY. Thank you, Dr. Brothers.

The Chair now recognizes Mr. Currie, for 5 minutes.

STATEMENT OF CHRIS P. CURRIE, DIRECTOR, EMERGENCY MANAGEMENT, NATIONAL PREPAREDNESS AND CRITICAL INFRASTRUCTURE PROTECTION, HOMELAND SECURITY AND JUSTICE TEAM, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. CURRIE. Thank you, Chairman McSally and Ranking Member Thompson. It is an honor to be here.

Today I would like to discuss GAO's work on some of DHS's most critical biosurveillance programs.

For almost a decade, we have evaluated DHS's efforts to implement BioWatch and the National Biosurveillance Integration Center, or NBIC.

Regarding BioWatch, this committee is well aware of the DHS acquisition challenges in implementing the Next Gen or Gen–3 system, and the decision to cancel the program in 2014. However, without Gen–3 to replace it, new questions were raised about how well the current system works.

Our report last October found that 12 years after the system was first deployed, DHS does not have reliable information about its capabilities, mainly because it was put in the field so quickly without performance requirements.

We also found that because the capabilities of the system were not fully tested, its uncertainties and limitations are not fully known.

Now, some may ask why this is important now since Gen–3 was canceled and the system has been in place for over a decade. It is important because right now DHS is considering improvements based on unknown capabilities of an aging system.

The next logical question is, what do we do about it now? So, we made a number of recommendations that we think are critical to any investments in the existing or future system.

First, we recommended that DHS not pursue upgrades to the system until it establishes performance requirements and tests against those requirements.

No. 2, we recommended that they fully account for any uncertainties and limitations in the system.

Last, that they incorporate best practices in any future developmental testing or upgrades to the existing or new system.

Let me now switch to NBIC. Since our 2009 report, the folks at NBIC have implemented all of our recommendations for strengthening collaboration and overcoming various challenges.

For example, they developed new products to communicate disease outbreaks to their Federal biosurveillance partners, like CDC and the Agriculture Department. However, late last year, we reported that persistent challenges still get in the way of it fully meeting the mission that you all set out for it.

For example, most of the primary Federal partners told us that NBIC's products and activities did not always add value, did not provide new meaning or did not help them identify biological events quicker. We also found that NBIC has difficulty getting the data it needs because partners won't share it or there are restrictions to sharing it.

These challenges are not easy to address, particularly by DHS or NBIC alone. We identified options for policy or structural changes

to help NBIC better fulfill its mission. These options ranged all the way from repealing NBIC's statute, all the way to providing NBIC with additional authority to better fulfill its mission.

Each option has benefits and limitations and funding implications and they are not easy. For example, granting NBIC access to more data did help them conduct additional analysis, but may not identify emerging threats earlier than they or other agencies can do now.

I want to wrap up by making a few broader points and connections. BioWatch and NBIC are critical programs; however, they are only pieces of a larger biosurveillance enterprise that Dr. Brothers mentioned.

As we and others, like the Blue Ribbon Panel, have pointed out, investments in these programs should be evaluated in terms of cost and benefit and compared to other programs across the Government as part of a National strategic plan.

Also critical is using the most recent threat information to guide decision making about these investments. For example, BioWatch is intended to detect a large, airborne bioattack. This threat must be weighed against other threats we now face, such as natural disease outbreaks, like Zika and Ebola.

Last, as you know, DHS is planning to merge OHA, pieces of S&T, with other parts of DHS into a new chem/bio rad nuke office. So, this will also impact these programs and DHS's role moving forward.

This completes my statement. I would be happy to answer any questions you have.

[The prepared statement of Mr. Currie follows:]

STATEMENT OF CHRIS P. CURRIE

FEBRUARY 11, 2016

GAO HIGHLIGHTS

Highlights of GAO–16–413T, a testimony before the Subcommittee on Emergency Preparedness, Response, and Communications; Committee on Homeland Security, House of Representatives.

Why GAO Did This Study

The potential threat of a naturally occurring pandemic or a terrorist attack with a biological weapon of mass destruction underscores the importance of a National biosurveillance capability—that is, the ability to detect biological events of National significance to provide early warning and information to guide public health and emergency response. The Implementing Recommendations of the 9/11 Commission Act of 2007 addresses this capability, in part by creating NBIC. The center was tasked with integrating information from human health, animal, plant, food, and environmental monitoring systems across the Federal Government, to improve the likelihood of identifying a biological event at an earlier stage. Similarly, DHS's BioWatch program aims to provide early indication of an aerosolized biological weapon attack.

GAO has published a series of reports on biosurveillance efforts spanning more than a decade. This statement describes progress and challenges GAO has reported in DHS's implementation of NBIC and BioWatch and considerations for the future of biosurveillance efforts at DHS.

This testimony is based on previous GAO reports issued from December 2009 through September 2015 related to biosurveillance. To conduct our prior work, we reviewed relevant Presidential directives, laws, policies, and strategic plans; and interviewed Federal, State, and industry officials, among others. We also analyzed key program documents, including test plans, test results, and modeling studies.

BIOSURVEILLANCE.—ON-GOING CHALLENGES AND FUTURE CONSIDERATIONS FOR DHS BIOSURVEILLANCE EFFORTS

What GAO Found

Since 2009, GAO has reported on progress and challenges with 2 of the Department of Homeland Security's (DHS) biosurveillance efforts—the National Biosurveillance Integration Center (NBIC) and the BioWatch program (designed to provide early detection of an aerosolized biological attack). In December 2009, GAO reported that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel—from its partner agencies, which may have been at least partially the result of collaboration challenges it faced. For example, some partners reported that they did not trust NBIC to use their information and resources appropriately, while others were not convinced of the value that working with NBIC provided because NBIC's mission was not clearly articulated. GAO recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. DHS agreed, and in August 2012, NBIC issued the NBIC Strategic Plan, which is intended to provide NBIC's strategic vision, clarify the center's mission and purpose, and articulate the value that NBIC seeks to provide to its partners, among other things. In September 2015, GAO reported that despite NBIC's efforts to collaborate with interagency partners to create and issue a strategic plan that would clarify its mission and the various efforts to fulfill its 3 roles—analyzer, coordinator, and innovator—a variety of challenges remained when GAO surveyed NBIC's interagency partners in 2015. Notably, many of these partners continued to express uncertainty about the value NBIC provided. GAO identified options for policy or structural changes that could help NBIC better fulfill its biosurveillance integration mission, such as changes to NBIC's roles.

Since 2012, GAO has reported that DHS has faced challenges in clearly justifying the need for the BioWatch program and its ability to reliably address that need (to detect attacks). In September 2012, GAO found that DHS approved a next-generation BioWatch acquisition in October 2009 without fully developing knowledge that would help ensure sound investment decision making and pursuit of optimal solutions. GAO recommended that before continuing the acquisition, DHS reevaluate the mission need and possible alternatives based on cost-benefit and risk information. DHS concurred and in April 2014, canceled the acquisition because an alternatives analysis did not confirm an overwhelming benefit to justify the cost. Having canceled the next generation acquisition, DHS continues to rely on the currently deployed BioWatch system for early detection of an aerosolized biological attack. However, in 2015, GAO found that DHS lacks reliable information about the current system's technical capabilities to detect a biological attack, in part because in the 12 years since BioWatch's initial deployment, DHS has not developed technical performance requirements for the system. GAO reported in September 2015 that DHS commissioned tests of the current system's technical performance characteristics, but without performance requirements, DHS cannot interpret the test results and draw conclusions about the system's ability to detect attacks. DHS is considering upgrades to the current system, but GAO recommended that DHS not pursue upgrades until it establishes technical performance requirements to meet a clearly defined operational objective and assesses the system against these performance requirements. DHS concurred and is working to address the recommendation.

Chairman McSally, Ranking Member Payne, and Members of the subcommittee: I am pleased to be here today to discuss our work on the Department of Homeland Security's (DHS) biosurveillance efforts. Biosurveillance, as defined by the July 2012 National Strategy for Biosurveillance, is the on-going process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health, for the purpose of: (1) Achieving early detection and warning, (2) contributing to overall situational awareness of the health aspects of the incident, and (3) enabling better decision making at all levels.

Threats of bioterrorism, such as anthrax attacks, and high-profile disease outbreaks, such as Ebola in West Africa and emerging arboviruses like chikungunya and zika in the Americas, highlight the continued need for systems that provide early detection and warning about biological threats.[1] We have an on-going body of biosurveillance work spanning more than a decade in which we have examined specific surveillance programs and activities carried out by DHS; the Departments of

[1] Arthropod-borne viruses (arboviruses) are transmitted to humans primarily through the bites of infected mosquitoes and ticks.

Health and Human Services; Agriculture; and several other Federal departments and agencies.[2]

We have also identified broad, cross-cutting issues in leadership, coordination, and collaboration that arise from working across the complex interagency, intergovernmental, and intersectoral biosurveillance enterprise. To address these issues, in 2010 we made recommendations that the Homeland Security Council direct the National Security Council staff to identify a focal point to lead the development of a National biosurveillance strategy that would, among other things: (1) Define the scope and purpose of a National capability; (2) provide goals, objectives and activities, priorities, milestones, and performance measures; and (3) assess the costs and benefits and identify resource and investment needs, including investment priorities.[3] In July 2012, the White House released the *National Strategy for Biosurveillance* to describe the U.S. Government's approach to strengthening biosurveillance, but it did not fully meet the intent of our prior recommendations, because it did not offer a mechanism to identify resource and investment needs, including investment priorities among various biosurveillance efforts.[4]

In 2014, a Blue Ribbon Study Panel on Biodefense was established to assess gaps and provide recommendations to improve U.S. biodefense. The panel's October 2015 final report identified several themes we have also highlighted in our biosurveillance work, including the lack of a centralized leader, no comprehensive National strategic plan, and no all-inclusive dedicated budget for biodefense. The panel's report highlights a sense of urgency to address the on-going and persistent biological threats—both naturally occurring, like Ebola and zika, and from enemies, like The Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) who have advocated for the use of biological weapons.

While consequences of a biologic event could be catastrophic, we have also previously reported that because the Nation cannot afford to protect everything against all threats, choices must be made about protection priorities given the risk and how to best allocate available resources.[5] As we testified before this committee in 2012, without a National strategy that provides a framework and tool set to evaluate trade-offs, it remains difficult for decision makers—in both the Executive and Legislative branches—to help ensure that biosurveillance resource allocation decisions within single departments and programs contribute to a coherent enterprise-wide approach.[6]

Nevertheless, challenges we have reported in 2 of DHS's specific biosurveillance efforts—the National Biosurveillance Integration Center (NBIC) and the BioWatch program—demonstrate the importance of following Departmental policies and employing leading management practices to help ensure that the mission of each program is clearly and purposefully defined and that subsequent investments effectively respond to those missions. NBIC, which was created to integrate data across the Federal Government with the aim of enhancing detection and situational awareness of biological events, has suffered from long-standing issues related to its clarity of purpose. Likewise, the BioWatch program, which is designed to detect bioterrorism attacks with specific aerosolized pathogens, has encountered challenges that

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[2] See, for example, GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts,* GAO–04–877 (Washington, DC: Sept. 30, 2004), which discusses select Federal and non-Federal human disease surveillance in humans; GAO, *Global Health: U.S. Agencies Support Programs to Build Overseas Capacity for Infectious Disease Surveillance,* GAO–07–1186 (Washington, DC: Sept. 28, 2007), which discusses 4 key programs aimed at building overseas surveillance capacity for infectious diseases in humans; and GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry,* GAO–13–424 (Washington, DC: May 21, 2013), which discusses the Department of Agriculture's efforts to better detect and control new or reemerging diseases in animals.

[3] GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader,* GAO–10–645 (Washington, DC: June 30, 2010). See also, GAO, *Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy,* GAO–12–55 (Washington, DC: Oct. 31, 2011), in which we recommended that the strategy also: (1) Incorporate a means to leverage existing efforts that support non-Federal biosurveillance capabilities, (2) consider challenges that non-Federal jurisdictions face in building and maintaining biosurveillance capabilities, and (3) include a framework to develop a baseline and gap assessment of non-Federal jurisdictions' biosurveillance capabilities.

[4] The National Security Council staff has since created an implementation plan for the National strategy. However, it is not yet clear the extent to which the plan has been widely shared among and adopted by interagency decision makers as a means to help identify opportunities to leverage resources and direct priorities.

[5] GAO, *21st Century Challenges: Reexamining the Base of the Federal Government,* GAO–05–325SP (Washington, DC: Feb. 1, 2005).

[6] GAO, *Biosurveillance: Observations on BioWatch Generation–3 and Other Federal Efforts,* GAO–12–994T (Washington, DC, Sept. 2012).

stem from not precisely defining the need its technologies should fill and how the technologies it pursued (and in some cases developed and deployed) responded to that need.

Finally, DHS is currently at a crossroads for decisions regarding not only NBIC and BioWatch, but also where these efforts fall within DHS's broader Chemical, Biological, Radiological, and Nuclear (CBRNE) programs. In June 2015, DHS provided Congress a report summarizing its review of the organization, operations, and communications of its Chemical, Biological, Radiological, and Nuclear programs and proposed merging 6 CBRNE-related organizational components into 1 unit.[7] This provides an opportunity for DHS to look strategically at its biosurveillance efforts.

This statement describes progress and challenges we have reported in DHS's implementation of NBIC and BioWatch and considerations for the future of these biosurveillance efforts at DHS. Our statement is based on our prior work issued from December 2009 through October 2015 on various biosurveillance efforts.[8] The work upon which this testimony is based was conducted in accordance with generally accepted Government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. To conduct this prior work, we reviewed relevant Presidential directives, laws, regulations, policies, and strategic plans; surveyed States; and interviewed Federal, State, and industry officials, among others. We also analyzed key program documents, including test plans, test results, and modeling studies. More information on our scope and methodology can be found in each of the reports cited throughout this statement.

BACKGROUND

DHS's Biosurveillance Roles and Responsibilities

According to DHS's 2014 Quadrennial Homeland Security Review (QHSR), biological threats and hazards—ranging from bioterrorism to naturally-occurring pandemics—are a top homeland security risk. The QHSR acknowledges that numerous departments and agencies at the Federal, State, local, Tribal, and territorial levels, as well as the private sector, contribute to the National effort to address biological threats and hazards. As such, according to the QHSR, DHS aims to focus on those activities and responsibilities assigned to it through statute or Presidential directive. Among the identified activities and responsibilities is one that is specific to biosurveillance—biosurveillance integration and detection—and others that can help to support efficient and effective biosurveillance action, such as information sharing and analysis, threat and risk awareness, and technical forensic analysis to support attribution.

NBIC

The Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) established the National Biosurveillance Integration Center (NBIC) within DHS.[9] NBIC was specifically tasked with integrating and analyzing information from human health, animal, plant, food, and environmental monitoring systems across the Federal Government and supporting the interagency biosurveillance community. As defined in the July 2012 NBIC Strategic Plan, integration involves combining biosurveillance information from different sources and domains (e.g., human, animal, and plant health; food and environmental safety and security; and homeland security) to provide partners and stakeholders with a synthesized view of the information, and what it could mean. Primary goals of integration in-

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[7] The Senate explanatory statement accompanying the Consolidated and Further Continuing Appropriations Act, 2013, directed DHS to conduct a review and to provide a report of the results. On December 10, 2016, the Department of Homeland Security CBRNE Defense Act of 2015, which would establish a CBRNE Office within DHS, was passed by the House of Representatives. H.R. 3875 (114th Cong.).

[8] GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing,* GAO–10–171 (Washington, DC: Dec. 18, 2009); GAO, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives Before Proceeding with BioWatch Generation–3 Acquisition,* GAO–12–810 (Washington, DC: Sept. 10, 2012); GAO, *Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center,* GAO–15–793 (Washington, DC: Sept. 24, 2015); GAO, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established,* GAO–16–99 (Washington, DC: Oct. 23, 2015).

[9] 6 U.S.C. § 195b.

clude creating a common picture or understanding of potential and on-going biological events and providing insights that cannot be gleaned in isolation.

The 9/11 Commission Act outlines certain requirements for NBIC. Drawing upon these requirements as well as the NBIC Strategic Plan, we identified 3 main roles that NBIC, as a Federal-level biosurveillance integrator, must carry out to achieve the duties and outcomes described by NBIC's authorizing legislation.[10] Senior NBIC officials agreed that these 3 roles—analyzer, coordinator, and innovator—are consistent with the center's responsibilities. These roles are not mutually exclusive and can reinforce one other. For example, NBIC's efforts as an Innovator might result in the development of data that could enhance its role as an analyzer by providing the center with another dataset to review. The biosurveillance integrators' roles we identified:

- *Analyzer*.—Use technological tools and subject-matter expertise to develop shared situational awareness by creating meaningful new insights from disparate datasets and information that could not be gleaned in isolation.
- *Coordinator*.—Bring together multi-disciplinary partners across interagency organizations to enhance understanding of new or potential biological events, such as through the collaborative development of products and services.
- *Innovator*.—Facilitate the development of new tools, technology, and approaches to address gaps in biosurveillance integration.

BioWatch

According to Homeland Security Presidential Directive 10 (HSPD–10): *Biodefense for the 21st Century,* a National bioawareness capability providing early warning, detection, or recognition of a biological weapon attack is an essential component of biodefense.[11] To contribute to this National capability, in 2003, DHS created the BioWatch program to provide early warning, detection, or recognition of a biological attack. The BioWatch program uses routine laboratory testing designed to detect an aerosolized biological attack for 5 specific biological agents considered high-risk for use as biological weapons. When DHS was established in 2002, a perceived urgency to deploy useful—even if immature—technologies in the face of potentially catastrophic consequences catalyzed the rapid deployment of many technologies. DHS completed the initial deployment of BioWatch quickly—within 80 days of the President's announcement of the BioWatch program in his 2003 State of the Union Address.[12] In 2005, DHS expanded BioWatch to an additional 10 jurisdictions, for a total of more than 30. The expanded deployment—referred to as Generation 2 (Gen–2)—also included the addition of indoor monitoring capabilities in 3 high-threat jurisdictions and provided additional capacity for events of National significance, such as major sporting events and political conventions.

In 2015, we reported that the BioWatch program collaborates with more than 30 BioWatch jurisdictions throughout the Nation to operate approximately 600 Gen–2 aerosol collectors. These units rely on a vacuum-based collection system that draws air through a filter. These filters are manually collected and transported to State and local public health laboratories for analysis. Using this manual process, a result can be generated from 12 to 36 hours after an agent is initially captured by the aerosol collection unit.

To reduce detection time, DHS began to develop an autonomous detection capability in 2003 for the BioWatch program—known as Generation 3 (Gen–3).[13] Envisioned as a laboratory-in-a-box, the autonomous detection system would automatically collect air samples, conduct analysis to detect the presence of biothreat agents every 4 to 6 hours, and communicate the results to public health officials via an electronic network without manual intervention. By automating the analysis, DHS anticipated that detection time could be reduced to 6 hours or less, making the technology more appropriate for monitoring indoor high-occupancy facilities such as transportation nodes and enabling a more rapid response to an attack. DHS also anticipated a reduction in operational costs by eliminating the program's daily manual sample retrieval and laboratory analysis. However, as we reported in 2015, the Gen–3 acquisition was canceled in April 2014, after testing difficulties and after an analysis of alternatives was interpreted by DHS as showing that any advantages

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[10] GAO–15–793.

[11] HSPD–10: Biodefense for the 21st Century (Washington, DC, April 2004).

[12] In the initial deployment of BioWatch—known as Generation–1—DHS deployed aerosol collectors to 20 major metropolitan areas, known as BioWatch jurisdictions, to monitor primarily outdoor spaces.

[13] Initially, DHS's Science & Technology Directorate, partnering with industry, led the development of technologies to support autonomous detection. DHS's Office of Health Affairs has had responsibility for overseeing the acquisition of this technology since fiscal year 2007.

of an autonomous system over the current manual system were insufficient to justify the cost of a full technology switch.

DHS HAS FACED CHALLENGES, SOME PERSISTENT, IN ITS EFFORTS TO CARRY OUT BIOSURVEILLANCE PROGRAMS

NBIC Has Faced Difficulty Demonstrating Value to Interagency Partners

In December 2009, we reported that NBIC was not fully equipped to carry out its mission because it lacked key resources—data and personnel—from its partner agencies, which may have been at least partially the result of collaboration challenges it faced. For example, some partners reported that they did not trust NBIC to use their information and resources appropriately, while others were not convinced of the value that working with NBIC provided because NBIC's mission was not clearly articulated.

In order to help NBIC enhance and sustain collaboration, including the provision of data, personnel, and other resources, in 2009, we recommended that NBIC develop a strategy for addressing barriers to collaboration and develop accountability mechanisms to monitor these efforts. In August 2012, NBIC issued the NBIC Strategic Plan, which is intended to provide NBIC's strategic vision, clarify the center's mission and purpose, articulate the value that NBIC seeks to provide to its partners, and lay the groundwork for setting interagency roles, responsibilities, and procedures. Further, in November 2014, NBIC completed its first biannual NBIC Federal Stakeholder Survey, which NBIC uses to assess the usefulness of its products and activities and to determine what improvements should be made on the basis of those results. We believe DHS's actions addressed the recommendations in our December 2009 report.

In September 2015, we reported that NBIC had actions and activities underway to fulfill all 3 of the roles we identified as essential to its ability to carry out its mission—analyzer, coordinator, and integrator. For example, to fulfill its analyzer role NBIC compiled information to create and circulate a variety of products to support disease outbreak monitoring on a daily, weekly, or period basis. Similarly, in its coordinator role, NBIC had put in place a variety of procedures and protocols to convene partners on a routine basis or in response to specific emerging events. Finally, in its innovator role NBIC had efforts to conduct gap analyses, fund pilot projects that aim to develop new biosurveillance tools and technology (such as examining the use of social media data to identify health trends), sought new sources of data and information, and made efforts to enhance its internal IT system.

Although NBIC had made efforts to collaborate with interagency partners to create and issue a strategic plan that would clarify its mission and the various efforts to fulfill its 3 roles, we reported a variety of challenges that remained when we surveyed NBIC's interagency partners for our 2015 report. Notably, many of these partners continued to express uncertainty about the value NBIC provided. Specifically, 10 of 19 partners stated that NBIC's products and activities enhance their agencies' ability to carry out their biosurveillance roles and responsibilities to little or no extent, 4 responded to a moderate extent, and 5 responded that they did not have a basis to judge.[14] Generally, partners that responded to little or no extent noted that NBIC products and activities do not, for example, identify trends and patterns or describe potential impacts of a biological event. For instance, one official stated that NBIC's products and activities do not "connect the dots" between dissimilar information, provide novel synthesis of information, or recommend possible courses of action. Moreover, most of the Federal partners with key roles in biosurveillance (8 of 11) stated that NBIC's products help their agencies identify biological events to little or no extent, generally because they already obtain such information directly from other Federal partners more quickly.

We also found in 2015, as in 2009, that a variety of challenges limited the extent to which Federal agencies shared data and personnel with NBIC, as envisioned by the 9/11 Commission Act. First, data that NBIC could use to identify and characterize a biological event of National concern using statistical and analytical tools, as called for in the 9/11 Commission Act, are limited. Also, apart from searches of global news reports and other publically-available reports generated by National

[14] Generally, these 5 partners stated that they did not have a basis to judge because they are biosurveillance information consumers or they considered their role in biosurveillance to be relatively small.

Biosurveillance Integration System (NBIS) partners,[15] NBIC has been unable to secure streams of raw data from multiple domains across the biosurveillance enterprise that would lend themselves to near-time quantitative analysis that could reveal unusual patterns and trends.[16]

Moreover, we found that Few federal partners (5 of 19) reported that they share the data they do have with NBIC, citing legal and regulatory restrictions, among other reasons. Some agencies are reluctant to share their data with NBIC because they are unsure how the information will be used. For example, one official explained that the agency does not share some data with NBIC because sharing such information too broadly might have substantial implications on agricultural trade or public perception of safety. Officials from another agency noted that there is sometimes reticence to share information and data with components of DHS because, given the Department's roles in law enforcement and National security, the information might be shared outside of the health security community in a way that lacks appropriate context and perspective. Finally, other agencies stated that they are unable to share data for regulatory or legal reasons, or because appropriately protecting the data would take too long.[17] Similarly, although NBIC would like to obtain liaisons from each of its Federal partners, only 3 of 19 partners provided NBIC with dedicated liaisons. Officials from one agency with key biosurveillance responsibilities stated that it is difficult to provide personnel to NBIC on a full- or part-time basis because of resource constraints. Further, officials from another agency noted that the lack of clarity about NBIC's value to its partners is a barrier to providing the center with detailees. We also reported in September 2015 that NBIC faces challenges prioritizing developmental efforts to identify and address needs for new biosurveillance tools. For example, partners noted limitations in NBIC's ability to address gaps, like limited resources and the difficulty in prioritizing the center's innovation efforts because its partners have diverse needs.

Multiple Structural and Policy Considerations Could Help Focus NBIC's Efforts

NBIC officials stated that the center is working to improve its products and its ability to contextualize the information it collects from open sources, and has sought partner input to do so. For example, beginning in late June 2015, partly on the basis of feedback the center received from its November 2014 Federal Stakeholder Survey, NBIC modified its daily Monitoring List to include an up-front summary that identifies the status of on-going biological events as worsening, improving, unchanged, or undetermined. Further, NBIC officials noted that the center is also working to better integrate forecasts and projections into its products and activities by collaborating with others and developing a common interagency vision for specific Federal capabilities and practical next steps leading to the application of reliable infectious disease forecasting models in decision-making processes.

Nevertheless, a persistent challenge NBIC faces is skepticism on the part of some of the NBIS partners regarding the value of the Federal biosurveillance mission as well as NBIC's role in that mission. In our 2009 report, most of the NBIS partners we interviewed at that time expressed uncertainty about the value of participating in the NBIS or confusion about the purpose of NBIC's mission. In September 2015, the NBIS partners and other major stakeholders in the biosurveillance community acknowledged—and we agreed—that no single problem limits NBIC's mission to in-

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[15] The NBIS is a consortium of Federal partners that was established to rapidly identify and monitor biological events of National concern and to collect; analyze; and share human, animal, plant, food, and environmental biosurveillance information with NBIC.

[16] NBIC acknowledged in its strategic plan that the data required to carry out its mission as envisioned in the 9/11 Commission Act either do not exist or are subject to a variety of information-sharing challenges that make a large information technology-centered solution less feasible than originally imagined. Additionally, NBIC and NBIS partners noted that there were several kinds of data that could be useful for this kind of biosurveillance integration, but these data may not exist or may not be in a usable form, such as real-time data on water quality and contamination from drinking water utilities and data on wildlife disease, which makes it difficult to fully understand the dynamics of zoonotic diseases. NBIC officials also noted that other kinds of data are maintained in formats that make them difficult to analyze, such as paper health records.

[17] For example, according to Centers for Disease Control and Prevention (CDC) officials, their agency receives electronic data from State, territorial, local, and Tribal sources for a variety of programs and purposes that are covered by data-use agreements that do not allow CDC to share the data outside the terms of those agreements and as allowed or required by applicable Federal laws, such as the Privacy Act of 1974 and the Freedom of Information Act, 5 U.S.C. § 552a; 552. CDC officials said of the data they can share, it would take extensive, time-consuming work to appropriately redact the data to ensure that individuals may not be identified and that privacy is protected, which results in the release of the data being postponed to the point that the data are no longer actionable.

tegrate biosurveillance data. Rather, over the years, several long-standing problems have combined to inhibit the achievement of this mission as envisioned in the 9/11 Commission Act. We identified options in our 2015 report for policy or structural changes that could help better fulfill the biosurveillance integration mission, which are summarized below. We identified these options and their benefits and limitations, on the basis of the roles of a Federal-level biosurveillance integrator we identified in the 9/11 Commission Act, NBIC's strategic plan, and the perspectives of the NBIS partners obtained during our structured interviews. These options are not exhaustive, and some options could be implemented together or in part.[18]

[18] In developing these options, we did not evaluate the financial implications of implementing each option, to the extent they are knowable, but we acknowledge they are likely to result in an increase, decrease, or shifting of funding based on the changes described.

TABLE 1.—BENEFITS AND CHALLENGES OF OPTIONS FOR POLICY OR STRUCTURAL CHANGES FOR THE NATIONAL BIOSURVEILLANCE INTEGRATION CENTER (NBIC)

Option	Description	Benefits	Challenges
Reinforce NBIC's Analyzer Role	Under this option, NBIC would be provided with new authorities and resources designed to access additional public and private data sources and statistical and modeling tools to develop meaningful information.	Developing meaningful information not otherwise available. Capitalize on new data sources and analysis techniques.	Uncertainty in knowing whether an event would be detected more quickly by overlaying various data streams and applying statistical and analytical tools to them. There may not be a significant amount of meaningful data available that is not already being provided to facilitate advanced analytical techniques. The concept of whether a Federal biosurveillance integrator would be able to identify patterns or connections that would lead to earlier warning of emerging events is unproven. Unknown impact of earlier detection. Increased costs.
Strengthen NBIC's Coordinator Role.	Under this option, NBIC would be provided with greater authority for coordinating the Federal biosurveillance enterprise.	This option would create clear leadership across the interagency. Better institutional connection .... Routine, institutionalized channels to monitor for emerging trends and patterns. Enhanced accountability for implementing the *National Strategy for Biosurveillance*.	Some of these responsibilities overlap with responsibilities that have historically been the purview of the National Security Council staff. It may be difficult for an agency at NBIC's level to successfully influence decision making across the interagency.

Expand NBIC's Innovator Role	Under this option, NBIC would be provided with new authorities and resources to lead research and development investments of new tools and technology that would address gaps across the biosurveillance community.	NBIC could foster the development of tools and technology that benefit multiple Federal partners and other members of the National Biosurveillance Integration System (NBIS). Coordinate research and development efforts.	Increased costs. A National integrator that focuses on innovation would likely need to acquire more expertise in research and development. Focusing attention on this role may represent a significant mission shift from the status quo, and may require very different sets of resources and procedures.
Continue to Execute the *2012 NBIC Strategic Plan*.	In this option, NBIC would continue to implement the mission, goals, and objectives detailed in the August 2012 NBIC Strategic Plan or subsequent NBIS-approved updates.	NBIC has made progress in this area and may continue to do so. Some agencies currently find value in NBIC's products.	NBIC will likely continue to face challenges in obtaining all the biosurveillance data it needs. Partners remain skeptical of NBIC's value.
Repeal the NBIC Statute	In this option, National biosurveillance integration would not be pursued through NBIC.	The cost of operating NBIC may not be worth its benefits.	Although Federal partners generally thought that NBIC's products and activities did not provide meaningful new information, they largely thought that the concept of having a Federal entity to integrate biosurveillance information across the Federal Government was important. Defunding NBIC could create a loss of investment, institutional learning, and progress made toward developing a Federal biosurveillance integrator. Another integrator may experience similar challenges.

Source: GAO analysis of DHS information. GAO–16–413T

BioWatch's Ability to Detect Attacks Uncertain Because It Lacks Performance Requirements That Correspond to a Clearly Defined Mission

Since 2003, DHS has focused on acquiring an autonomous detection system to replace the current BioWatch Gen–2, but has faced challenges in clearly justifying the BioWatch program's need and ability to reliably address that need. In September 2012, we found that DHS approved the Gen–3 acquisition in October 2009 without fully developing critical knowledge that would help ensure sound investment decision making, pursuit of optimal solutions, and reliable performance, cost, and schedule information. Specifically, we found that DHS did not engage the early phases of its Acquisition Life-cycle Framework, which is designed to help ensure that the mission need driving the acquisition warrants investment of limited resources and that an analysis of alternatives (AoA) systematically identifies possible alternative solutions that could satisfy the identified need. BioWatch officials stated that they were aware that the Mission Needs Statement prepared in October 2009 did not reflect a systematic effort to justify a capability need, but stated that the Department directed them to proceed because there was already Departmental consensus around the solution. However, we found that the AoA prepared for the Gen–3 acquisition did not reflect a systematic decision-making process. As with the Mission Needs Statement, program officials told us that they were advised that a comprehensive AoA would not be necessary because there was already Departmental consensus that autonomous detection was the optimal solution. Because the Gen–3 AoA did not evaluate a complete solution set, consider complete information on cost and benefits, and include a cost-benefit analysis, we concluded that it did not provide information on which to base trade-off decisions.

To help ensure DHS based its acquisition decisions on reliable performance, cost, and schedule information developed in accordance with guidance and good practices, in our September 2012 report, we recommended that before continuing the Gen–3 acquisition, DHS reevaluate the mission need and possible alternatives based on cost-benefit and risk information. DHS concurred with the recommendation and in 2012, DHS directed the BioWatch program to complete an updated AoA.[19] In April 2014, DHS canceled the acquisition of Gen–3 because the AoA did not confirm an overwhelming benefit to justify the cost of a full technology switch to Gen–3.

Having canceled the Gen–3 acquisition, DHS continues to rely on the Gen–2 system for early detection of an aerosolized biological attack. However, we found DHS lacks reliable information about BioWatch Gen–2's technical capabilities to detect a biological attack, in part, because in the 12 years since BioWatch's initial deployment, DHS has not developed technical performance requirements for Gen–2. We reported in 2015 that BioWatch has been criticized because it was deployed quickly in 2003 to address a perceived urgent need, but without sufficient testing, validation, and evaluation of its technical capabilities.[20] In 2015, we reported that DHS officials said that the system can detect catastrophic attacks, which they define as attacks large enough to cause 10,000 casualties. DHS has commissioned tests of Gen–2's technical performance characteristics, but DHS has not developed performance requirements that would enable it to interpret the test results and draw conclusions about the system's ability to detect attacks.[21] According to DHS guidance and standard practice in testing and evaluation of defense systems, in order to assess Gen–2's capability to detect a biological attack, DHS would have to link test results to its conclusions about the deployed detectors' ability to detect attacks in BioWatch operational environments. This would ordinarily be done by developing and validating technical performance requirements based on operational objectives, but DHS has not developed such requirements for Gen–2.

In the absence of technical performance requirements, DHS officials said their assertion that the system can detect catastrophic attacks is supported by modeling and simulation studies. However, we found none of these studies were designed to incorporate test results from the Gen–2 system and comprehensively assess the system against the stated operational objective. The modeling and simulation studies were designed for purposes other than to directly and comprehensively assess Gen–

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[19] DHS contracted with the Institute for Defense Analyses to conduct the updated AoA, which they issued in December 2013.

[20] GAO–16–99. See also Institute of Medicine and National Research Council, BioWatch and Public Health Surveillance (Washington, DC: National Academies Press, 2011).

[21] In addition to these tests, DHS commissioned a demonstration of the system in an outdoor environment and conducts quality assurance tests on an ongoing basis. Both of these provide additional information about the system's capabilities; however, we do not include them in our list of key tests because neither was designed to produce estimates of key performance characteristics, including sensitivity, or to support conclusions about the types and sizes of attack the system can reliably detect.

2's operational capabilities. For example, one set of modeling and simulation studies, conducted by Sandia National Laboratories (Sandia) in collaboration with other National laboratories, did not incorporate information about the actual locations of Gen–2 collector units, because they were designed to model hypothetical BioWatch deployments in which collectors were placed in optimal locations. Sandia also analyzed ranges of hypothetical system sensitivities rather than incorporating the test results on the performance characteristics of Gen–2. Therefore, these studies drew no conclusions about the actual capabilities of the deployed Gen–2 system.[22] DHS officials also described modeling and simulation work that used a measure of operational capability that does not directly support conclusions about the BioWatch objective of detecting attacks large enough to cause 10,000 casualties.[23]

Additionally, we found that because none of the modeling and simulation work was designed to interpret Gen–2 test results and comprehensively assess the capabilities of the Gen–2 system, none of these studies has provided a full accounting of statistical and other uncertainties—meaning decision makers have no means of understanding the precision or confidence in what is known about system capabilities.[24] Because it is not possible to test the BioWatch system directly by releasing live biothreat agents into the air in operational environments, limitations of the tests described earlier limit the applicability of the results and underscore the need for a full accounting of statistical and other uncertainties, without which decision makers lack a full understanding of the Gen–2 system's capability to detect attacks of defined types and sizes.

Understanding BioWatch's Current Capabilities Could Help Inform Future Biodetection Investments

At the time DHS canceled the Gen–3 acquisition, it also announced that S&T will explore development and maturation of an effective and affordable automated aerosol biodetection capability, or other operational enhancements, that meet the operational requirements of the BioWatch system. As such, DHS officials told us they are considering potential improvements or upgrades to the Gen–2 system. However, because DHS lacks reliable information about Gen–2's technical capabilities, decision makers are not assured of having sufficient information to ensure future investments are actually addressing a capability gap not met by the current system. Also, because DHS lacks targets for the current system's performance characteristics, including limits of detection, that would enable conclusions about the system's ability to detect attacks of defined types and sizes with specified probabilities, it cannot ensure it has complete information to make decisions about upgrades or enhancements.

In our September 2015 report, to help ensure that biosurveillance-related funding is directed to programs that can demonstrate their intended capabilities, and to help ensure sufficient information is known about the current Gen–2 system to make informed cost-benefit decisions about possible upgrades and enhancements to the system, we recommended that DHS not pursue upgrades or enhancements to the current BioWatch system until it establishes technical performance requirements necessary for a biodetection system to meet a clearly-defined operational objective for the BioWatch program; assesses the Gen–2 system against these performance requirements; and produces a full accounting of statistical and other uncertainties and limitations in what is known about the system's capability to meet its operational objectives. DHS concurred and is taking steps to address the recommendation.

As DHS faces decisions about investing in the future of the BioWatch program, there are lessons to be learned from the program's recent attempt to acquire an autonomous detection system, Gen–3. Our recent work on BioWatch also evaluated DHS's efforts to test the Gen–3 technology from 2010 through 2011 against best practices for developmental testing. In our 2015 report, we recommended that DHS incorporate the best practices we identified to help enable DHS to mitigate risk in future acquisitions, such as upgrades or enhancements to Gen–2. DHS concurred and stated its updated acquisition guidance largely addresses these best practices.

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[22] Additionally, DHS had not prepared an analysis that combines the modeling and simulation studies with the specific Gen–2 test results to assess the system's capabilities to detect attacks.

[23] In general, these studies use a measure called fraction of population protected, or *Fp*. Roughly speaking, *Fp* represents a system's probability of successfully detecting simulated attacks, but calculated in a way that gives more weight to attacks that infect more people and less weight to attacks that infect fewer people.

[24] Best practices in risk analysis and cost-benefit analysis require an explicit accounting of uncertainties so that decision makers can grasp the reliability of, and precision in, estimates to be used for decision making. See Morgan and Henrion, Uncertainty, OMB Circular A–94, and OMB Circular A–4.

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

Ms. MCSALLY. Thank you, Mr. Currie.

I now recognize myself for 5 minutes, for initial questions.

So, I want to start with BioWatch, and I appreciate your testimony and all the work that has been done by all of the witnesses. We can all agree we need to make improvements, I think, to our current detection system, that we rolled out BioWatch in a hurry, and so that comes with limitations. Obviously as we look back now 12 years later, the limitations are real.

As far as the archaic nature, Dr. Brinsfield, you mentioned the manpower intensivity of it, maybe lack of nimbleness. Certainly, I think we can all agree we probably want something that has more, newer technology, that is a little bit more responsive.

With 2 years past since Gen–3 was canceled, where are we at? So, like, what has been going on in the last 2 years? What is the plan for us to be able to see? Are you trying to fix Gen–2 and upgrade Gen–2? Are you looking at requirements for a follow-on system that is Gen–4 that is maybe a long-term project, and then in the mean time maybe bridging the gaps with some off-the-shelf stuff during its final development?

I mean, these are some of the things that we talked about with industry partners yesterday. But I mean, what is the bottom line? Where are we at and what can we expect and what time line for, you know, the improvement of this system?

Dr. Brinsfield.

Dr. BRINSFIELD. So, I think, if I can, I will answer that in 2 ways, yes and yes. We are looking both at improvements to the current system with our partners at S&T. I am happy to say that the BioWatch program has reached out to its stakeholder communities, the interagency, multiple cities, sat down and asked them on a few occasions, what is most important to you? What do you need to see improved for the current BioWatch system to really be more useful and to have greater, you know, ability to affect your decision making?

To that end, a number of requirements were generated that have been passed and worked on with S&T. I will let Dr. Brothers address that.

Then on a second point, we have also been working with S&T on the new IPT process and have identified timeliness of environmental detection and how we improve that as a longer-term goal.

Mr. BROTHERS. Sure. I think what we have done is we have looked at improvements in terms of 2 different time frames. We have got a near-term time frame, 1 to 3 years, and a longer-term time frame, 3 to 8 years or so.

If you look, kind-of, the chain of the way BioWatch works, from collection, et cetera, to the eventual laboratory analysis, we have broken that down into the different areas. We have looked at that and said, what kind of improvements can we do?

Now, I agree with Mr. Currie. You know, we have to have the right kind of requirements before we can do the right job to actually figure out specifically what we want. But as you know, technology is changing rapidly, right? This whole idea of data analytics,

predictive analytics, different ways of understanding threats, different type of bioassays, et cetera, has advanced tremendously.

Therefore, what we need to do, even as we are trying to generate these kind of requirements that we are talking about, we have to understand what the art of the possible is.

In the pursuit of that art of the possible, we are reaching out to industry. We fully realize that we don't have all the answers internally. The answer is with this incredibly creative S&T ecosystem, right? This is the industry, laboratories, academia, et cetera. We are fully cognizant of that.

As such, we are reaching out with broad area announcements, requests for information, et cetera, to understand what that art of the possible is. Once we understand that, that is when we start taking that along with the kind of requirements that we are getting working with OHA to start understanding in this architecture, in this architecture we are talking about, this layered architecture that Dr. Brinsfield mentioned, and what are the right things we have to put in play.

So, some near-term things we are looking at in terms of improving the equipment that we have, and then there is some stuff we are looking at working with industry to actually make a much better system.

Ms. MCSALLY. So, time line-wise for any of this, can we—I don't want to be holding my breath. So, are we expecting requests to us? Is there something you need from Congress or a report back to Congress in the next single-digit months, or are we talking double-digit months or single-digit years on, like, here is the plan for the follow-on for BioWatch?

Dr. BRINSFIELD. So, I think from the incremental improvements I will speak to that. We are looking at a time line that would hopefully have us coming back to start being able to do the acquisition process and acquire some of those improvements in the next planned fiscal year, so by fiscal year 2018.

Ms. MCSALLY. Okay, great. Now, when we meet with just a handful, it wasn't the whole industry obviously, yesterday and they had shared, and I want to make sure that I get this right, they had received some RFIs and they gave feedback. That was about 2 years ago, right? About 2 years ago. Then they were, like, well, what did you do with the information we gave back to you?

So I think they explained that they really felt like there was some off-the-shelf technology, because technology is developing so rapidly, that could be deployed in the interim. The perfect being the enemy of the good, you know, being our constant challenge here where we are chasing a perfect solution, but taking too long and then having an inadequate solution for a long period of time.

Is there something that could be deployed more rapidly, from your assessment, off the shelf in order to either augment BioWatch or start to replace it as we continue to move towards that longer-term solution?

Either Dr. Brothers or Dr. Brinsfield.

Mr. BROTHERS. So, let me say, right now we are trying to determine that. I think there is a lot of technologies out there. We have got expertise in-house that understands some of those technologies. But I think it is a mistake for us to choose what that is without

getting a good survey of the landscape. So that is what we are doing right now.

So, we have 4 to 6 RFIs that are either out or going out shortly. So the industry folks should be seeing those.

Ms. MCSALLY. Got it.

So, fiscal year 2018, Dr. Brinsfield, I mean, so you are basically saying, for the next year-and-a-half we can expect DHS to stay with the status quo?

Dr. BRINSFIELD. So, for the next year-and-a-half, we can expect to be able to do maybe, you know, working with our partners, these kind of incremental improvements, but for the acquisition process to truly build through and make sure we do it correctly, follow MD–102 and all the guidelines, that that is about the time to build all the pieces through to meet that guideline process.

Ms. MCSALLY. Okay.

Dr. BRINSFIELD. I think one of the other challenges, if I can just sort of go to it, has been whether or not these systems can be deployed in an indoor environment. Clearly, that was identified strongly by the stakeholders as something that they want to be able to do and that sets a different set of problems for them.

They want to be able to make decisions on whether to evacuate, you know, different kinds of decisions than you make on whether or not you are going to treat a large population.

To that end, some of these RFIs are actually looking at how we take existing technologies, pair them together in a way that they can work on top of the current BioWatch detection system for that type of deployment.

So, I do think that what we are going to see here, even though there are incremental improvements of off-the-shelf technologies, will be significant improvements in the usability of the BioWatch system.

Ms. MCSALLY. Great. One last question, and then I will hand it over to the Ranking Member here, on Bioshield, is that the Blue Ribbon Study Panel related the need to implement better military and civilian collaboration.

Dr. Brothers, you know, you came from the DOD. So, can you speak to any sort of collaboration that you are doing with DOD?

Mr. BROTHERS. Absolutely. Right now we are working with DOD's JPEO Chemical and Biological Defense, that is under JPM, and we are working with them, we have signed an MOU with them. We just spoke with them. Actually, I just spoke with them a couple of weeks ago.

They have a program called Jupiter. The program Jupiter is really about biodefense, biosurveillance. Now, they are developing a number of different types of technologies that we are collaborating on the development of. So, I think that we have a very close relationship.

Outside of that MOU, we also have a relationship in a group called the capabilities development working group, CWDG. That is chaired by myself and under secretary AT&L, where we meet to discuss a variety of issues. This is one of the issues we discuss.

We also have collaboration through the mission executive council. So, there is a number of forum, as well as through the committee on homeland national security as well, so there are a number of

different forums where we are co-chairing committees and subcommittees where we have the opportunity to collaborate across the agencies.

Ms. MCSALLY. Okay, great. Thank you.

I want to now recognize Ranking Member Thompson for questions, for 5 minutes.

Mr. THOMPSON. Thank you very much, Madam Chair.

In my opening statement, I kind of dated myself on this issue that, you know, we have been here before. To be honest, I want to make sure that I am just not hearing another hearing for another Congress, saying the same thing.

So, convince me that we have changed the technology. Convince me that we have acquired better equipment and that we are getting to where Mr. Currie said we ought to be.

Dr. Brinsfield, can you help me out with that?

Dr. BRINSFIELD. So, sir, if I can use an example, in your opening statement you referred to what has been known as the false positives. I think in the past history of BioWatch, there were times when there were detections that were perhaps true detections of what the system was looking for, but weren't useful for public health or law enforcement agencies.

Since then, the program has done much to improve its assays, change the way it does those, done quality assurance, so that we don't actually have those false detections anymore. As a matter of fact, instead what we have is a number of detections of low-level environmental agents that have shown to actually be related to human disease.

This uptick in the disease *Francisella tularensis* happened in this past summer, so that we have actually had the system truly detect an environmental uptick in disease where there were a limited number of people who became ill and that those detections were worked with both the CDC, FBI, and other partners.

Now, it is not a detection of a terror attack and that, you know, is a good thing. Surely, no detection of a biological agent will ever determine alone if that release was naturally occurring or intentional from a terror attack. That is what our partnership with law enforcement and the FBI is intended to do. But it does show that the system has progressed in its ability to detect and has actually had true detections in this area.

Mr. THOMPSON. So, Mr. Currie, do you agree with that?

Mr. CURRIE. Sir, I think one of the—I have many of the same questions Chairman McSally had about what is actually happening right now. I think there are two different issues. You have the system that is in place in over 30 cities and it has been in place for over a decade now. We have found there are limitations with that system and the testing has not been fully completed and they did not set performance requirements.

Our concern, though, is that when we talked about some of these improvements, that that information and that system is being used as the baseline for those improvements. So, that is one issue.

The second issue is on the next generation of technology, which is in the R&D realm. This could be things that don't even look like BioWatch looked. So, there is very little detail about what exactly

the next step is, because you mentioned, "Has the technology gotten better?"—What is the next step?

We are using the same technology we have been using. It is not clear what the next technology is going to look like at this point.

Mr. THOMPSON. Dr. Brothers, can you help us out on this?

Mr. BROTHERS. Sure. I think that we are looking at advanced—so looking forward, so, Mr. Currie, you are saying, you know, what is, kind of, next? But we are looking forward, in essence, is what Dr. Brinsfield is talking about, which is a fully-layered approach.

The fully-layered approach involves integration of biosurveillance, the type of thing the NBIC does, along with advanced biodetection. There are a number of technologies that are out there that they may be agent agnostic. Maybe you are looking at next-generation sequencing or something like that. Maybe you are looking at some type of advanced mass spectrometry. There is a number of technologies that are out there that people are talking about that could be useful in these type of architectures.

I think we are simultaneously looking at what these advanced architectures could be. I am not going to say that we are going to give you an exact architecture right now, but we know what we have to find, right? It has to be this rapid response network. We are actually looking at advanced IT infrastructures to enable this advance infrastructure.

The point is we need to understand what is out there and that is what we are doing right now. We do have an existing system that is providing important properties. We are trying to improve that.

Mr. THOMPSON. I understand that. But we are on the same horse and we need, and I am being a little—not crass, but I think we need to get to the next level of technology because we are still using that same equipment. I am not certain if we can.

I understand the layered part, but we still have the same equipment. So, how are we going to change this?

Mr. BROTHERS. So, from S&T's perspective, we are making sure we understand, not just technology, but we also do a good job of characterizing potential threats. Right? So, that is what we do through our NBAC and through the BTRA and these kinds of things. So, we understand the science of the agents or the pathogens, but we also understand the technologies.

Then in terms of the requirements, that is why we are turning to our partners in OHA to understand what we should be building for the next-generation system.

Mr. THOMPSON. Okay, I am going to go at another round, Madam Chair.

Now, I am told that what we are doing is based on incidents where there is 10,000 or more. Are we doing anything on incidents less than 10,000?

Dr. BRINSFIELD. So, it certainly raises a good question. As the program was initially rolled out, it was intended to detect incidents of 10,000 or more. As we look at our State and local partners and what they are asking us for, they are asking for inter-venues and different levels of population affected than the system has initially been.

Certainly, the changing nature of the terrorist threat and what we need to play for is a significant piece of what we are going to be looking at as we roll out future requirements. To that end, we really want to make sure we continue to partner with them and hear from them where they are interested in. They are interested in subway systems. They are interested in sports venues. They are interested in a whole host of things which will set up ways to detect much less than potentially 10,000 people.

Mr. THOMPSON. Madam Chair, since I am the elder in the group, you know, we have heard this before. I am trying to get us down the road. So my angst in this is, when can we expect the next roll-out? You don't have to tell us what it looks like, but we just need to have some idea that we are not still working with 12-, 15-year-old situations when things have changed.

Dr. BRINSFIELD. So, I can only speak to the near-term roll-out and those improvements on the product, as you mentioned. Those ones, as we said, we are working through an acquisition process that we hope to build into the budget, that will provide the improvements.

When you speak of the next stage, that is really our R&D problem.

Mr. THOMPSON. Well, R&D?

Mr. BROTHERS. So, I can't give you a time frame, you know? This is an exploratory process right now. I think we are working with OHA on the near-term, but in terms of a next-generation system, like I said, we have set time frames for 3 to 8 years for the longer-term improvements. I am unable to give you greater fidelity than that.

Mr. THOMPSON. But you do understand the concern of Congress in this issue.

Mr. BROTHERS. I absolutely under the concern. I absolutely understand and share your concern, absolutely.

Mr. THOMPSON. Mr. Currie, can you provide some guidance on this?

Mr. CURRIE. Well, I will try. One of my concerns about—so as I said, again, there are 2 issues here. There is a long-term R&D issue, which it is not really clear exactly what that looks like and that is probably natural to R&D, but then there is the improvements that the administration is talking about.

My concern about the improvements is the improvements are based on the existing technology as far as I understand it. We had some concerns about the testing in the way the existing technology was rolled out and the uncertainties in the system. They have done some testing. I am not saying that is bad, it just hasn't been a comprehensive set of tests to tell you whether it does what it is supposed to do.

So, if they are going to take the current system and they are going to incrementally improve it, then that has implications for that. That concerns us.

I think that gets back to our recommendations. It may seem like we are asking folks to go back in time to set requirements and do the testing for a system that is almost 12 years old; however, if you are going to use the current system to improve, then it makes sense to do that.

Mr. THOMPSON. Absolutely.

I yield back, Madam Chair.

Ms. MCSALLY. The gentleman yields back.

The Chair now recognizes my subcommittee Ranking Member, Mr. Payne, for 5 minutes.

Mr. PAYNE. Thank you, Madam Chair and Ranking Member.

To follow the Ranking Member's angst, the technology, what rolled out as next gen, I guess, is 12, 15 years old. The actual technology is 50 years old, correct?

Mr. CURRIE. You are referring to the laboratory component of the technology. The testing, yes.

Mr. PAYNE. Yes. I, you know, I am just a Member of Congress in my second term and, you know, no stretch of the imagination, the experts you are, but you would think that we would have been able to move the marker in some manner over 50-year-old technology. I mean, my watch is going to be obsolete next month, you know, and I bought it a year ago.

Does the Department of Defense use any of these type of equipment or something to watch for issues around this?

Dr. BRINSFIELD. So, actually, the Department of Defense uses BioWatch collectors are some of its sites. If we are talking about the technology that is the polymerase chain reaction, which is the current technology they are using to validate the organism, that is one of the questions we will be asking in the RFI to see if anybody has a better technology, as you mentioned sequencing.

But we have also looked in the past with the National Academy of Sciences at other possible technologies that could be used in this area, none of which had a readiness level that were ready to be deployed yet.

Certainly, as, you know, the biological sciences improve, and they are vastly improving our ability to do things, such as sequencing, may come and be fast enough and readily available enough that it is something we could actually deploy throughout the country in the labs. That is, you know, part of the reasoning for the FBI. That is what we are hoping to find.

Mr. PAYNE. Mr. Currie, would GAO know of types of equipment that the Department of Defense is using that could potentially be helpful to DHS?

Mr. CURRIE. Well, I couldn't name very specific pieces of technology they might be able to use in the same way that BioWatch is being used. We do know from our work that DHS does coordinate with the Defense Department a lot. I will say, though, that technology development for homeland security purposes is very different than for defense or for the warfighter.

Mr. PAYNE. Okay.

Mr. CURRIE. There may be more restrictions. You have privacy restrictions. These things have to operate in public places. I think it can be challenging to do that.

However, one of the things that we—that is why it is so important to follow the acquisition process and set requirements early on. What I mean by requirements are, is, what do you want that technology to do and how should it function in whatever environment it is supposed to function? You have to set that early on and then you have to test to those requirements. Sometimes it is not

quick. You can't just take a piece of technology off the shelf and throw it out there, and that is kind-of what happened at the very beginning of the program.

It is difficult. But it is a laborious process, but it is necessary to make sure it is going to be successful.

Mr. PAYNE. Okay. Let us see, I still have time.

Ms. MCSALLY. Take a little more time.

Mr. PAYNE. Okay.

Dr. Brinsfield, GAO proposed several paths forward to improve, you know, the effectiveness of NBIC. Can you describe the process OHA is using to evaluate these proposals?

Dr. BRINSFIELD. So, I want to really congratulate NBIC on getting out there and reaching its stakeholder community and trying to make sure they are meeting their needs.

So, on a number of issues, one is they signed a memorandum of agreement with all the different departments and agencies that we work with on the Federal level and set up a structure on how we will actually govern NBIC. I have a co-chair on the oversight body for NBIC. It was HHS last year, this year it is USDA. We hope to continue to work in that manner.

Our current partnership with USDA in chairing the oversight body of NBIC has led a number of great ideas in terms of how we will change the way we use detailees and structure that process.

NBIC has also looked at changing the way that it does its reports and reporting. As you know, many people here get them. I think it is important to realize we are not trying to give human health information to human health agencies, we are trying to coordinate information and we are trying to make it available to people who maybe don't regularly get that type of information.

We get great feedback from our partners in Commerce, in other types of departments, that don't day-to-day deal with health information. They like the new setup for the reports, they like the way they are set up so they are getting the bottom line up front and really getting the information they need to help them make decisions.

In fact, when the Association of State and Territorial Health Officials went yesterday to meet with Energy and Commerce to talk about Zika, they were asked what they could do to help State and local public health people, and they said we would like better access to the NBIC reports.

So, you know, those kind of feedback and comments really help us understand that we are meeting some of the outreach parameters that we need to do.

Now, we know without a doubt that we need to do a better job at sharing data across human health, animal health, and environmental health. To Mr. Currie's point, there are pieces here we may be able to do on our own and pieces that are a larger Government issue and pieces which may have technology solutions that Dr. Brothers at S&T can really help us with. We are looking forward to those types of improvements.

Mr. PAYNE. Mr. Currie, would you like to comment?

Mr. CURRIE. Sure. I agree with Dr. Brinsfield. I mean, part of what we found in our work is that the Federal agencies, and we actually didn't go out and talk to State and locals, too, but the Fed-

eral agencies that aren't routinely involved in public health issues did find the NBIC reports useful.

I want to make it clear that, you know, we aren't saying that what NBIC produces is bad. The folks over there have worked really hard to implement our recommendations. What we are saying is that its core mission, in addition to coordination, was to integrate biosurveillance information. Part of that is providing new meaning to the information that is out there, collecting it, analyzing it, and providing new meaning.

What we heard from the primary biosurveillance partners, these are folks like USDA, CDC, is that that information, they already have it, they already understand it, and it is not new to them, and it really doesn't provide any new meaning.

So, that is what we pointed out in our report. The reason we did not make specific recommendations to NBIC is because we have made many in the past, and those have been implemented to address these challenges, but the challenges still exist.

Part of what we did was try to offer you all, as the policymakers, options to consider in moving forward.

Mr. PAYNE. Okay, thank you.

Dr. Brinsfield—oh, well, my goodness, my time is—are you sure? Okay. Thank you, Madam Chair.

[Laughter.]

Mr. PAYNE. Dr. Brinsfield, you are probably wishing my time was up.

[Laughter.]

Dr. BRINSFIELD. I enjoy coming to visit you, Mr. Payne.

Mr. PAYNE. Could you give a little explanation, your funding request for 2017, it doesn't appear to be a request for new funding for NBIC to carry out, you know, the mission in response to the GAO report?

Dr. BRINSFIELD. Sir, our funding for these programs has remained——

Mr. PAYNE. Or the authorities.

Dr. BRINSFIELD. Our funding for these programs, our funding request for these programs has remained level across these different years. As you know, you have graciously given NBIC extra funds in past years to do different sorts of demonstration projects to look at potential improvements, and that was greatly appreciated.

But these funds remain level from prior years' requests.

Mr. PAYNE. So, are you attempting to gain favor with my colleagues on the other side of the aisle by not asking for more funds?

Dr. BRINSFIELD. I think, sir, it is a complex risk space and we are looking at a lot of potential threats and risks. As Chairman McSally is very well aware, we are also very concerned about our responsibilities in the chem space. We are trying to balance our many responsibilities in this area in what is really a changing-nature threat.

Mr. PAYNE. I understand.

Okay, well, Madam Chair, I will yield back at this time.

Thank you.

Ms. MCSALLY. Thank you.

Thanks. I have some more questions. I think is Congressman Donovan coming, do you think? Okay. Well, we will just—so I do

want to just wrap up a little bit on BioWatch and technology and engagement with industry.

My staff reminded me that one of the RFIs you guys put out had 10,000 responses to it. So, obviously, industry has got a lot to share and respond to regarding these RFIs.

I know DHS, sometime in the near future, is doing an industry day related to stuff that we are dealing with with the visa program and all that kind of stuff.

Have you had industry days or are you interested in industry days or even round tables where, you know, we are all sitting together and sort-of us meeting with industry yesterday and you today? Like, sometimes, let us all just sit down together and try and figure out how we can move some things forward faster? That includes us, whether there is new authorities or anything needed.

Mr. BROTHERS. So, I can tell you this, that one of the things that we have been trying to do since I have been here, since 2014, been trying to do greater outreach to industry, quite frankly.

One of the areas we have been trying to do greater outreach has been into the Silicon Valley, the Bostons, the Austins, those kind of areas to understand what new technologies there are.

So for an example of what you are talking about, we do do industry days, but we are taking a somewhat nontraditional approach to this. Our approach has been to actually have an ideation event where we pose a problem to creative people, and then we actually do a workshop. This type of workshop is around principles developed by the Stanford University Design School. Coming out of that, then we generate a solicitation.

We have also worked with the under secretary of management to try to streamline our acquisition practices so that we can more quickly get investment dollars to companies.

Because as you know, many companies, unless they are used to doing business with the Government, they don't have a kind of accounting system set up and it becomes very difficult for them to deal with some of our acquisition practices. So, we are trying to speed that up, speed up both the pace at which we get solicitations out, speed up the pace at which we evaluate those proposals that we receive in, and speed up the pace where we actually get the investment dollars out.

The point is that as fast as technology is changing, as I mentioned earlier, we need to be able to engage at that same tempo and to be able to quickly vet so we have fast failures and move on and efficiently use the taxpayers' dollars.

Ms. MCSALLY. Great, thanks.

I want to now switch over to some of my questions on the NBIC. You know, we are always formed by our own experiences and I have a lot of experiences in the military of being in operation centers, the last of which was at AFRICOM.

We were hoping to be more of an interagency operations center, right? We were a military authority, but we really wanted other agencies to be there, we wanted other agencies to share information with us, and it was painful because we didn't have any authority to direct them to and it was only as good as the information that they provided.

It seems to me it is the same exact dynamic, you know, with what we are talking about with the NBIC. Which is, if you are directed to be coordinating, you are basically an operations center, you are integrating information, that is what every kind of operations center does, trying to provide decision-quality information to your customers.

But you don't have the authority to direct other agencies to participate. You have to beg them to or ask them to volunteer and participate. They are only going to do that if it is in their best interest and under limited resources.

Then the information is only as good as what they are sharing with you. So, it is this circular, of course it is not useful because everybody is not participating. So you are wanting to do that role and that mission, but you are limited by, I guess, not the authority to, you know, be directing that.

So, are there any new authorities that are required for NBIC to be more effective and directive of other agencies?

I don't know if you can answer that, Dr. Brinsfield.

You might need to answer that, Mr. Currie.

I mean, is the issue authorities? Because again, I feel the pain because I know what that is like. You know, what needs to change so that it is—and it has to be useful. We don't need to direct people to do things that are not within their interests, because they have missions with limited resources as well.

Mr. CURRIE. Absolutely. I think you have hit the nail right on the head. Great summary.

You know, I think we did talk a little bit in the report about these options and what it would take to actually execute some of these options. For example, in order to get NBIC access to certain data, there would have to probably be laws requiring sharing or something would have to happen to require agencies to share.

However, one of the reasons we didn't make specific recommendations is that that wouldn't necessarily guarantee it would fix all these problems. I mean, it wouldn't just sort-of fix everything right off the bat.

I think one of the interesting questions that we asked the Federal partners, though, even given what they said about NBIC, was, do you think that this idea of having somebody be a Federal integrator for biosurveillance is a good idea? They said yes, somebody absolutely needs to serve in that role.

I think the question just is, you know, who should it be? That is a difficult question to answer. I mean, it has been one could question whether moving this to another agency would fix the problems, maybe they would have the same exact issues trying to get information from the other agencies, too.

So, it is a difficult problem, but it is one that, you know, it is not going away. We have been seeing this for, you know, over half a decade now, and I think it just needs to be considered.

Ms. MCSALLY. So, of the options that you listed, Mr. Currie, in the report, which would you personally recommend?

Mr. CURRIE. Well, we didn't recommend anything on purpose because, you know, at GAO we are not the policymakers, you are. So, what we tried to do is just do our best to give the pros and cons of each, the limitations.

The other issue is, and we didn't do an analysis on this because it is very difficult, but this has funding implications. I mean, if you are going to give additional authorities, then you probably have to give money to somebody and take it away from somebody else. That is difficult and challenging to do that. So, we did not come out with any one approach.

Ms. MCSALLY. It seems that, as you mentioned, some of the Federal agencies that are already in this space are probably like, you know, this report of the master of the obvious is not new information. But those that could benefit from it are the State and local, you know, individuals that are having to deal are the first responders, the public health officials.

So, can you share a little bit about the—did you engage with them during the GAO——

Mr. CURRIE. No, we did not. We had to survey over 15 different Federal departments, so it was outside of our scope to actually go and talk to the State and locals. But I mean, we did hear from the folks at NBIC about situations where they provided these reports to folks in advance of special events, like, you know, Super Bowl and things like that.

Ms. MCSALLY. So, Dr. Brinsfield, can you just share the level of collaboration with State and local authorities?

Dr. BRINSFIELD. So, we like to make sure in 2 ways that our reports are well-coordinated with the interagency. So, first off, you know, if we are sharing reports on this, we are making sure that CDC, HHS has looked specifically at the information and they are comfortable that it is relevant and exactly where we are. We have also worked——

Ms. MCSALLY. So, how long does that take? I mean, that just made my head hurt. I mean, you want timely information, but if you are coordinating amongst multiple bureaucracies, then often your information can be quite old.

Dr. BRINSFIELD. They have really done a fantastic job at speeding that process up and creating products that can give us the brief report so we can get immediate information out and then more, you know, in-depth reports later. So, yes, we are getting information out in a regular cycle.

The State and locals have numerous ways they can get these reports. They can sign up direct, they can go through the associations, Association of State and Territorial Health Officials, you know, city and county health officials. They also at times, during certain events, CDC has distributed the NBIC reports.

Ms. MCSALLY. Is it just to health officials, but also to, like, law enforcement, first responders, fire?

Dr. BRINSFIELD. So, we work with different groups and we have opportunities for them to sign up and get these reports as well. Some of them find them quite useful.

We have also worked with the Governors, the homeland security advisers and some of those other groups to make these available. As a matter of fact, there are many people here in this building who get these reports and also find them quite useful.

Ms. MCSALLY. Okay, great.

So, I am assuming you were involved in the Ebola response then, and NBIC had a role to play there. You know, in the military we

do AARs, after-action reviews, and then we identify some people called them lessons learned, I call them lessons identified because they usually are not learned unless they are implemented.

So, did you identify or do you have a process to identify lessons identified? Or did you do an AAR after Ebola? How is that playing out as far as what you are doing with the Zika virus?

Dr. BRINSFIELD. So, there is an on-going AAR process with Ebola, looking at some of these different issues. The information-sharing piece was not identified as a deficiency, it was actually considered to be something that went fairly well and I think will continue to do that.

Most of it has to do with organizational structure and how information is shared. We certainly are participating on an interagency basis with Zika. As a matter of fact, NBIC first identified and reported on an unknown Brazilian disease in March 2015 and reported on Zika first in April 2015 and have been coordinating closely with our HHS partners.

Ms. MCSALLY. Okay, great.

Ranking Member, do you have another round of questions?

Mr. PAYNE. Let us see. This is for Dr. Brinsfield and Dr. Brothers.

You know, as you know, the committee recently enacted legislation that would consolidate the activities of OHA in certain chem/bio activities at S&T into a new CBRNE office. At this point, the chem and bio research and development activities would remain at S&T.

Can you describe the current working relationship between S&T and OHA with respect to pursuing the new biodetection technologies?

Dr. BRINSFIELD. Yes, sir. So, currently, we co-chair the bio IPT. This is something we are looking to continue to do in the future. We are working with FEMA to develop those gaps, if you will, that need to be filled in the biospace.

Mr. BROTHERS. Yes, I think, so, as I mentioned in my opening statement, we develop these IPTs as a way to consolidate capability gaps across the Department. One of those IPTs is biothreat. Dr. Brinsfield and FEMA are the co-chairs of the biothreat IPT.

Through that IPT, we have already got to the point where we have identified 5 high-priority areas. These have to still be further vetted and sent to the Secretary, but we have done it. I have got to commend Dr. Brinsfield for just the good work on this IPT, because we have got to these capability gaps we haven't had before.

These will then be used as a way to drive our research investment in those gap areas, try to close those gaps.

Mr. PAYNE. Okay. In light, you know, of how those things are going, do you anticipate chem/bio research and development staying at S&T or eventually moving over to the new office?

Mr. BROTHERS. So, I think there has been a lot of discussion about this. Questions have come up of, what are the best models for R&D? I think in a number of people's estimation, and mine as well, if you look objectively at it, a lot of the advances in technology these days, the innovation that people talk about, come about because of the convergence of ideas.

So, for example, MIT has an institute called the Convergence Institute. What they do is they look at the convergence of engineering and biology and physics and mathematics. They are saying they are putting people in those different areas of disciples in one place. What research has shown is that when you put people of disciplines in one place, you make a critical mass of ideas of a diverse set of ideas across disciplines. So what you end up with is a greater result than you could get than if you just had these individuals in isolation.

So, here is an example. If you look at some of the advancements that have been made in the biological sciences recently, in genomics and proteomics and these kinds of things, it really has to do with advancements in data analytics, which is mathematics and computer science.

So, if you didn't have people in mathematics and computer science co-located with people in biology, they wouldn't know about these kind of problems to solve. What it comes down to is creative people like to solve hard end-point problems, but they have to understand what these problems are.

So, it is important to put them into environments of diverse creativity. When you do that, they find out problems they never had before.

So, now, if you keep chem/bio in an environment where you have other types of research and development going on, where you have other types of problems being addressed, you start getting a cross-pollinization that is a very powerful influence to innovation.

Mr. PAYNE. Okay.

Mr. Currie, along that line, you know, the committee just passed the legislation authorizing the consolidation. I understand DHS has begun a review of the consolidation proposal. Can you give us an overview of your preliminary findings?

Mr. CURRIE. Well, sir, we are actually doing that work for Mr. Thompson and you. We are right in the middle of that review, so we don't have any final results of that yet.

However, we have been watching current events. For instance I just took a look at the budget request that came out for the new office and it looks like I had the same questions about: Are there going to be any changes in these programs in the new office? It looks like there is not, they were just simply merged together.

But quite frankly, there are not a lot of detailed plans right now about the specifics of the reorganization. Part of that, DHS has told us, is because they are waiting on the legislation to be final and passed, still got to go through the Senate.

So, they are sort of on hold according to them right now, until they get legislation to move forward on that.

Mr. PAYNE. Okay, thank you.

In the interest of time, I will yield back, Madam Chair.

Ms. MCSALLY. Thank you.

I just have one final question, Dr. Brothers, about FEMA co-chairing the biological threat IPT. FEMA's a response organization. I didn't think they were much involved in R&D and technology, per se. I mean, they obviously need to respond to crises.

So, can you just talk a little about what their role is and kind-of how they ended up there?

Mr. BROTHERS. I can. I appreciate the question actually. So, one of the things I firmly believe in is what is called user-producer innovation. What that is is when you get the actual stakeholders, the people who are on the ground, whether it be FEMA or Customs and Border Protection or Coast Guard, involved in the creative process.

Again, research has borne this to be true.

Ms. MCSALLY. Got it.

Mr. BROTHERS. When you get the users involved in the creative process, you get a better result more efficiently and effectively.

Ms. MCSALLY. Got it. Okay. Great, thank you.

All right. Well, I want to thank all of our witnesses for your valuable testimony today, and Members for their questions.

Members of the subcommittee may have additional questions for the witnesses. I will ask you to respond to these in writing.

Pursuant to the committee Rule 7(e), the hearing record will be held open for 10 days.

Without objection, the subcommittee stands adjourned.

[Whereupon, at 3:22 p.m., the subcommittee was adjourned.]