

**BIOWATCH PRESENT AND FUTURE: MEETING
MISSION NEEDS FOR EFFECTIVE BIOSURVEIL-
LANCE?**

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON EMERGENCY
PREPAREDNESS,
RESPONSE, AND COMMUNICATIONS

AND THE

SUBCOMMITTEE ON CYBERSECURITY,
INFRASTRUCTURE PROTECTION,
AND SECURITY TECHNOLOGIES

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BIOWATCH PRESENT AND FUTURE: MEETING MISSION NEEDS FOR EFFECTIVE BIO- SURVEILLANCE?

Thursday, September 13, 2012

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOMELAND SECURITY,
SUBCOMMITTEE ON EMERGENCY PREPAREDNESS,
RESPONSE, AND COMMUNICATIONS, AND
SUBCOMMITTEE ON CYBERSECURITY, INFRASTRUCTURE
PROTECTION, AND SECURITY TECHNOLOGIES,
WASHINGTON, DC.

The subcommittees met, pursuant to call, at 3:14 p.m., in Room 311, Cannon House Office Building, Hon. Gus M. Bilirakis [Chairman of the Subcommittee on Emergency Preparedness, Response, and Communications] presiding.

Present: Representatives Bilirakis, Lungren, Marino, Clarke of New York, and Richardson.

Mr. BILIRAKIS. Good afternoon. The joint hearing of the Committee on Homeland Security Subcommittee on Emergency Preparedness, Response, and Communications and the Subcommittee on Cybersecurity, Infrastructure Protection, and Security Technologies will come to order.

The subcommittees are meeting today to receive testimony on the Department of Homeland Security's biosurveillance efforts and particularly the BioWatch program.

I now recognize myself for my own statement.

Established in 2003 in the wake of the anthrax attacks that killed five people, the BioWatch program was the first Nationally-deployed system designed to detect an aerosol attack with anthrax and other agents of bioterrorism. Now very near the 11th, of course the 11th anniversary of the attacks that prompted the program's development, it is time to take a step back and ask what Gen-2 has accomplished for us, what it has not achieved, and how we can better understand its relevancy to an overall biodetection architecture that must be dynamic and capable of meeting evolving threats.

BioWatch is currently in its second generation known as Gen-2, and accounts for the vast majority of the budget at the Office of Health Affairs.

The Department of Homeland Security is currently in the process of testing technology for a third generation of BioWatch known as Gen-3. Gen-3 would be a lab in the box, eliminating the need for daily collection of samples, and, if successfully implemented, the detection time could be reduced from the current 12 to 36 hours

down to 4 to 6 hours. This goal is certainly laudable; however, Chairman Lungren and I have expressed serious concerns about the status of this acquisition.

One of the many important functions of the Congress is to ensure we avoid and eliminate wasteful spending. This becomes even more vital in the difficult times, of course, that we are currently facing. Yet I am concerned that without corrective action, we may be heading down a path at DHS with a Gen-3 procurement that we have been down before, and with the potential life-cycle costs of \$5.8 billion, among the most costly DHS acquisitions; we cannot afford to fail.

Over the course of its existence, DHS has seen a number of failed large-scale acquisitions, be it through a failure to conduct an analysis of alternative or cost-benefit analysis or to adequately define requirements. We must ensure that BioWatch does not go down the way of SBI-net or the ASP program. However, I am concerned that DHS is not taking appropriate steps to ensure the success of Gen-3. As the GAO notes in its report, without a systematic effort to justify the need for the acquisition and the control of its costs, benefits, and risks, DHS has pursued goals and requirements for Gen-3 with limited assurance that they represent an optimal solution.

I am pleased our subcommittees could convene today to consider the future of BioWatch, and particularly the findings of GAO's report as it pertains to Gen-3.

Chairman Lungren and I have posed numerous questions to the Department about the Gen-3 procurement, but have not received satisfactory responses. How can we proceed with procurement of a new system when we don't fully understand the capabilities of the current system? Where is the cost-benefit analysis that proves that this generation system will be sufficient—would be of sufficient improvement over the existing system? Where is the analysis of alternatives that says that BioWatch 3 is the answer versus improving the Gen-2 system or investing in improved performance and data integration? How is it possible that the Department is down to only one single competitor when we know, without a doubt, that many engineering and biotechnology companies are making biodetectors for the Department of Defense and even for DHS itself?

I am hopeful that our witnesses will provide us with answers to these and other important questions about the future of this program today.

It is also important to recognize that BioWatch is one component of an overall biosurveillance architecture which must be multifaceted in order to be successful. I look forward to hearing from Dr. Garza on recent developments with OHA's other biosurveillance initiatives and how they will help us achieve true situational awareness to the greatest extent possible.

We all want to ensure our Nation has a comprehensive biosurveillance capability in place; however, we must be smart about how we accomplish this goal. We must ensure that the development and procurement of the next generation of BioWatch is based on sound science, we are getting an appropriate return on our investment, and that we do not lose sight of the greater goal by harnessing all our resources toward one single and static technology.

With that, I welcome our witnesses, and I look forward to your testimony and working with you to ensure we have an effective program in place.

The Chairman now recognizes the Ranking Member on the Subcommittee on Emergency Preparedness, Response, and Communications, the gentle lady from California, Ms. Richardson. You are recognized for your statement.

Ms. RICHARDSON. Thank you. Good afternoon, our witnesses here today, and thank you Chairman Bilirakis and Mr. Lungren and Ranking Member Clarke for us all coming together on this very important joint hearing.

As Ranking Member on the Subcommittee on Emergency Preparedness, Response, and Communications, I am committed to ensuring that the money allocated to make our communities safer and that mitigate the devastation that follows a major incident is carefully targeted to develop the best solutions to pressing capability gaps. We must ask whether, however, it is appropriate to invest in the potential of technologies when simple cost-effective solutions might suffice as well.

In March 2008, DHS advanced its integrated planning guidance for year 2012 through 2014, which included specific criteria for the generation of the BioWatch, although the Department has not engaged in the process of identifying the capability and determining whether addressing it is worth the cost.

One of the trends that has been reported that we need to bring clarification to today is the GAO's report, and in that report it appears that it has been a foregone conclusion that automated bi-detection was the only way to make BioWatch technology cheaper and faster. The momentum of this acquisition process appears to have been driven potentially by individuals who were wedded to the concepts of deploying an automated biodetection system regardless of the increasing costs, the questionable benefits and the repeated delays.

At this point we are all looking at the fact of spending \$104 million that we have invested in developing Gen-3 that could have been potentially spent on local and State governments that could have invested the money in a very effective way to protect the citizens.

It is unfortunate that we do not know who made these decisions or why at the time; however, continuing on a faulty procurement process does not seem to be most prudent for us.

Steps in the acquisition process designed to inject thought and analysis into the process were completed in a cursory manner to speed along the process. Although I am pleased that the Department has agreed to partially adopt the GAO's recommendations and to reevaluate the mission need, and the alternatives and the update associated with the cost and the scheduled information, I am concerned that this will occur simultaneously while the Gen-3 is in the performance testing phase. Simultaneously conducting an analysis of alternatives while performance testing will allow payment for a product that the Government may never use.

Finally, I am concerned that the performance testing that sets stage for a predetermined outcome. Now, I come from California, and the *Los Angeles Times* has been covering this issue pretty

heavily and reported, released yesterday, marked an opportunity to stop and reevaluate Gen-3 and assess where BioWatch fits into our Federal biosurveillance efforts.

For almost a decade now many have believed that BioWatch is the answer that we have sought. The *Los Angeles Times* has also reported that there have been 56 BioWatch actionable alerts since the program's inception; however, no jurisdiction has ever initiated the distribution of the countermeasures as a result.

Although I understand that the BioWatch program office has improved with its guidance, and I want to commend Dr. Garza for your work, and you have always been here, and have faced the music, and answered the questions and made the commitments to address the concerns of this committee, so that has been a part of the process that we have witnessed, although we are still concerned and remain concerned of the continuation of this program.

I look forward to the testimony of all the witnesses today, and above all we have to remember in all times, even these tough times, that it is our ultimate responsibility to make sure that the scarce resources that we have available are spent appropriately.

With that I yield back the balance of my time.

Mr. BILIRAKIS. Thank you very much.

The Chairman now recognizes the Chairman of the Subcommittee on Cybersecurity, Infrastructure Protection, and Security Technology, the gentleman from California, Mr. Lungren.

Mr. LUNGREN. Thank you very much, Mr. Chairman.

In just a few weeks, as you suggested, we do mark the 11th anniversary of the anthrax attacks. Since that difficult time, initiatives ranging from screening the mail to monitoring the environment, to integrating National biosurveillance efforts have been undertaken in a vigorous effort to identify the presence of harmful infectious agents. But after 11 years of refining our detection technology and fostering information-sharing partnerships, the question remains: Have we improved our capability substantially to identify and respond to a biological attack?

Today it is our purpose to examine the Department of Homeland Security's BioWatch program and how effective it has been in countering the bioterror. As my colleague Chairman Bilirakis has indicated, we need to put this program in proper perspective. We know from our oversight and from lots of good work from the GAO, the DHS, other Federal agencies, and States and localities have taken many steps to improve biosurveillance. But truly integrated surveillance remains to be achieved.

Efforts to establish a working National biosurveillance and integration center, while not without flaws, however, have at least demonstrated where some of our capability gaps remain. The problems are not intractable, nor do I suggest that they are.

What is necessary is a well-thought-out architecture that balances the contributions of static and dynamic sensors. Many good ideas, some in the research phase, some being piloted, some operational, are already making positive contributions. Astute physicians and advanced patient-side diagnostics may play an important role far earlier in the wake of an attack than that for which they are commonly given credit.

The DHS Science and Technology Directorate is working on a number of advanced biodetection efforts, and we hope to hear from our witnesses how these might complement our efforts to automate BioWatch. We have heard over the years from many constituencies about the successes and challenges of the deployed BioWatch system Generation 2. The good news is that through this program, many U.S. localities have been able to partner with their Federal Government and with each other to enhance their biosurveillance capabilities.

BioWatch, in fact, depends on the very important contributions from State and local public health laboratories, and their service to this program is essential, and for that and we thank them. But the Gen-2 system has its deficiencies, and I look forward to hearing from Dr. Garza about the Department's plan to mitigate them.

To meet some of Gen-2's lack of capacity, OHA has proposed BioWatch Generation 3, an advanced automated detection system undergoing DHS acquisition.

The GAO, at least from the written testimony that I have perused, will tell us today that DHS did not fully develop critical information for decision making on this major acquisition, with lifecycle cost estimates now approaching \$6 billion.

As has been mentioned, delays now put full deployment, if approved, as I understand it, at the year 2022. If biosurveillance is such an urgent need, do we need more to ensure that we are not going to wait for 10 more years to improve the program?

Those are some of the questions I have got. I look forward to hearing from our witnesses as to what we can do now to make us more secure from the biothreat.

GAO has offered several recommendations for how DHS can self-correct this acquisition. DHS agreed with GAO's recommendations and plans to implement them, but is nevertheless pushing forward with the acquisition process to avoid further delays. I understand both sides of that equation, but it will be interesting to see how you address those. My concern is not the delays, but whether multiple acquisition weaknesses identified by our committee's oversight hearings have been addressed, and whether this very expensive acquisition will be properly handled.

We have already spent \$100 million on Gen-3, and even in Washington that is a lot of money. The House has not provided funds for fiscal year 2013. If we support this program, we have to just justify to our colleagues as to why we should continue to fund it in substantial ways. Shouldn't an acquisition of this size have a cost-benefit analysis at the very least to justify in our minds going forward? But we also have the burden as this committee to convince our colleagues that there is a cost-benefit analysis that justifies it.

We also need to understand all the opportunities to protect human life from bioattack before we adopt a specific path forward. We can only do this with a thorough analysis of alternatives, which should include proposals to refine and improve the Gen-2 system—as least this is my thought—before pushing forward to the next generation.

Rapid post-event detection is unquestionably critical, but clearly we need to refine our focus on defining the problem and then deter-

mining the total architecture, from hardware to software to the human element, that can best meet the challenge. I would like to see a truly open competition where all the bright minds in small business, big industry, our National labs, all of them come together to meet the challenge.

So I look forward to the testimony. We were going to start at 3 o'clock. We were interrupted by votes. Unfortunately for me I have other things that I have got to meet as well, so I will remain here as long as possible, but I will assure you that we will go over with a fine-tooth comb your written and your oral presentation. So I thank you.

Mr. BILIRAKIS. The Chairman now recognizes the Ranking Member of the Subcommittee on Cybersecurity, Infrastructure Protection, and Security Technologies, the gentlewoman from New York Ms. Clarke. You are recognized for your statement.

Ms. CLARKE of New York. Thank you very much, Mr. Chairman, and good afternoon to you, Ranking Member Richardson, and of course to Chairman Lungren, and thank you for holding this hearing on our efforts to assess the BioWatch program.

I would like to also acknowledge and thank today's witnesses for being here to testify before us today.

The Nation's capacity to respond to bioterrorism depends in part on the ability of clinicians and public health officials to detect, manage, and communicate during a bioterrorism event. Information technologies and decision support systems have the potential to aid clinicians and public health officials to respond effectively to a bioterrorist attack. The information that public health officials require to prepare for and respond to a bioterrorism event can be considered in relation to the decisions they must make, the interpretation of the surveillance data, the investigation of outbreaks, the institution of epidemiologic control measures, and the issuance of surveillance alerts.

If we are going to do detection systems right, there are capabilities we must have: Portability, a large number of samples that can be run simultaneously, a large number of biothreat agents that can be identified, and whether both toxins or organisms can be identified. As we have seen from previous efforts, these capabilities are not easy to achieve.

It seems clear that the private sector does not yet assess or possess the technological expertise necessary to produce next and future generation versions of BioWatch. I believe it makes sense that DHS S&T should resume responsibilities for the R&D required. It has become clear that OHA is not, nor was it ever, envisioned by Congress to be an R&D organization.

BioWatch contract management has historically been problematic, but it has been difficult determining exactly why. What is clear is that OHA has had to put a stop to Gen-2.5 and now Gen-3.0, but well after a lot of money has been spent. Too much money being spent should be an indicator to managers that there is something wrong. It is also not clear to me why the management directorate did not step in earlier.

Let me put a little historical perspective on this issue. Years ago OHA handled the interface with the State and local public health labs that house BioWatch-related activities poorly. OHA leadership

recognized this and made some positive changes. The relationships have improved since then, with money going into the States and locals just recently. However, as recent media stories and previous testimony have indicated, no one has very much faith in the BioWatch system even as it stands right now, including the public health lab directors.

There is a question as to whether OHA or S&T have been keeping up with the technology changes used by other agencies. For example, why is the Secret Service using different biological-sensor technology than BioWatch? Where is DOD with their continued development of biological sensors, and how, if at all, is that information being shared with DHS or anyone else?

Importantly, the majority of OHA's budget goes to NBIC and BioWatch. If funding were to be cut for NBIC and BioWatch, and funds for R&D were to be given back to S&T, then there wouldn't be that much left for whatever else OHA does.

From an oversight perspective, one has to ask whether what is left at OHA would constitute an entire office at DHS with its own assistant secretary and staff. As I remember, the original model for OHA was just the chief medical officer, one person, with two other people assisting. GAO has noted on a number of occasions in assessing contractors in the workforce and DHS that use of contractors to perform certain functions can place the Government at risk of transferring Government responsibilities to contractors, and potentially results in the loss of Government control over and accountability for policy and program decisions.

In its latest findings, GAO told DHS to stop BioWatch in its tracks, and reevaluate the mission need and alternatives, and develop performance schedule and cost information in accordance with guidance and good acquisition practices. That is about as blunt as you can get.

Is it true that DHS plans to proceed with the acquisition of Gen-3 while implementing acquisition and performance guidelines to avoid further delay? I hope we will find out today.

GAO believes the recommendation should be enacted before DHS proceeds with the acquisition as discussed in this report, and I agree with GAO.

The Secretary should be more involved in this problem. There are substantial sums of taxpayer money, over \$5 billion, at stake here, and a huge amount of the money already spent to no productive end. My colleagues on our two subcommittees have written the Secretary in detail about our concerns with this program. DHS should act now, follow GAO's recommendations, and with haste.

With that, Mr. Chairman, I yield back.

Mr. BILIRAKIS. Thank you, Ms. Clarke. I appreciate it very much.

I am pleased to welcome our distinguished panel of witnesses at this time. Our first witness is Dr. Alexander Garza. Dr. Garza is the assistant secretary for health affairs—

Ms. CLARKE of New York. Excuse me. I am sorry, Mr. Chairman.

Mr. BILIRAKIS. You are recognized.

Ms. CLARKE of New York. Thank you so much, Mr. Chairman.

I wanted to ask unanimous consent to submit for the record the testimony statement of Ranking Member Thompson.

Mr. BILIRAKIS. Without objection, so ordered.

Ms. CLARKE of New York. Thank you, Mr. Chairman.
[The statement of Mr. Thompson follows:]

STATEMENT OF RANKING MEMBER BENNIE G. THOMPSON

SEPTEMBER 13, 2012

As many of us remember, one week after the September 11 attacks, the Nation was subjected to anthrax attacks. Envelopes containing a powder laced with anthrax spores were delivered in the mail and were directed at Capitol Hill offices and various media outlets. These poisoned envelopes killed 5 people and infected 17 others. According to the FBI, the ensuing investigation became “one of the largest and most complex in the history of law enforcement.”

The legislative response to these attacks was to enact a measure that would provide an early warning system to detect the release of harmful biological or chemical compounds in our major cities. We called the program BioShield. Eleven years and \$800 million dollars later, the program is called BioWatch. Eleven years and \$800 million dollars later, we still do not have an early warning system that can quickly and efficiently detect the release of a harmful biological or chemical compound in our major cities. Eleven years and \$800 million dollars later, it is time to reconsider the likelihood of the risk and adjust our priorities.

Although today’s hearing is about Generation 3 of BioWatch, I wanted to provide the historical context of this program because we must understand that we are on Generation 3 because Generations 1 and 2 did not work. The technological component of this program, which originally began in 2003, has suffered from poor planning, poor execution, and poor performance throughout its life cycle.

We should seriously consider whether the technology Congress envisioned is capable of being produced. It seems that the answer is—not yet. GAO recommends that before continuing with the acquisition, DHS reevaluate the mission need, investigate alternatives and develop performance, schedule, and cost information. Given the history of this program and the \$800 million that has been spent, GAO’s recommendations seem reasonable and sound.

I urge DHS to reconsider its plan to proceed with the acquisition. Before yielding back, I want to make note that not all of BioWatch should be reconsidered. It is my understanding that the program has strengthened interactions and partnerships between the Federal, State, and local public health community. The increased interaction and information sharing that has come about as a result of those relationships will serve this Nation well. We know that those relationships were important a few years ago when we were concerned about a flu pandemic.

The interaction among the public health sector helped this Nation quickly mobilize, take preventive action, and provide precautionary vaccines to millions of people. So Mr. Chairman, whatever the fate of Biowatch, I think we all benefit by continuing to provide grants and other incentives for the public health community to work together.

Mr. BILIRAKIS. Dr. Garza is the assistant secretary for health affairs and chief medical officer of the Department of Homeland Security.

Following Dr. Garza we will hear from Mr. Rafael Borrás, and he is the under secretary for management at the Department of Homeland Security, a position he has held since April 2010.

Next we will hear the testimony from Mr. William Jenkins. Mr. Jenkins is director of homeland security and justice issues at the United States Government Accountability Office.

Finally, we will hear—we will receive testimony from Ms. Frances Phillips. Ms. Phillips is the deputy secretary for public health services for the Maryland Department of Health and Mental Hygiene, a position she has held since December 2008.

I want to welcome the witnesses. Your entire written statements will appear in the record. I ask that you summarize your testimony for 5 minutes. We will begin with Dr. Garza.

Welcome, sir. Thank you. You are recognized.

**STATEMENT OF ALEXANDER G. GARZA, M.D., MPH, ASSISTANT
SECRETARY FOR HEALTH AFFAIRS, CHIEF MEDICAL OFFI-
CER, U.S. DEPARTMENT OF HOMELAND SECURITY**

Dr. GARZA. Thank you, Chairmen Bilirakis, Lungren, Ranking Members Richardson and Clarke, and distinguished Members, thank you for inviting me to speak with you today. I appreciate the opportunity to update you on the Office of Health Affairs BioWatch program, and I am honored to testify with Under Secretary Borrás, Director Jenkins, and Ms. Phillips.

Terrorism continues to be a threat to our Nation, including the use of biological organisms as a means. In fact, in a recent publication by a known terrorist organization, it was stated that the use of poisons or chemical-biological weapons against population centers is allowed and is strongly recommended due to its great effect on the enemy.

Recent events also demonstrate the potential lethality and complexities of response to biological agents. Just last month in a small village in Russia, 14 people were hospitalized and 1 person died from an outbreak of anthrax. Local authorities declared a state of emergency, quarantined the area, and began vaccinating people and animals, but only after people were sick and dead.

We also know that with rapid advances in biotechnology and life sciences, the barrier to successfully using biological agents as a method of terrorism has never been lower.

Though the risk of using biological agents is constantly shifting and evolving, one thing is clear: BioWatch has the potential to provide early warning to public health officials before sick and dying people show up in the emergency department. It complements public health surveillance systems and ultimately can save lives.

As you know, BioWatch is the Nation's only Federally-managed, locally-operated Nation-wide biosurveillance system designed to detect select aerosolized biological agents. The system is collaborative. It is an effort across all levels of government, supported by a Nation-wide network of lab personnel, local public health officials, responders, and Federal partners.

The program's current capabilities consist of air collectors with a filter that requires manual retrieval and analysis at a local public health lab. If the analysis indicates that a filter contains DNA from an organism of concern, the local lab director declares a BioWatch Actionable Result, or a BAR.

Now, allow me to clarify some misconceptions about what a BAR means. It is a detection of targeted DNA. It has never been promoted nor described as a declaration of a bioterrorist attack. Humans decide what is an act of terrorism, not machines. Furthermore, a BAR does not dictate any public action. It is a piece of data.

While the current BioWatch system is extremely beneficial, as you mentioned, it is resource-intensive, and the results may not be readily available. This is time that is required to deploy medical countermeasures. It is clear that technology needs to improve if we are ever to defeat the tyranny of time imposed by these agents. This is consistent with the President's National Strategy For Biosurveillance, which states, "Rapid detection and enhanced situa-

tional awareness are critical to saving lives and improving incident outcome.”

Automated biodetection eliminates the need for manual filter retrieval, can provide continuous sample collection and analysis, and have results transmitted virtually to public health officials. These capability improvements are encompassed in the next generation of biological detectors known as Generation 3, or Gen-3. All told, this automated detection technology holds the promise of reducing the detection from the current 12 to 36 hours to 4 to 6.

What I am describing here is a game-changer. Moving from manual retrieval and analysis to essentially a lab in a box would bring DHS and National security to the leading edge of detection technology. This type of leading-edge technology demands a complex and agile strategy that can accommodate iterative improvements while ensuring that rigorous performance standards are met. This is exactly how we approach this acquisition.

Phase 1 testing for Gen-3 acquisition was completed in June 2011 and assessed the maturity and technical capability of the biotechnology market, including assay and field testing.

Besides the technical work, BioWatch continues to make certain that Generation 3 acquisition is consistent with Department directives. DHS concurs with the two GAO recommendations, and we are moving forward in a manner that ensures best practice compliance. Where we differ on is the execution. To that end, Under Secretary Borrás chaired a meeting of the Acquisition Review Board for Generation 3 acquisition on August 16, where the release of solicitation for an analysis of alternatives including a cost-benefit study and a request for proposals for performance testing was conditionally approved.

In addition, OHA will deliver required acquisition documents for approval and meet again with the ARB before awarding of performance contracts.

I appreciate this subcommittee’s interest in BioWatch and Generation 3 acquisition and your continued partnership as we work to improve the Nation’s biosurveillance.

Thank you for the opportunity to appear before you today, and I look forward to answering any questions.

[The prepared statement of Dr. Garza follows:]

PREPARED STATEMENT OF ALEXANDER G. GARZA

SEPTEMBER 13, 2012

Chairmen Bilirakis & Lungren, and distinguished Members of the subcommittees: Thank you for inviting me to speak with you today. I appreciate the opportunity to update you on the Office of Health Affairs’ (OHA) BioWatch Program and I’m honored to testify with Under Secretary Borrás and my distinguished colleague from the Government Accountability Office.

Bioterrorism remains a continuing threat to the security of our Nation. We know that terrorist organizations continue to call for chemical, biological, radiological, nuclear, and explosive (CBRNE) attacks targeting the West.

At the same time, the rapid global development of biotechnology, which provides important new capabilities for industry, medicine, and scientific research, is also making the capability to develop biological weapons increasingly accessible. The threat environment is constantly evolving and the early detection of a biological attack, as supported by the BioWatch Program, is an essential part of an effective bio-defense posture.

As you know, the BioWatch Program is the Nation’s only Federally-managed, locally-operated Nation-wide biosurveillance system designed to detect the intentional

release of select aerosolized biological agents. Deployed in more than 30 metropolitan areas throughout the country, the system is a collaborative effort of health personnel at all levels of government.

In accordance with the President's July 2012 *National Strategy for Biosurveillance*, the BioWatch Program is strengthening local partnerships and building capacity to improve biosurveillance, enabling rapid, well-informed decision-making. BioWatch is supported by a network of laboratory personnel, local public health and responder personnel, and Federal partners including the Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation, the Department of Defense and the Environmental Protection Agency.

The current detection capabilities used by the BioWatch Program consist of outdoor aerosol collectors whose filters are manually retrieved for subsequent analysis in a State or county public health laboratory that is a member of the CDC Laboratory Response Network (LRN). The results are generally received 8–10 hours after sample delivery to the laboratory. If the analysis indicates the filter contains genetic material from an organism of concern, a BioWatch Actionable Result (BAR) is declared by the director of that public health laboratory or their designee. To be clear, a BAR does not mean a terrorist attack has occurred, a viable agent has been released, or that people have been exposed. Additional information is needed to determine if an attack has occurred and if there is a risk to public health. A BAR simply means that targeted DNA is present.

Each BioWatch jurisdiction has a BioWatch Advisory Committee (BAC) made up of State, local, and Federal partners who operate the program and are responsible for leading response efforts. When a BAR has been declared, the BAC is informed within 1 hour and a National conference call is generally conducted within 2 hours. The National conference call brings together all the necessary State, local, and Federal response partners, allowing for rapid characterization of the public health threat, if any, and can put into motion the actions necessary to save lives. These actions may include deploying medical countermeasures or notifying hospitals to be aware of certain symptoms. An early warning of an attack allows exposed populations to protect themselves before they become acutely and critically sick, reducing symptomatic cases and casualties. By providing such warning for certain biological threat agents, the BioWatch Program complements and strengthens the existing public health surveillance system and allows information to be rapidly shared with health care providers. Such early warning may also empower the U.S. Government to take actions to further protect the country from follow-on attacks.

Fostering preparedness is a key part of BioWatch operations. To this end, the BioWatch Program provides guidance documents to assist jurisdictions in preparing response plans and conducts exercises of the notification and response processes. Additionally, the BioWatch Program manages the National notification process and offers laboratory support, environmental sampling, and event modeling.

While the current BioWatch system is extremely beneficial, it is labor-intensive and results may not be available until 12–36 hours after the release of a biological agent has occurred. In the event of a bioterrorism attack, a shorter time to detect could mean thousands of additional lives saved. The incubation periods of biological agents vary, but in general, the rapid deployment of medical countermeasures is critical to saving as many lives as possible.

As the *National Strategy for Biosurveillance* states, we must foster innovation to facilitate new biosurveillance activities—including new detection technologies. To give public health officials the timeliest information possible to help them make these high-consequence decisions, the Department of Homeland Security (DHS) determined that it should test the viability of developed autonomous biodetection technology. Congress supported this approach in the 2009 DHS Appropriations Act, by calling for a competitive bid process for Phase I of the BioWatch Generation 3 (Gen-3) acquisition.¹ DHS implemented the Gen-3 acquisition, which aims to reduce the time between potential exposure and confirmation of a potential biological attack through automated detection.

Automated detection will eliminate the need for manual filter retrieval and is intended to provide continuous collection and analysis of samples within the unit. The results of this automated analysis would be transmitted electronically to public health officials. With Gen-3, the time to detect could be reduced to 4–6 hours, handing back precious time to public health officials faced with responding to a potential bioterrorism event.

Moving from the manual analysis of a filter towards what would essentially be a “laboratory in a box,” marks a true sea change, bringing DHS to the forefront of

¹ See pages 655–656 of the House Appropriations committee print, H.R. 2638; Pub. L. 110–329, which presents the final legislative text and explanatory statement.

state-of-the-art biological detection technology. However, acquiring a first-of-kind technology requires a robust and agile acquisition strategy that can accommodate iterative improvements and open competition, while ensuring rigorous performance standards are met.

Phase I testing for the Gen-3 acquisition, which was completed in June 2011, assessed the maturity and technical capability of the biodetection technology market against a robust set of system requirements. To accomplish this goal, Phase I included assay/characterization testing and field testing of candidate Gen-3 detectors. We are currently preparing to enter Phase II, which will allow us to test a small number of production-level units to ensure they meet performance standards. Once they do, the remainder of the Phase II acquisition will be a full and open competition, and vendors will be evaluated equally in accordance with the terms of the Request for Proposal (RFP).

At the outset of the Gen-3 acquisition, OHA followed prior existing guidance which has since been revised as the Department has matured its acquisition process. I appreciate the Government Accountability Office's (GAO) draft report on the status of the Gen-3 acquisition and we are currently working to develop, revise, and update the requisite acquisition documentation as appropriate and in line with current Departmental acquisition directives. I will continue to partner with Under Secretary Borras to ensure we meet the rigorous standards called out in the Department's acquisitions directives.

To that end, Under Secretary Borras chaired an Investment Review Board (IRB) meeting for the Gen-3 acquisition on August 16, 2012. The Acquisition Decision Authority (ADA) gave contingent approval for the BioWatch Program to release the solicitation for an analysis of alternatives (AoA) and the RFP for Gen-3 Phase II Stage 1, which provides for performance testing of a small number of detector units from each competitively-selected vendor. These next steps are contingent upon the BioWatch Program updating and receiving approval of the system's Operational Requirements Document and several other acquisition documents. OHA will return to the IRB prior to awarding a Phase II performance testing contract.

This course of action addresses the core of GAO's recommendations which call for a re-evaluation of the mission need and an AoA based on cost-benefit and risk information, as well as updates to acquisition documents to consider cost-benefit and risk information. As a result of the guidance provided in the last IRB, we are in the process of updating the Mission Need Statement, commissioning an independent organization to conduct the AoA, which will include a cost-benefit analysis, and updating all the required documents to ensure they comply with the current Departmental guidance for acquisitions as outlined in Management Directive 102-01.

I appreciate the subcommittees' oversight of the BioWatch Program and the Gen-3 acquisition as well as your continued partnership as we work to improve our Nation's biosurveillance. Thank you for the opportunity to appear before you today. I look forward to your questions.

Mr. BILIRAKIS. Thank you, Dr. Garza.

Now we will call on Secretary Borras. You are recognized for 5 minutes, sir.

**STATEMENT OF RAFAEL BORRAS, UNDER SECRETARY FOR
MANAGEMENT, U.S. DEPARTMENT OF HOMELAND SECURITY**

Mr. BORRAS. Thank you, Chairman Bilirakis, Chairman Lungren, Ranking Member Richardson, and Ranking Member Clarke, and other distinguished Members of the committee, I appreciate the opportunity to appear here today.

I am pleased to be here with Dr. Alexander Garza, along with my other distinguished colleagues on this panel. While Dr. Garza described the history and the objectives of the BioWatch program, I would like to discuss with you very briefly how we have been maturing our acquisition and oversight procedures to help minimize the risk for important Department of Homeland Security programs, in this case specifically BioWatch Gen-3.

As Chief Acquisition Officer for DHS, I oversee the policies, processes, and procedures used to acquire and oversee more than \$18 billion of goods and services each year. I have focused significant

attention on improving the analysis and the rigor for all phases of acquisition life cycle during my tenure from the requirements development phase through implementation. This includes applying a more disciplined approach and requiring more detail analysis before authorizing programs to proceed to the next phase of development and life cycle.

The technical requirements for the BioWatch and Gen-3 technology are highly specialized and complex. I am pleased that our Science and Technology Directorate is working closely with the Office of Health Affairs on the technical strategy for the third generation of BioWatch.

The Office of Program Accountability and Risk Management, which reports directly to me, is also working closely with S&T and OHA to provide high-quality acquisition management support. The record of the Department's acquisition oversight for BioWatch Gen-3 is clear. Since 2009, BioWatch Gen-3 program has been reviewed by the Department's Acquisition Review Board five times. Most recently I directed the BioWatch Gen-3 program to refine the developmental and operational test and evaluation subphases based on the findings from the study conducted by the Government Accountability Office and an independent assessment commissioned by the Secretary and carried out with the Homeland Security Studies and Analysis Institute.

I also gave contingent approval to release two competitive procurements. The first is to conduct analysis of alternatives to identify and document an optimal solution for the identified mission capability gap, and the second is to conduct a system performance testing that verifies attainment of technical performance and validates required operational effectiveness and suitability.

Prior to any award of Gen-3 performance testing contract, the program must be reviewed again by the Acquisition Review Board to evaluate the results of the testing and to determine if the program is able to meet the revised targets of the program plan.

Regarding costs, I, too, have concerns regarding the life-cycle costs of this program and have directed the program leadership to develop a more credible cost estimate which provides an exhaustive and structured accounting of all the resources and associated cost elements.

At DHS we have worked diligently to improve our acquisition processes, and these efforts have produced more effective governance and significant improvements to the future of our current acquisitions. The BioWatch Gen-3 program is an example of the application of these improved processes. I will continue to evaluate the risk of this program in my role as the Department's Chief Acquisition Officer and as the chair of the Acquisition Review Board, and will only provide authorization to proceed when pre-established criteria are met.

While there is still much work to do, the Department has made significant strides to improve our acquisition and investment management. We are making progress. Our investment decisions are now more empirically driven, and qualified technical expertise is available to support program managers at each phase of the life cycle.

Thank you again for the opportunity to testify regarding the improvements in our acquisition investment, and specifically the BioWatch Gen-3 program.

[The prepared statement of Mr. Borrás follows:]

PREPARED STATEMENT OF RAFAEL BORRAS

SEPTEMBER 13, 2012

Chairman Bilirakis, Chairman Lungren, Ranking Member Richardson, Ranking Member Clarke, and other distinguished Members of the committees, I thank you for the opportunity to appear before you today.

As Chief Acquisition Officer, I oversee the policies, processes, and procedures used to acquire and oversee over \$18 billion in goods and services each year. During my tenure, I have focused significant attention on improving the analysis and rigor for all phases of the acquisition life cycle, from the requirements-development phase through implementation. This includes applying a more disciplined approach and requiring more detailed analysis before authorizing programs to proceed to the next phase of the life cycle. Historically, we have sometimes let urgency outweigh prudence when making investment decisions. This has sometimes resulted in well-documented programmatic failures.

When I first arrived at DHS over 2 years ago, the organization was in the process of strengthening its acquisition policies and procedures. I directed our program management function to ensure any new procedures be steeped in established management principles and balance risk mitigation with the need for rapid deployment. I wanted an oversight process with clear and logical approval “gateposts” and business intelligence which could “flag” programs that were off track. Finally, I asked that risk be a significant factor at all acquisition decision events, especially at the planning phase when strategies are developed. While the preference is to seek “existing” technologies, I understand the Department’s mission may sometimes require development of higher-risk, emerging technology.

In the past year, we have solidified a vast majority of our policies and procedures and worked with each component so they understand the rigor expected for all new programs. For some existing programs that were not subject to the rigors of our new policies and procedures, we asked that they provide additional documentation before they could proceed to the next phase of implementation.

Today, I am here to discuss how the Management Directorate is supporting the success of the BioWatch program and how our maturing acquisition and oversight procedures are minimizing risk.

BIOWATCH GEN-3 INVESTMENT AND ACQUISITION OVERSIGHT ACTIVITIES

Dr. Garza provides a detailed description of the history and objectives for the BioWatch program. I will, therefore, not repeat this information to the committee. It is clear that the program has a long history and its opportunity for success relies both on emerging technology and well-coordinated partnerships with industry, other Federal agencies and State/local governments. The technical requirements for this technology are complex and I am pleased that our Science and Technology (S&T) Directorate is working closely with the Office of Health Affairs (OHA) on the technical strategy for the third generation (Gen-3).

As indicated by Dr. Garza, there have been some schedule delays in the acquisition of Gen-3 technology for the BioWatch program because earlier generations were governed by outdated, less rigorous standards. I am confident that our technical, acquisition, and oversight environments are sufficiently settled so future generations of BioWatch equipment will be well-supported.

S&T is in a unique position to evaluate new and emerging technologies against capability gaps, which will increase technological expertise and assist the Department in making better technology “buy” decisions. S&T and OHA are working closely to pursue this highly specialized detection technology while the Office of Program Accountability and Risk Management (PARM), which reports directly to me, is positioned to offer high-quality acquisition management support.

In October 2009, the Deputy Secretary led an Acquisition Review Board to review its Phase 1 testing, which resulted in authorization for the program to proceed; however, OHA was required to provide a quarterly report to the Deputy Secretary and to my predecessor. The July 2010, program review examined initial performance of the BioWatch Gen-3 Assay Evaluation Test and resulted in the authorization to execute the remainder of the BioWatch Gen-3 Phase 1 test events.

I conducted program reviews of BioWatch in December 2010, April 2011, and August 2012. The first Acquisition Review Board was a program review focused on challenges with BioWatch Gen-3 testing, which highlighted vendor failure during Phase I testing. The April 2011 review focused on the constraints of testing due to the testing environment in Chicago. All work under the BioWatch Gen-3 Phase I testing contract was completed at a cost of about \$50 million. These reviews resulted in additional requirements for the BioWatch Gen-3 Program, including: The development of an acquisition plan; the completion of program planning through development of a life-cycle cost estimate; the creation of a concept of operations; and the creation of an integrated logistics support plan. All of these requirements were conditions precedent to the program progressing to its next acquisition milestone.

In February 2012, the program requested I convene an ARB to obtain approval to release the BioWatch Gen-3 Phase II performance testing solicitation. Since the program had not completed the conditions set forth in prior program reviews, the BioWatch Gen-3 request was denied. Both the Program Management and Cost Estimating COEs worked with BioWatch Gen-3 on program and cost challenges to assist them in getting ready for this milestone. OHA submitted the required acquisition documentation for the program to the Department for review in July 2012.

The BioWatch program presents challenging acquisition issues under the most optimal circumstances, but this form of acquisition is not unique. There are no current, active procurements for BioWatch Gen-3. The first and second generations are in the operations and maintenance phase—and were prior to my tenure—while third generation technology is within the acquisition life cycle and is currently working through technology demonstration and planning. As chair of the Acquisition Review Board, I will continue to monitor the progress of the program and will not allow Gen-3 to proceed unless it is meeting actions from the ADM.

I directed the BioWatch program to refine the developmental and operational test and evaluation sub-phases earlier this month based partially on the findings from a study conducted by the Government Accountability Office (GAO) and an independent assessment commissioned by the Secretary and carried out by the Homeland Security Studies and Analysis Institute (HSSAI). I granted contingent approval to release two competitive solicitations. The first is to conduct an Analysis of Alternatives (AoA) and the second to conduct system performance testing. This is contingent upon the Chief Procurement Officer's approval of the Acquisition Plan and the Acquisition Review Board's approval of a Gen-3 Integrated Master Schedule. Prior to the award of the BioWatch Gen-3 performance testing contract, the program must be reviewed again by the ARB to determine if the program is able to meet the revised targets in the program plan.

CONCLUSION

DHS has worked diligently to improve its acquisition processes and these efforts have produced more effective governance and significant improvements to future and current acquisitions. The BioWatch program is an example of the successful application of the Department's improved acquisition oversight process. The program has accepted feedback from the Department and been open to revising strategies to ensure that risk is balanced against benefits. I will continue to evaluate the risk of this program in my role as the Department's Chief Acquisition Officer and will only provide authorization to proceed when pre-established criteria are met.

While there is still much work to do, the Department has made significant strides to improve acquisition and investment management for the Department's portfolio of major programs. I believe we are making progress to shifting the paradigm so investment decisions are more empirically driven and there is qualified technical expertise to support program managers at each phase of the life cycle.

Mr. BILIRAKIS. Thank you, Secretary Borrás.
Now we will recognize Mr. Jenkins for 5 minutes.

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

Mr. JENKINS. Chairmen Bilirakis and Lungren, Ranking Members Richardson and Clarke, and other distinguished Members of the subcommittee, I appreciate the opportunity to be here today to discuss our work on biosurveillance generally and specifically on our report on BioWatch released yesterday.

A large-scale biological event, such as a terrorist attack with a deadly pathogen or a naturally-occurring pandemic, could result in hundreds of thousands of casualties and have devastating effects on the Nation. Recognizing that a bioterrorist attack could be difficult to prevent, attention has been focused on biosurveillance; that is, the ability to quickly detect and characterize a biological attack or the emergence and spread of a deadly infectious disease.

The new National Biosurveillance Strategy states that the goal of biosurveillance is to achieve a well-integrated National enterprise that saves lives by providing essential information for better decision making at all levels. Reliable early detection is a key component of effective biosurveillance, which includes a wide variety of programs and activities by Federal, State, and local governments, hospitals, doctors, and others.

Determining how much to invest in what program requires an objective assessment of the key capabilities each activity or program is intended to address. Gen-3's estimated life-cycle costs, some \$5.8 billion, makes it one of the largest DHS acquisitions, and the question is whether it justifies that level of investment.

DHS has developed a sound formal acquisition process, but the BioWatch program has not fulfilled some of the key requirements of the first two phases of the process. These two phases are intended to: No. 1, conduct an analysis that identifies the capability gap or other mission need and why that need warrants the investment of resources. This results in a mission needs statement; No. 2, select an optimal solution to meet the mission need by evaluating viable alternatives based on cost, benefits, and risk. The result is an analysis alternatives document.

Abbreviated forms of both these analyses were completed on an expedited basis in 2009, but neither met the requirements of the DHS acquisition life cycle framework.

First, the mission needs analysis. The purpose of the mission needs statement is to identify a need, not to specify a solution for meeting that need. In March 2008, the Secretary of DHS issued the DHS Integrated Planning Guidance, which sets specific goals for BioWatch that are still the basic Gen-3 goals: Develop a lab in a box, reduce costs by more than 50 percent, and shorten notification times to 6 hours or less. The October 2009 mission needs statement basically reiterated those specific goals. We interviewed multiple officials in various DHS offices who had knowledge of the process used to justify the need for Gen-3. None could describe the processes, if any, DHS followed to determine that need. Rather, we were told that there was a departmental consensus that automated detection was needed and could save lives.

Second, the analysis of alternatives is intended to identify the best solutions to meet the approved need. The 2009 analysis for BioWatch did not reflect a systematic effort to identify an optimal solution based on cost-benefit and risk information. It fell short in three areas.

No. 1, it considered only two alternatives, Gen-2 with more frequent filter collection and Gen-3. The DHS guidance calls for a minimum of three alternatives.

No. 2, it used only one cost metric, cost per detection cycle, that favored Gen-3.

No. 3, it contained no analysis of benefits. Rather, it assumed that earlier detection would save lives and limit economic losses, a basic benefit of all biosurveillance efforts worthy of investment.

The Gen-3 program is pushing the frontiers of technology, and experience has shown that such programs often encounter unexpected difficulties, delays, and cost increases. Given the growing cost of BioWatch and the fact that estimated full deployment is almost a decade away, it would be prudent to step back and conduct a careful mission needs analysis and an independent analysis of alternatives to meet the defined need. The results of those analyses may still lead to Gen-3, but they may not.

Because the current 2000 missions needs statement presupposes the need for Gen-3, we are concerned that an analysis of alternatives based on that needs statement would be unlikely to foster alternatives much different from Gen-3. We appreciate that DHS, in its response to our recommendations, is willing to reevaluate Gen-3, but it appears somewhat contradictory to us to do so at the same time it is issuing a contract solicitation and considering proposals to move to the next phase of Gen-3 testing.

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

[The prepared statement of Mr. Jenkins follows:]

PREPARED STATEMENT OF WILLIAM O. JENKINS, JR.

SEPTEMBER 13, 2012

GAO HIGHLIGHTS

Highlights of GAO-12-994T, a testimony before the Subcommittees on Emergency Preparedness, Response, and Communications and Cybersecurity, Infrastructure Protection, and Security Technologies, Committee on Homeland Security, House of Representatives.

Why GAO Did This Study

A catastrophic biological event could have devastating consequences. The U.S. Government has efforts to provide early detection and warning of biological threats. DHS's BioWatch, which aims to detect certain pathogens in the air, is one such program. DHS has been pursuing a third generation of BioWatch technology (Gen-3) to further enhance detection. GAO has published a series of reports on National biosurveillance efforts, including a report released today on DHS's efforts to acquire Gen-3. This statement discusses: (1) Prior biosurveillance work and related Federal efforts, (2) today's report on the Gen-3 acquisition, and (3) prior strategy recommendations and the White House's July 2012 National Strategy for Biosurveillance. This statement is based on GAO reports published from December 2009 to September 2012 and GAO's review of the National Strategy for Biosurveillance in relation to prior GAO recommendations for a National biosurveillance strategy.

What GAO Recommends

In prior reports, GAO made biosurveillance recommendations to DHS and the White House Homeland Security Council. DHS concurred with prior recommendations. The White House did not comment. In today's report, GAO recommended that before continuing the Gen-3 acquisition, DHS reevaluate the mission need and alternatives and update associated performance, schedule, and cost information. DHS concurred but stated it plans to reevaluate the acquisition and pursue performance testing concurrently. We believe DHS should first develop the critical information we recommended.

What GAO Found

The Department of Homeland Security (DHS) and the White House have acted to strengthen biosurveillance consistent with prior GAO recommendations made from December 2009 through October 2011. In August 2012, DHS issued a strategic plan for its National Biosurveillance Integration Center (NBIC) that officials say was written in coordination with Federal partners and designed to respond to GAO's December 2009 findings that NBIC did not have key resources to carry out its mission, in part due to collaboration issues it faced. In July 2012, the White House released the National Strategy for Biosurveillance, which describes guiding principles, core functions, and enablers for strengthening biosurveillance. In June 2010, GAO recommended a National biosurveillance strategy to provide a unifying framework for building and maintaining a National biosurveillance capability. In October 2011, GAO also recommended the strategy account for the need to leverage resources and respond to challenges while partnering with non-Federal entities. The July 2012 strategy partially responds to the issues GAO called for such a strategy to address, but does not fully address them, as discussed below. A strategic implementation plan is to be published within 120 days of strategy issuance (October 2012), and may align the strategy more fully with the array of issues GAO identified.

DHS approved the Generation-3 (Gen-3) acquisition in October 2009, but it did not fully engage its acquisition framework to ensure that the acquisition was grounded in a justified mission need and that it pursued an optimal solution. The performance, schedule, and cost expectations presented in required documents when DHS approved the acquisition were not developed in accordance with DHS guidance and good acquisition practices—like accounting for risk in schedule and cost estimates. Since October 2009, the estimated date for full deployment has been delayed from fiscal year 2016 to fiscal year 2022. The 2009 life-cycle cost estimate—a point estimate unadjusted for risk—was \$2.1 billion. In June 2011, DHS provided a risk-adjusted estimate at the 80 percent confidence level of \$5.8 billion. Several steps remain before DHS can fully deploy Gen-3 including additional performance testing, operational testing, and developing location-specific deployment plans.

The White House's National Strategy for Biosurveillance serves as a foundation for enterprise-wide efforts and begins to define mission, goals, and objectives, as we called for in making the June 2010 strategy recommendation; however, the strategy does not yet offer the mechanism GAO recommended to identify resource and investment needs, including investment priorities. Accordingly, the biosurveillance enterprise remains without a framework to guide the systematic identification of risk, assessment of resources needed to address those risks, and the prioritization and allocation of investment across the entire enterprise. In recommending a National strategy, GAO recognized the challenges individual Federal programs and agencies face prioritizing resources to help ensure a coherent effort across the dispersed biosurveillance enterprise. Today's report on Gen-3 offers a timely and concrete example of this challenge—to assess the extent to which Gen-3 warrants the investment of scarce resources when the incremental value of the environmental monitoring Gen-3 offers is considered as part of a layered biosurveillance strategy.

Chairmen Bilirakis and Lungren and Members of the subcommittees: I am pleased to have the opportunity to be here today to discuss our biosurveillance work, with particular focus on the Department of Homeland Security's (DHS) BioWatch Generation-3 (Gen-3) program.¹ A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally-occurring pandemic, could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten National security. In recent years, there has been an increasing awareness of the potential for biological agents to be used as weapons of mass destruction and of the threat of catastrophic effects arising from emerging strains of infectious disease. For example, events like the 2001 Amerithrax incident, which killed 5 people and sickened 17, and the global pandemic resulting from emergence of a novel strain of influenza in 2009, have brought increased attention to intentional and naturally-occurring biological threats.

The U.S. Government has a long history of employing disease surveillance activities to help limit malady, loss of life, and economic impact. Traditional disease sur-

¹ The National Strategy for Biosurveillance defines "biosurveillance" as the process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health to achieve early detection and warning, contribute to overall situational awareness of the health aspects of an incident, and enable better decision-making at all levels.

veillance activities involve trained professionals engaged in monitoring, investigating, confirming, and reporting in an effort to further various missions including, but not limited to, detecting signs of pathogens in humans, animals, plants, food, and the environment. However, in recent years, experts and practitioners, reacting to an increasing awareness of the speed and intensity with which a biological weapon of mass destruction or highly pathogenic strain of emerging infectious disease could affect the Nation, have sought to augment traditional surveillance activities with biosurveillance programs and systems. DHS's BioWatch program is an example of such an effort. It aims to reduce the time required to recognize and characterize potentially catastrophic aerosolized attacks by detecting the presence of five biological agents—considered to be at a high risk for weaponized attack—in the air.

The currently deployed BioWatch technology—Generation-2 (Gen-2)—can take 12 to 36 hours to confirm the presence of pathogens. DHS has been pursuing Gen-3 with the goal of implementing a system that will perform automated testing, potentially generating a result in under 6 hours and eliminating certain labor costs. Expressing questions about whether DHS had undertaken a rigorous effort to help guide its Gen-3 decision making, two subcommittees of this committee asked us to examine issues related to the Gen-3 acquisition. Today, we released a report that evaluates the acquisition decision-making process for Gen-3.² In addition, since December 2009, we have published three other reports about efforts across the Federal Government and with non-Federal partners to enhance the Nation's biosurveillance capabilities.³ This statement: (1) Describes recent Federal efforts that align with our biosurveillance work published from December 2009 through October 2011, (2) discusses our Gen-3 acquisition findings, and (3) makes observations about our prior strategy recommendations and the White House's recently released *National Strategy for Biosurveillance*.

To describe recent Federal efforts that align with our work published from December 2009 through October 2011, we reviewed the *National Biosurveillance Integration Center Strategic Plan* and the *National Strategy for Biosurveillance*, and obtained information from DHS officials. To develop findings in the report released today about Gen-3, which this statement is largely based on, we reviewed DHS's acquisition guidance, including Acquisition Management Directive 102-01. Additionally, we reviewed acquisition documentation and interviewed agency officials from the BioWatch program and other DHS offices with development, policy, and acquisition responsibilities. We then compared the information developed from our documentation review and interviews against the guidance. More detailed information on our scope and methodology appears in our published work. To make observations about the *National Strategy for Biosurveillance*, we analyzed the strategy and assessed its alignment with findings and recommendations about a the need for a National biosurveillance strategy in prior work. We conducted this work from August 2012 to September 2012 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.

DHS AND THE WHITE HOUSE HAVE TAKEN ACTION TO ENHANCE BIOSURVEILLANCE

In December 2009, we published a report assessing DHS's efforts to establish the National Biosurveillance Integration Center (NBIC). 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, a situation that could be at least partially attributed to collaboration challenges NBIC faced. We recommended that NBIC work with its Federal partners to develop a strategy to enhance collaboration—including sharing data, personnel, and other resources—and to establish effectiveness measures for that collaboration. DHS generally concurred with our findings and recommendations and stated that NBIC would work with its partners to develop a collaboration strategy to clarify both the mission space and roles and responsibilities

²GAO, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives Before Proceeding With BioWatch Generation-3 Acquisition*, GAO-12-810 (Washington, DC: Sept. 10, 2012).

³GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, DC: Dec. 18, 2009); *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader*, GAO-10-645 (Washington, DC: June 30, 2010); and *Biosurveillance: Non-federal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy*, GAO-12-55 (Washington, DC: Oct. 31, 2011).

for all partners.⁴ In August 2012, DHS issued the *National Biosurveillance Integration Center Strategic Plan*. According to DHS officials, the plan articulates a clear approach with a series of measurable steps and initiatives to enhance the Nation's biosurveillance capability. In late August 2012, when providing us with a copy of the strategy, officials stated that they believe it satisfies the intent of our recommendations. Officials said the plan was written in coordination with NBIC's Federal partners and is the result of a deliberative process examining NBIC's current capabilities and capability gaps. We are currently assessing the extent to which the plan fully responds to the recommendations.

In June 2010, we reported on Federal efforts that support a National biosurveillance capability and the extent to which mechanisms were in place to guide the development of a National biosurveillance capability. We reported that a National biosurveillance capability would largely rely on an interagency effort because the activities and accompanying resources that support the capability—personnel, training, equipment, and systems—are dispersed across a number of Federal agencies. However, we found that the Federal Government did not have a unifying framework and structure for integrating dispersed capabilities and responsibilities and no Federal agency had authority to guide and oversee the development and implementation of a National effort that encompassed all stakeholders with biosurveillance responsibilities. We concluded that without such a framework and an entity with the authority, resources, time, and responsibility for guiding its implementation, it would be very difficult to create an integrated approach to building and sustaining a National biosurveillance capability. We recommended that the Homeland Security Council within the White House direct the National Security Staff to identify, in consultation with relevant Federal agencies, a focal point to lead the development of such a strategy.

Our June 2010 report also noted that a National biosurveillance capability depends upon participation from State, local, and Tribal governments, because few of the resources required to support the capability are wholly owned by the Federal Government. In October 2011, we reported on how the Federal Government worked with its non-Federal partners to support biosurveillance, activities those partners identified as essential to their biosurveillance efforts, and particular challenges those partners faced. We recommended that the strategy we called for in June 2010 incorporate a means to leverage existing efforts that support non-Federal biosurveillance capabilities, consider challenges that non-Federal jurisdictions face, and include a framework to develop a baseline and gap assessment of non-Federal jurisdictions' biosurveillance capabilities.⁵ The White House did not comment on these recommendations.

In July 2012, the White House released the *National Strategy for Biosurveillance* to describe the U.S. Government's approach to strengthening biosurveillance. The strategy describes guiding principles, core functions, and enablers for strengthening biosurveillance. The strategy states that its approach emphasized teamwork between and within Federal departments, across all layers of government, and with private-sector partners. A strategic implementation plan is to be completed within 120 days of the strategy issuance. The strategy does not fully meet the intent of our June 2010 and October 2011 recommendations, as discussed later in this statement, but it is possible that it will when the implementation plan is complete.

DHS DID NOT DEVELOP CRITICAL KNOWLEDGE BEFORE PROCEEDING WITH THE GEN-3 ACQUISITION

DHS Proceeded With the Gen-3 Acquisition Before Establishing a Mission Need

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, DHS did not engage the initial phase of its Acquisition Life-cycle Framework, which is designed to help ensure that the mission need driving the acquisition warrants investment of limited resources.⁶ In the Acquisition Life-Cycle

⁴ GAO-10-171.

⁵ GAO-12-55.

⁶ According to DHS officials, the Gen-3 acquisition was on-going when Acquisition Management Directive 102-01 was issued. The officials said that many DHS programs that were on-going in 2009 faced similar challenges. Nevertheless, DHS Management Directive 1400, which preceded Acquisition Management Directive 102-01, was similarly designed to, among other things, ensure that investments directly support and further DHS's missions. Like Acquisition Management Directive 102-01, Management Directive 1400 describes a phased life-cycle investment construct in which the first step is defining the mission need in a Mission Needs Statement. As with the Mission Need Statement called for in Acquisition Management Directive 102-

Framework design, it is not the purpose of the Mission Needs Statement to specify a technical solution. Rather it is to serve as a touchstone for subsequent acquisition efforts by focusing on the capability gap to help articulate and build consensus around the goals and objectives for a program.

However, DHS began to pursue a specific autonomous detection solution well before completing a Mission Needs Statement. Specifically, DHS's Integrated Planning Guidance (IPG) for fiscal years 2010–2014, which was finalized in March 2008, included specific goals for the next generation of BioWatch—to deploy in all major cities an autonomous BioWatch detection device reducing the operating cost per site by more than 50 percent and warning time to less than 6 hours. The purpose of DHS's IPG is to communicate the Secretary's policy and planning goals to component-level decision makers to inform their programming, budgeting, and execution activities. As such, this specific set of goals for BioWatch Gen-3 demonstrates that DHS leadership had established a course for the acquisition by March 2008, in advance of efforts to define the mission need through the Mission Needs Statement process, which was finalized more than a year and a half later.

DHS officials in multiple departments described a climate, in the wake of the September 11, 2001, terrorist attacks and the subsequent Amerithrax attacks, in which the highest levels of the administration expressed interest in quickly deploying the early generation BioWatch detectors and improving their functionality—as quickly as possible—to allow for faster detection and an indoor capability. 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. Accordingly, the utility of the Mission Needs Statement as a foundation for subsequent acquisition efforts was limited.

DHS Did Not Systematically Analyze Alternatives

Additionally, DHS did not use the processes established by its Acquisition Life-cycle Framework to systematically ensure that it was pursuing the optimal solution—based on cost, benefit, and risk—to mitigate the capability gap identified in the Mission Needs Statement. The DHS Acquisition Life-cycle Framework calls for the program office to develop an Analysis of Alternatives that systematically identifies possible alternative solutions that could satisfy the identified need, considers cost-benefit and risk information for each alternative, and finally selects the best option from among the alternatives.

However, the Analysis of Alternatives prepared for the Gen-3 acquisition did not reflect a systematic decision-making process. For example, in addition to—or perhaps reflecting—its origin in the predetermined solution from the Mission Needs Statement, the Analysis of Alternatives did not fully explore costs or consider benefits and risk information as part of the analysis. Instead, the Analysis of Alternatives focused on just one cost metric that justified the decision to pursue autonomous detection—cost per detection cycle—to the exclusion of other cost and benefit considerations that might have informed decision makers.⁷ Additionally, the Analysis of Alternatives examined only two alternatives, though the guidance calls for at least three. The first alternative was the currently deployed Gen-2 technology with a modified operational model (which by definition was unable to meet the established goals). The second alternative was the complete replacement of the deployed Gen-2 program with an autonomous detection technology and expanded deployment.

BioWatch program officials acknowledged that other options—including but not limited to deploying some combination of both technologies, based on risk and logistical considerations—may be more cost-effective. As with the Mission Needs Statement, program officials told us that they were advised that a comprehensive Analysis of Alternatives would not be necessary because there was already departmental consensus that autonomous detection was the optimal solution.

Because the Gen-3 Analysis of Alternatives did not evaluate a complete solution set, did not consider complete cost information, did not consider benefits, and did not include a cost-benefit analysis, it does not provide information on which to base trade-off decisions. For example, it does not provide information about the extent to which various aspects of the solution—such as the number of participating jurisdictions—results in a reduction of risk and at what cost. Given the uncertainty related to Gen-3's costs, benefits, and risk mitigation potential, DHS does not have

01, the statement in Management Directive 1400 was to be a high-level description of a capability gap rather than a specific solution.

⁷ Cost per detection cycle is the cost each time an autonomous detector tests the air for pathogens or the cost each time a Gen-2 filter is manually collected and tested in a laboratory.

reasonable assurance that the strategy of expanding and completely replacing the existing Gen-2 program with autonomous detection technology is the most cost-effective solution.

DHS Did Not Fully Develop Performance, Cost, and Schedule Information

In October 2009, DHS approved the Gen-3 acquisition at Acquisition Decision Event (ADE) 2A—one of the key formal decision points in DHS's Acquisition Life-cycle Framework—based on information contained in acquisition documents provided by the BioWatch program. One critical purpose of the ADE-2A documentation set required by DHS's acquisition guidance is to describe the expected performance, cost, and schedule parameters for an acquisition. However, the ADE-2A Acquisition Decision Memorandum stated that significant data necessary for the proper adjudication of an ADE-2A decision were missing. Further, we reported that some performance, cost, and schedule expectations presented at ADE-2A were not developed in accordance with DHS guidance and good acquisition practices—like accounting for risk in schedule and cost estimates.

On the basis of the Gen-3 documentation submitted at ADE-2A, DHS expected to acquire a system that would cost \$2.1 billion, be fully deployed by fiscal year 2016, and meet certain performance requirements. However, the performance, cost, and schedule parameters for the Gen-3 acquisition have changed. Specifically, certain performance requirements have been revised, the estimated date for full deployment has been delayed from fiscal year 2016 to fiscal year 2022, and the expected life-cycle cost has changed from the \$2.1 billion point estimate prepared for ADE-2A to a risk-adjusted \$5.8 billion estimate, calculated at the 80 percent confidence level.⁸

BioWatch program officials told us that they had to prepare ADE-2A documentation quickly because ADE-2A had been accelerated by more than a year. Additionally, DHS officials from multiple offices described a climate around the time of ADE-2A in which the department's business processes—including acquisition practices—were maturing and thus were less rigorous in their adherence to best practices for cost and schedule estimating. However, in the absence of complete and reliable information, DHS had limited assurance that the acquisition would successfully deliver the intended capability within cost and on schedule. Comprehensive and systematic information developed using good practices for cost and schedule estimating could help ensure that more reliable performance, cost, and schedule information is available for future acquisition decision making.

We recommended that before continuing the acquisition, DHS reevaluate the mission need and alternatives and develop performance, cost, and schedule information in accordance with guidance and good acquisition practices. DHS concurred with the recommendations but plans to proceed with the next step in the acquisition—performance testing—while implementing them. We are pleased that DHS plans to implement the recommendation but are concerned by DHS's intention to continue the acquisition efforts before ensuring that it has fully developed the critical knowledge a comprehensive Acquisition Life-cycle Framework effort is designed to provide.

Several Steps Remain before Gen-3 Is Ready for Deployment

The BioWatch program completed initial testing and evaluation on a Gen-3 prototype technology in June 2011, but several steps remain before Gen-3 can be deployed and operational.⁹ For example, the BioWatch program must complete additional testing. The characterization testing conducted in 2010 and 2011 was intended to assess the state of available technology. This testing sought to demonstrate the performance of available candidate Gen-3 technologies against the requirements established by the BioWatch program, and consisted primarily of labora-

⁸The \$2.1 billion life-cycle cost estimate (a point estimate) submitted at ADE-2A was the estimate used for planning purposes at the time. In the June 2011 Life-cycle Cost Estimate, the BioWatch program recommended the 80 percent confidence level for planning purposes. We present these estimates here in comparison because they are the two estimates used for planning purposes. However, it is important to note that June 2011 estimates at the 28 percent and 80 percent confidence level are risk adjusted and the 2009 point estimate is not. The point estimate at the 28 percent confidence level in the June 2011 Life-Cycle Cost Estimate was \$3.8 billion. The confidence level indicates the probability that the actual cost will be at or below the estimate. For example, the June 2011 estimate of \$5.8 billion conveys that (at the time of that estimate) the program anticipated 80 percent probability that the cost would be \$5.8 billion or less.

⁹A second candidate technology participated in two test events— aerosol collection subsystem testing and assay evaluation—but did not complete all testing because the candidate system did not meet program requirements during the assay evaluation. Specifically, the second candidate technology yielded both false positives—detecting a BioWatch agent when none was present—and false negatives—not detecting an agent when one was present.

tory testing of individual system components. This testing did not demonstrate the performance of the full system in detecting live pathogens in the operational environment. It also did not test the information technology network that will transmit results for public health officials. Now the program plans to conduct the next phase of testing—performance testing in three independent laboratories and operational test and evaluation in four BioWatch jurisdictions. On the basis of the June 2011 Life-Cycle Cost Estimate, the BioWatch program estimates this testing will take approximately 3 years and cost approximately \$89 million (risk adjusted at the 80 percent confidence level).

The Deputy Secretary of Homeland Security and other senior officials met on August 16, 2012 for an Acquisition Review Board, during which the BioWatch program was seeking approval to initiate the next phase of the acquisition. DHS did not make a final decision, but authorized release of a solicitation for performance testing under the next testing phase. In response to the recommendations we made in the Gen-3 report, DHS officials stated that before awarding a performance testing contract—which would allow the program to acquire a small number of test units—the program office is directed to return to the Acquisition Review Board for approval.

Before undertaking the remaining steps in the acquisition, the program office is directed to return for Acquisition Decision Event-2B (ADE-2B)—the next formal decision point in DHS's Acquisition Life-cycle Framework—with updated information, including an Analysis of Alternatives and Concept of Operations, as we recommended. No time frame for completing these actions has been specified, but according to DHS officials, it may take up to 1 year to update the Analysis of Alternatives. In preparation for the August 16, 2012, meeting, the BioWatch program had updated key acquisition documents—including the Life-cycle Cost Estimate and Acquisition Program Baseline—as required by the Acquisition Decision Authority in a February 2012 memo. However, in order to inform the ADE-2B decision, these documents must accurately reflect changes to Gen-3 performance requirements and updated cost and schedule estimates for the acquisition and therefore may require further revisions.

If approved at ADE-2B, the BioWatch program plans to conduct operational testing of Gen-3 units in four BioWatch jurisdictions. Following operational testing, DHS intends to decide whether to authorize the production and deployment of Gen-3. If Gen-3 is approved, the BioWatch program plans to prepare for deployment by working with BioWatch jurisdictions to develop location-specific plans to guide Gen-3 operations. DHS estimates based on the June 2011 Life-Cycle Cost Estimate show that about \$5.7 billion of the \$5.8 billion life-cycle cost (risk adjusted at the 80 percent confidence level) remains to be spent to test, produce, deploy, and operate Gen-3 through fiscal year 2028.

OBSERVATIONS ABOUT PRIOR STRATEGY RECOMMENDATIONS AND THE JULY 2012 NATIONAL STRATEGY FOR BIOSURVEILLANCE

In the report on Gen-3 released today, we noted that beyond the uncertainty related to the costs and benefits of the planned Gen-3 approach, there is additional uncertainty about the incremental benefit of this kind of environmental monitoring as a risk mitigation activity because of its relatively limited scope. As the study committee for a 2011 National Academies evaluation of BioWatch noted, there is considerable uncertainty about the likelihood and magnitude of a biological attack, and how the risk of a release of an aerosolized pathogen compares with risks from other potential forms of terrorism or from natural diseases. The National Academies report also notes that while the BioWatch program is designed to detect certain biological agents (currently five agents) that could be intentionally released in aerosolized form, detecting a bioterrorism event involving other pathogens or routes of exposure requires other approaches.¹⁰

In the report we released today, we stated that given the total estimated operating cost for the Gen-3 program, it is important, especially in an increasingly resource-constrained environment, to consider the benefit—in terms of its ability to mitigate the consequences of a potentially catastrophic biological attack—that the investment provides. We noted that the scope limitations of this kind of environ-

¹⁰ Institute of Medicine and National Research Council of the National Academies, Committee on Effectiveness of National Biosurveillance Systems, *BioWatch and the Public Health System, BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats* (Washington, DC: 2011).

mental monitoring provide context in both the consideration of mission need and in analyzing cost-effectiveness.¹¹

However, it was not within the scope of our BioWatch Gen-3 study nor was it our intention to reach a firm conclusion about the value of this kind of activity as part of a layered biosurveillance strategy. Rather, we believe the need to consider value within the larger biosurveillance enterprise as part of an effort to define mission need for a single Federal program like Gen-3 provides a timely and concrete illustration of the kind of issues we sought to address with our June 2010 recommendation. The recommendation for the Homeland Security Council to direct the National Security Staff to identify a focal point to lead the development of a National biosurveillance strategy was grounded in previous work on desirable strategy characteristics for complex homeland security missions. We recognized the difficulty that decision makers and program managers in individual Federal agencies face prioritizing resources to help ensure a coherent effort across a vast and dispersed interagency, intergovernmental, and intersectoral network. Therefore, we called for a 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.¹²

We stated that one of the aims of a National biosurveillance strategy should be to help prioritize where resources and investments should be targeted and guide agencies to allocate resources accordingly. Further, we reported that a National strategy could begin to address the difficult but critical issues of who pays and how funding for biosurveillance will be sustained in the future. Finally, we noted that in an environment with competing priorities, a strategy could help address situations where investments must be carefully weighed and sound judgments made about the most cost-effective approaches, but doing so would require information about the cost, benefits, and risks associated with the whole biosurveillance enterprise.¹³

The *National Strategy for Biosurveillance* includes four guiding principles that are designed to serve as a foundation for enterprise-wide efforts, four core functions that are designed to promote a deliberate and shared approach, and four enabling capabilities that are designed to represent areas for on-going focus.¹⁴ These planks of the strategy align with our call for a strategy that would help to clarify the scope and purpose of a National biosurveillance capability and the goals of that capability. Our June 2010 report described several categories of Federal efforts to improve the personnel, training, and systems and equipment that support a National capability. These included responding to workforce needs, facilitating information sharing, and applying technologies to enhance surveillance. Among the planks of the *National Strategy for Biosurveillance*, it is possible to discern support for each these categories. For example, the enabling capability called build capacity, discusses both workforce and information-sharing issues. The four guiding principles that serve as the strategy's foundation encourage broad-based and cross-cutting actions to leverage constrained resources, responding, in part, to our call for the strategy to help identify the resources currently being used, additional resources that may be needed, and opportunities for leveraging resources.

However, the strategy does not yet offer a mechanism to identify resource and investment needs, including investment priorities among these various efforts. Accordingly, the enterprise is still without a framework to guide the systematic identification of risk, assessment of resources needed to address those risks, and the prioritization and allocation of investment across the entire biosurveillance enterprise, as we recommended in June 2010. For example, in the case of the broader contextual information needed to inform the BioWatch Gen-3 mission need, the strategy has language indicating that advances in science and technology are a priority. In fact, the capability enabler called fostering innovation specifically calls for science and technology capabilities, including new detection approaches. However, the strategy does not facilitate analysis or provide tools to assess the risks to be addressed—in the context of enterprise-wide goals—by such science and technology approaches or the value they should offer the enterprise relative to their costs.

¹¹ GAO-12-810.

¹² GAO-10-645.

¹³ GAO-10-645.

¹⁴ The guiding principles articulated in the strategy are to: (1) Leverage existing capabilities, (2) embrace an all-of-Nation approach, (3) add value for all participants, and (4) maintain a global health perspective. The core functions are to: (1) Scan and discern the environment, (2) identify and integrate essential information, (3) inform and alert decision makers, and (4) forecast and advise about potential impacts. The enablers are to: (1) Integrate capabilities, (2) build capacity, (3) foster innovation, and (4) strengthen partnerships.

Without such a framework and tool set, it remains difficult for decision makers—in both the Executive and Legislative branches—to help ensure that their resource allocation decisions contribute to a coherent enterprise-wide approach.

We are encouraged by the National Strategy for Biosurveillance and the work the White House has done to date to provide a platform for achieving a well-integrated National biosurveillance enterprise. We are hopeful that the forthcoming strategic implementation plan which promises to include specific actions and activity scope, designated roles and responsibilities, and a mechanism for evaluating progress will help to address the on-going need for mechanisms to help prioritize resource allocation.

Chairmen Bilirakis and Lungren, this concludes my prepared statement.

I would be happy to respond to any questions you or the other committee Members may have.

Mr. BILIRAKIS. Thank you very much.

Now we will recognize Ms. Phillips for 5 minutes.

**STATEMENT OF FRANCES PHILLIPS, DEPUTY SECRETARY,
PUBLIC HEALTH SERVICES, DEPARTMENT OF HEALTH AND
MENTAL HYGIENE, STATE OF MARYLAND**

Ms. PHILLIPS. Good afternoon, Chairmen Bilirakis and Lungren, Ranking Members Clarke and Richardson, and also distinguished Members of the subcommittee. My name is Frances Phillips, and I am the deputy secretary for public health from Maryland's Department of Health and Mental Hygiene. In that role I oversee public health, our public health lab, as well as our public health preparedness.

I do thank you for the opportunity to speak with you on this important subject, which I would like to do in connection with Maryland's experience with regard to both the challenges and the benefits that we have experienced in our participation in the BioWatch program.

First, I would like to express Maryland's continued support for the BioWatch program as an important and useful addition to our existing biosurveillance programs. BioWatch is still evolving and will continue to drive improved communications and foster more robust relationships as the technology develops.

Public health, as it has been stated, has a vital role in the detection, response to and recovery from bioterrorism and emerging infectious diseases. Public health has been in the business of monitoring population health, detecting diseases, and designing and implementing interventions to mitigate against diseases for generations.

With the events of September 11, 2001, and the anthrax attack of that year, it became clear that new tools and systems were needed to detect previously unimaginable events. Governor Martin O'Malley has been a strong supporter of expanding biosurveillance capabilities in Maryland. In his first administration he published the strategic goals for homeland security, and goal No. 5 sets out a vision for a State-wide biosurveillance system that integrates new technologies along with our traditional public health disease surveillance monitoring.

BioWatch is one of several tools in the public health toolbox. In Maryland, another important tool is the electronic surveillance system for early notification of community-based epidemics. That is a mouthful; we call it "ESSENCE." ESSENCE captures, integrates, and interprets on a daily basis electronic data from all of Mary-

land's emergency room departments, from over 300 pharmacies with regard to prescription and over-the-counter pharmaceutical sales, from all of our school districts with regard to student absenteeism, as well as the nature and volume of all calls to our poison control center.

BioWatch, even with the limitations that I will mention, has provided benefits to the overall biosurveillance capability and complements tools such as ESSENCE.

Maryland has worked with our local jurisdictions, with our neighboring States and various Federal agencies to collaborate and continuously improve on the management of BioWatch alerts. This collaboration has improved the evaluation of the alerts, has identified gaps in coordination, and resulted in enhanced communication and response capabilities across our region.

In addition, the internal notification protocols at the State and local level have been strengthened as a result of evaluations after each BioWatch alert. The benefit of these enhanced protocols has reached across the all-hazards spectrum in Maryland.

From the department's perspective, there have been challenges with BioWatch program. This is a program designed to be an early warning system. So in the instances when the technology produces an alert, a diverse and very expert team must be promptly convened in real time for interpretation and decision making.

Our BioWatch response decision making requires the integration of our all of our biosurveillance systems along with environmental and seasonal data, technical considerations, and coordinated threat assessment input from State and local enforcement, law enforcement, security, and our fusion center partners.

You have heard about false positives. I would like to mention the issue of false positives, which is a familiar challenge to the BioWatch program. On a few occasions in Maryland, we had detected—the program, the lab has detected gene targets from naturally-occurring microorganisms. These alerts are true positives in that the technology correctly detected presence of a select organism, but were false positives in that the organism was later determined to be naturally occurring and not a public health threat. None of these alerts resulted in the activation of public response; however, the multi-agency collaboration and applied data integration associated with these BioWatch alerts has enhanced our overall capability to respond to all manner of public health emergencies.

We are maintaining an effective working relationship with the Department's Office of Health Affairs, and every week our State lab conducts hundreds—I am sorry—daily conducts regulated and highly-tested BioWatch filter samples. Our State lab has been supported in that regard by the Department with regard to salaries, supplies and, just recently, administrative expenses.

So to conclude, biosurveillance is a core competency of preparedness. Using and exercising multiple systems has helped Maryland enhance its ability to identify and respond to a wide range of threats. We support continued improvement in BioWatch and other components of surveillance.

Thank you for the opportunity to provide one State's perspective on this important issue. I would be happy to answer any questions you may have.

[The prepared statement of Ms. Phillips follows:]

PREPARED STATEMENT OF FRANCES PHILLIPS

SEPTEMBER 13, 2012

Good afternoon, Chairman Bilirakis, Chairman Lungren, and subcommittee Members: My name is Frances Phillips. I am the Deputy Secretary for Public Health Services in the Maryland Department of Health and Mental Hygiene. In that role I oversee Public Health Emergency Preparedness for the Department. Thank you for giving me the opportunity to speak with you on this important topic. There are several points that I plan to speak about today, based on the experience that Maryland has had with the BioWatch program. I want to address our overall experience with BioWatch in Maryland, tell you about the benefits that have resulted from our participation in the program, and discuss some of the challenges inherent in the program.

First, I want to express Maryland's continued support of the BioWatch program as an important and useful addition to existing biosurveillance programs. BioWatch is still evolving and will continue to drive improved communications and foster more robust relationships as the technology advances.

Public health has a vital role in the detection, response to, and recovery from bioterrorism and emerging infectious diseases. Public health has been in the business of monitoring population health, detecting diseases, and designing and implementing interventions to mitigate the impact of resulting diseases for generations. With the events of September 11, 2001 and the anthrax attack of that year, it became clear that new tools and systems needed to be developed to detect previously unimagined threats. Governor Martin O'Malley has been a strong supporter of expanding biosurveillance capabilities within Maryland. In his first administration he published the Strategic Goals and Objectives for Homeland Security. Goal No. 5 sets out a vision for a State-wide biosurveillance system that integrates new technology and traditional public health disease surveillance systems to monitor human illness and sensor-based monitoring for chemical and radiological threats.

BioWatch is one of the several tools in the Public Health "tool box." Other tools include the Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE), Maryland's syndromic surveillance system. ESSENCE captures, aggregates, and interprets electronic data reported daily by all Maryland hospitals on the nature and volume of emergency department visits, by over 300 pharmacies on prescription and over-the-counter pharmaceutical sales, by all Maryland school districts on student absenteeism, and by the Maryland Poison Control Center on the nature and volume of calls.

BioWatch, even with limitations that will be discussed later, has provided benefits to overall biosurveillance capability and complements tools such as ESSENCE. BioWatch is intended to reduce the time needed to identify potential incidents of covert bioterrorism. The sooner that exposures to dangerous pathogens are identified, the sooner interventions can be implemented and the rates of morbidity and mortality reduced. Another benefit of BioWatch is the standardization of sampling and testing protocols across all BioWatch areas. This allows for a common operating picture and ensures that National discussions of potential incidents are based on a shared analytical protocol and have a common terminology.

Maryland has worked with local jurisdictions, neighboring States, and various Federal agencies to collaborate on and continuously improve the management of BioWatch alerts. This collaboration has improved the evaluation of the alerts, identified gaps in coordination, and resulted in enhanced communication and response capabilities across the region. In addition, the internal notification protocols at the State and local level have been strengthened as a result of evaluations after each BioWatch alert. The benefit of these enhanced protocols has reached across the all-hazards spectrum for Maryland.

From the Department's perspective, there are also challenges with the BioWatch program. This program is designed to be an "early warning" system. In instances when the technology produces an alert, a diverse and very expert team must be promptly convened for real-time interpretation and response decision-making. The ensuing situational analysis is based on relevant data drawn from clinical, environmental, technical, and security intelligence. Clinical reporting systems include rou-

tine data reporting from sentinel laboratories as well as from ESSENCE. All of this data is needed to bring context to a Biowatch alert.

Our BioWatch response decision-making also requires integration of pertinent environmental and seasonal conditions, technical considerations regarding signal strength, and coordinated threat assessment input from State and Federal law enforcement, security, and fusion center partners.

Certainly, when confirmatory testing is positive, a BioWatch alert triggers action. Interdisciplinary consultation among a team of experts representing State, local, and Federal laboratorians, public health professionals, environmental experts, law enforcement officials, and emergency management officials is needed to fully assess the risk and to determine the appropriate protective response. Rigorous communication protocols have been developed and refined to direct a hierarchy of response communications.

The issue of "false positives" is a familiar challenge to the BioWatch program. On a few occasions in Maryland the BioWatch system detected gene targets from naturally occurring microorganisms. These alerts were "true positives" in that the technology correctly detected the presence of a select organism, but were "false positives" in that the organism was later determined to be naturally-occurring and not a public health threat. None of these alerts resulted in the activation of a public response. However, the multi-agency collaboration and applied data integration associated with Biowatch alerts and exercises enhances our overall capability to respond to all manner of public health emergencies.

Maryland's Department of Health and Mental Hygiene maintains an effective working close relationship with the BioWatch Systems Program Office within the U.S. Department of Homeland Security Office of Health Affairs. This relationship has improved markedly over the years from what initially had been a very closed and top-down Federal approach to what is now a far more collaborative partnership. This strong State-Federal relationship is essential to the success of BioWatch since both routine laboratory operations and infrequent alerts require State and Federal partners assume interdependent roles and responsibilities.

Every day of the week, the Maryland State Public Health Laboratory conducts highly-regulated testing on filter samples delivered from various locations in the State. The Federal BioWatch Office has supported our lab's work through grants to cover a full-time lab scientist salary, supplies, and equipment and administrative expenses. This has helped us upgrade our preparedness for a wide range of threats.

Our department actively participates in the Baltimore/Washington/Richmond BioWatch Core Work Group which meets quarterly to coordinate planning, communications, and exercises across the greater National Capital Area region.

Biosurveillance is a core component of preparedness. Using and exercising multiple systems has helped Maryland enhance its ability to identify and respond to a wide range of threats. We support continued improvement in BioWatch and other components of biosurveillance.

Thank you again for the opportunity to provide one State's perspective on these important issues.

That concludes my remarks. I would be happy to answer any questions you may have.

Mr. BILIRAKIS. Thank you very much for your testimony.

The entire panel: Thanks for your patience as well, and thanks for sticking to the time allotted.

I am going to go ahead and recognize Chairman Lungren first for any questions he might have. You are recognized, sir, for 5 minutes.

Mr. LUNGREN. Thank you very much, Mr. Chairman, and thank you for that courtesy.

Dr. Garza, you heard from Mr. Jenkins and the suggestion that your operation is receptive to reviewing the mission needs statement and doing the more vigorous approach to the alternatives to Gen-3, but Mr. Jenkins stated that it seemed to be contradictory that you would be going forward in as aggressive a way with letting a contract at the same time those two things remain in question. How would you directly respond to that, please?

Dr. GARZA. Yes. Thank you, Mr. Chairman. That is a very good question.

So the approach that we are taking, and I will let Under Secretary Borrás chime in on this as well, is you are absolutely right that we are doing all the required documentation for acquisitions, which is doing an effective AOA, a cost-benefit analysis, a mission needs statement. All of those things take time, and during that time period, we do not want to delay the performance side or the technology side as well.

So the issuance of an intent to release an RFP also takes time. So there is not going to be any contracts being let; there is not going to be any performance testing that is being done during that time period. So, in essence, we are actually going to be—when you come at the end of the day, we are going to be aligned with exactly what GAO is saying, with completing these documents before we start performance testing.

Under Secretary Borrás informed you that we are going to have to come back to the ARB in order to get approval to do any performance contracting. So the release of the RFP does not necessarily guarantee the release of any performance contracting for testing.

So, in essence, we are following the same paradigm, it is just the timing is a little bit—

Mr. LUNGREN. So if I were one of those that were pursuing one of the alternatives, would I be encouraged or discouraged by that approach with respect to me pursuing my approach and the receptivity with which I would be received by your operation?

Dr. GARZA. Sure. That is an excellent question.

So the requirements for the request for proposals is a full and open competition. It is not wed to any technology whatsoever. We will put out the requirements that the Department is going to need. But just because we have used PCR-based technology in the past does not mean that any other technology cannot come forward.

Mr. LUNGREN. Let me ask you this: Now, you got to understand my dad was a doctor, I wanted to be a doctor at one time, I have great respect for doctors. I have a rich and long-standing experience with the *L.A. Times*, so I think you know where my—where my loyalties would lie. But with regard to certain press claims about the false positives, and if such claims are inaccurate, as I understand you have stated, and that they are all true positives—I love science, I respect science. I am always a little worried when I hear that they are all perfect, we have no false positives.

Now, Ms. Phillips gave us a view of the false positive from her perspective. Could you elaborate a little bit more on that? Because it is difficult for me to go to my colleagues and say, don't worry about the program, we have been assured by Dr. Garza that there are never and—there are no false positives, there never have been. I just have to tell you that is difficult for people to accept. So would you try and enlighten us on that?

Dr. GARZA. Yes, sir, and thank you again for the question and bringing that up, because I think it has caused an immense amount of confusion out in the community.

I believe what Ms. Phillips said is absolutely right. We have had true positives on our tests, which means I ask the machine to go out and look for targeted DNA, and it has done that every single time. Now, I also agree with you that no test is perfect, but every

time that we have looked at any of these organisms that we have had a detection on, it has always been a true positive.

Now, where the confusion comes in is with the term “BioWatch Actionable Result,” or the BAR, and this was something that was brought up again in the National Academy of Sciences report as well, where some people will interpret that as an indication of bioterrorism, which it is not. It is an indication that we have found some bacteria that is of interest, and that we need to come together and discuss what it actually means.

So what does that mean? That means we get together with our State and local partners and with our Federal partners, and it is not just public health. It is our security people, it is our intelligence folks, it is many different people from many different disciplines that come together to look at the results and say, first of all, is this bioterrorism, yes or no. The people make that decision, not the machine and not BioWatch.

The second question is—equally important—is this a threat to public health? So it could be a naturally occurring organism and still be a threat to public health. I think that sometimes gets lost in the conversation.

But I appreciate your concern over stories that come out, and I think some misconceptions about what false positives and what true positives actually are.

Mr. LUNGREN. Mr. Chairman, can I just follow up on that?

Mr. BILIRAKIS. You are recognized, sir.

Mr. LUNGREN. So would that suggest that the hits have been on close cousins of what you were looking for, not the actual bad bacteria? Is that what you are telling me, or is it something different than that? I am trying to figure this out.

Dr. GARZA. Right. So without going too much into the organisms that we look for, for a particular organism there is what is considered a subspecies of the organism, very, very closely linked, so closely linked that when BioWatch was rolled out in 2003, there was not a test to distinguish between the different subspecies of organisms. So by and large what we find is that very low-level subspecies of that organism.

Now, since that time we have learned that—and, frankly, many people didn’t know this even existed in the environment in some of the cities that we are in, so it was a surprise to them when we were finding this there. So, you know, we rewrote the book on where bacteria live. But the question is what are we doing about it? So what we did do about it is after we discovered, hey, we are finding these things, but this is of no consequential public health or terrorism event is looking at ways to improve our detection technology. We have done that.

So we have been partnering with the DOD to build more specific assays. I believe we are going to be rolling out some of these assays in the fall time frame, but, again, we have to make sure this is in concert with our State and local partners.

Mr. LUNGREN. Thank you very much.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. You are welcome.

Now I recognize the gentle lady from California, our Ranking Member Ms. Richardson. You are recognized 5 minutes.

Ms. RICHARDSON. Thank you, Mr. Chairman.

Dr. Garza, you might recall that when you were last here, I asked you a question regarding the first responders, and I wanted to get an update on the pilot project to voluntarily administer the anthrax vaccine to first responders.

Dr. GARZA. Sure. I know that it is in the works right now, and let me find my notes here on that. But I will tell you where it is right now. We have been working on this very diligently with a lot of different people, and that includes our State and locals, with NGOs, and with our Federal suite of families including the CDC.

Now, as you can imagine, this is a very complex endeavor. This is delivering anthrax vaccine, I have been in the military, I have been vaccinated, and I know how much of a challenge it is for the military to get this done, and so it is no small feat get this done.

Be that as it may, it has been a very collaborative effort. There has been a lot of good work that has been done on this, and where we are right now is I think the last time I was briefed on this is we are starting to put the final touches on it so that we can start reaching out to our State and locals and soliciting who would be interested in participating in these pilot projects.

As you can imagine, there are a lot of questions out there with State and locals, as there should be, and so this takes a lot of discussion. It takes a lot of communication back and forth before we roll this out. We want it to be an instrument of success, and so we are being very deliberate in how we approach this problem.

So the time frame I can't give you right now, but I can say that it is—we are fairly close to having this rolled out.

Ms. RICHARDSON. Could you at least give us—do you anticipate by the end of the year, midyear, next year? What is your general—

Dr. GARZA. Right. So in addition to working through the communications strategy and all those other things, there are certain bureaucratic mechanisms we need to go through as well, and some of that will depend on some of those mechanisms. You know as well as I do that it is difficult to put a time line on some of those.

If pressed I would say, you know, I don't know, early next year would probably be an end date.

Ms. RICHARDSON. Okay. So have you decided how you are going to—are you going to reach out to certain particular agencies in an area or a particular—you know, meaning are you looking at doing geographic areas, or areas by professions, or all in general, or have you had any thought about that, or do you have members of these organizations who are involved in these discussions?

Dr. GARZA. Yes, ma'am. So we want the pilot projects to be instruments of success, and so we want to make sure that they are geared towards first it has to be an at-risk place, so it doesn't make as much sense to roll these programs out where we don't feel that the population is at risk. But also it has to have a pretty robust infrastructure to handle this type of program, whether that be with occupational health, being able to track who has received vaccines, things like that.

So right now we have been—people have come to us and talked about participating in the program, and some, I think, are much further along in setting up that sort of infrastructure than others

are. But certainly those are the two factors that I think that we are really keying on is at-risk cities, and do you have the infrastructure to support this?

Ms. RICHARDSON. So but what you didn't answer is will you be determining like, let us say, only police, or only fire, or a combination of the two?

Dr. GARZA. Right. Yes, ma'am. So if I remember correctly, and I will make sure that we get you the information that you need on this, we are not limiting it to any particular demographic or any particular profession. It is really up to the municipality. So we view ourselves more as a pass-through. So remember, we don't own the vaccine. We are merely assisting State and locals to have access to it. So we are leaving as much as possible to the State and locals to determine what their needs are.

Ms. RICHARDSON. Okay. If and when Gen-3 is fully implemented, what percentage of the OHA's budget do you expect the program will represent?

Dr. GARZA. If and when it is fully implemented, assuming full deployment, issues like that, I am guessing probably around 90 percent of the budget.

Ms. RICHARDSON. So what reassurance could you give to this committee that the other aspects of the work that you do would not lose sight and priority of their need?

Dr. GARZA. Right. So regardless of what the budget size is, so that budget pays for a lot of other things, right? So it pays for assistance to our State and locals to run local BioWatch programs. A portion of it is run here at headquarters. It is a Federally-managed program. But that does not diminish the mission that we have to DHS for occupational and operational medicine, for biosurveillance, for food, ag and vet defense. So in that sense it is all on equal footing with that.

Ms. RICHARDSON. Thank you.

Mr. BILIRAKIS. Thank you very much.

I will now recognize myself for 5 minutes. The first question is for Mr. Jenkins.

Your report recommends that DHS reevaluate the mission need for BioWatch Generation 3. You wrote that this document was essentially prepared after the fact in order to justify a predetermined solution.

Was DHS ignoring its own best practices when it began to pursue autonomous detection prior to establishing the mission need, and was this reassessed at any point in the last 3 years to ensure that the acquisition was on track to meet a specific mission need?

Mr. JENKINS. Well, the current acquisition process wasn't—hadn't been in place, but the basic requirement of a mission need statement was in place in the prior acquisition process. So from our perspective, the mission needs statement that should have been provided under the new process should also have been provided under the old process.

In general what we found was that there had been sort of an assumption that this—from very early on, even before the Secretary's guidance in 2008, that automating Gen-2 was the way to go. So all of the decisions basically sort of flowed from that assumption, and what was—what we were told was a consensus within the De-

partment, and that this was the way to go. So it never was a real refreshing new look at the mission needs statement, as far as we know.

Mr. BILIRAKIS. Thank you.

Next question for Dr. Garza. The President's fiscal year 2013 budget request included an increase of almost \$40 million to fund continuing testing of Gen-3. I believe Chairman Lungren referred to this. The House bill did not provide an increase.

What strikes me as the most troublesome about this kind of expenditure is that GAO has confirmed for us there has been no comprehensive cost-benefit analysis done to ensure that all of these millions, specifically \$5.9 billion, incredible, over the project life cycle will buy down risks sufficient to justify the expenditure. Despite this estimate we still do not know just how much of an improvement Gen-3 would be over Gen-2.

Where is the cost-benefit analysis? How much more certainty do we get with these machines? What is the decrease in human morbidity or mortality? How much are we helping people; and if we are not, shouldn't these millions be spent on other biosurveillance programs showing promise, like the integration and information-sharing initiatives that Congress has funded?

Dr. GARZA. Thank you, Mr. Chairman. Allow me to entertain some of the points that you made.

First off, you are absolutely right. The President's budget was around \$40 million, and I agree with you that we do need to have a thorough analysis of alternatives as well as a mission needs statement and a cost-benefit study done. As I mentioned in my opening remarks, and I am sure that Under Secretary Borrás supports this as part of our acquisition program, and it is documents that we are in the midst of completing. So I don't think there is any disagreement that we do need to have this thorough look at the BioWatch program.

Let me address, though, the costs that you were putting out there, the \$5.9 billion—

Mr. BILIRAKIS. Please, please.

Dr. GARZA [continuing]. Over a 20-year life cycle. So I want to make sure that everybody understands that is a 20-year life-cycle cost. This isn't—we haven't spent any money on procuring anything right now. We have taken—and I think the management of DHS has been—should be commended for this. It is setting up several gates to make sure that we are meeting all of the required documentation, as well as doing all of our due diligence in evaluating the technology so that the Secretary and the Department can make a very effective, robust, and minimize risk to the Department on the decision that they plan on making.

As far as the capabilities that we bring, I highlighted some of those in my opening statement. The true benefit that it brings to the Department, to the Nation is decreasing that time to detection from 12 to 36 hours to 4 to 6. If you look at the mortality curve for bacillus anthracis, there is a certain amount of time that people are exposed, it is incubated, they become sick, and then you get the steep curve on the mortality side. Any time you can move that curve to the left where you are able to detect, decide, deploy, and treat medical countermeasures, you will save lives.

Really, time is the currency that we barter with when it comes to bioterrorism. The quicker that we can get pills in mouths, the more lives we are going to save.

Mr. BILIRAKIS. Let me follow up with one last question. We know that Gen-2, the currently developed version of BioWatch, could use some relatively simple upgrades to its assays that could make it substantially less likely to alarm on bacteria that are close cousins to ones we actually care about. Might it be better to balance costs and mission needs to spend a little to improve Gen-2 and to send a "lab in a box" notion back to S&T for research? I know, again, Chairman Lungren agreed. Why not improve Gen-2 as opposed to spending more money on Gen-3?

Dr. GARZA. Thank you, sir.

Regardless of what happens with our acquisition program in Gen-3, we are already moving forward with improving Gen-2 in just the issues that you discussed, with improving the assays so that we can differentiate between close cousins of the different bacterias. That is already in the works. The issue with that is making sure that we have good communication with our State and locals, because, again, this is going to change the way that we do business. So the only thing that this is waiting on is making sure that we have firm concepts of operations on how we are going to roll this assay out.

So there is no question that we are improving Gen-2. You talked or you asked about whether optimizing Gen-2 versus Gen-3 would be—would that fit the bill. I think the answer is I think that will be part of our analysis of alternatives is would it be possible to just optimize Gen-2, and would that be sufficient to replace or to forego Gen-3.

So I am happy to take a look at that question, but be that as it may, the most important aspect as well is that reduction in time from the 12 to 36 hours to the 4 to 6.

Don't forget that the Gen-3 technology is also slated to go indoors, where Gen-2 is not now, which is an important part that sometimes gets lost in the conversation; that not only are we going to be improving the timeliness, we are going to be able to move this inside where we think some of the threat will be emanating from.

Mr. BILIRAKIS. Thank you very much.

Now I will yield and give 5 minutes or so to the ranking gentle lady from New York, Ms. Clarke. You are recognized, ma'am.

Ms. CLARKE of New York. Thank you very much, Mr. Chairman.

Dr. Garza, I understand from the GAO report that the annual cost to operate Gen-3 is estimated to be about four times more than the cost of current Gen-2 deployment, and that Gen-3 will involve the deployment of 2,322 detectors, a marked increase from the 594 detectors currently deployed.

What is the rationale behind this deep increase in the number of detectors deployed, and where are these additional detectors going? Can you explain why Gen-3 will be so much more expensive to operate?

Dr. GARZA. Thank you for that question, and I think this brings up a very good point. This, again, I think it gets a little confusing because you are not comparing apples to apples anymore. The slo-

gan that I use to my office is you are not even comparing apples to oranges; you are comparing apples to elephants.

Gen-2 was designed to be an outdoor collector. It was designed to take 12 to 36 hours to cycle. Typical municipalities will collect the filter once a day. The moved—or the plans for Gen-3 are to move it indoors into high-concentration areas. So these would be places like shopping malls, football stadiums, you know, subways, things like that, where there is a high concentration of people where there could be a possibility of high levels of infectivity in a short amount of time. So that was a goal as well.

The difference in the cost is if we were going to collect Gen-2 three times a day, you would absolutely see an increase in cost, and then you would start approximating where we are at with Gen-3, because that would include people to go pick up the filter to run the PCR analysis and be able to report out. So for Gen-3 it cycles, again, three times more than Gen-1/2. We will be going into many more locations, and frankly, the original plans were to expand it to over 50 cities, where it is currently at 30.

So comparing just bottom-line numbers between the two is not a—it is not really a fair comparison. When you get down to the cost of—and Mr. Jenkins mentioned this as well—the cost of running that sample drops tremendously from the Gen-2 to the Gen-3 side because of the efficiencies that are built into the automation. I did—and I hope that answers your question, Ms. Clarke.

Ms. CLARKE of New York. Just a little clarification. So are you saying that there are components of Gen-2 that will not be utilized in Gen-3 because of the apples to elephants, or—

Dr. GARZA. Right. So what I am saying is when you look at the entire system. So the entire system when it was first developed back in, gosh, probably 2007, 2008, before my time—

Ms. CLARKE of New York. Uh-huh.

Dr. GARZA [continuing]. It was pictured as expanding across the country to over 50 cities, going indoor to all of these locations. This is the number of machines that we think we are going to need. So that is what generates your life-cycle cost.

We haven't bought machine one, frankly, and I think as Under Secretary Borrás said, look, we are going to have to take a look at this program as well when it comes to procurement and say, do we really need to be in over 50 cities? Do we really need to be in all of these locations? I think that is appropriate given our financial constraints. So we have to come up with the proper sizing of the system.

Now, in reference to your question with Generation 2, though, I don't think anybody can sit here and tell you today what the optimal system looks like. So whether that is going to be all Gen-3, whether that is going to be all Gen-2, or whether it is going to be some sort of combination of the two, nobody can tell you that right now until we have gone through all of the acquisition documents that we need to complete as well as finish our performance testing so we have an understanding of what this technology can do for us.

Ms. CLARKE of New York. Well, is there, I guess, a vision of Gen-3 being an overlay on top of Gen-2, or that a new system would be created that would make Gen-2 obsolete?

Dr. GARZA. So if I recall correctly, when I first came into the office, I believe that the vision when it was started was Gen-3 would eventually take over for Gen-1/2.

Ms. CLARKE of New York. Uh-huh.

Dr. GARZA. But I believe that since that time there has been a lot of discussion about really what is the optimal solution. I think that is where the appropriate acquisition documents come into play is what can be an optimal solution?

So I would say right now, you know, although we have to develop our documents based on something, which is where our life cycle cost estimates come from, there is still, I think, going to be plenty of discussion on what that optimal system looks like.

If I may, though, I want to come back to a comment that Chairman Bilirakis said, and that was in regard to R&D and S&T. So OHA does not do basic research and development. S&T clearly has that responsibility. What we do is we do operational testing on technology that we think is beneficial to the Nation. We have had the prototyping that is evaluated by two different independent groups on where this is in the technology scheme. Both of them independently came back with this is a mature technology. It is not in the development stage; it is in the operational evaluation stage. That is a big difference.

The requirements that we put on our machines are much different than the requirements that are put onto basic design. We have to make sure these machines can operate in many different environments, whether it is hot, cold, raining, snowing. We have to make sure they can operate in train tunnels, or in football stadiums, or on a street corner, which is much different than developing something in a lab or in a building.

So I just wanted to make that point clear, that we are not doing basic research and development. What we are doing is evaluating technology.

Ms. CLARKE of New York. Thank you very much.

Mr. Chairman, I yield back.

Mr. BILIRAKIS. Thank you. Thank you.

One last question for Mr. Philips. What outreach, if any, has DHS done with the BioWatch practitioner such as yourself in developing the next-generation detector?

Ms. PHILLIPS. Thank you very much, Mr. Chairman. The ongoing relationship and communication enhancement that the department—that our department has with OHA is largely in the context of a working group. We have a BioWatch core working group that includes representatives from Maryland, from the District of Columbia, and from Virginia. It is the Baltimore, Washington, Richmond Working Group, and it is in that context that we review communication protocols.

We—on the occasion when there is an alert, we conduct a hot wash and after-action review. We have discussed improvements on communications and other protocols. So it is within that context. I will point out that that is clearly an improved and much closer working relationship that our State has had, has benefited with the Department in the past. I will say that in my past experience prior to coming to the State, I was a local health officer in Maryland and had the opportunity to be connected with BioWatch, and it was a

very different culture, and it was a very different connection with State and local officials than what we are experiencing now.

Mr. BILIRAKIS. Thank you.

Do you see value in the type of system envisioned in Generation 3?

Ms. PHILLIPS. Well, Mr. Chairman, the comments that you have heard have to do with the acceleration or the decompression of the time from what we currently have in Gen-2, which can be up to 36 hours, to reduce that down to something that is much quicker in terms of an alert. As I mentioned in my testimony, when we get an alert, there are oftentimes now that that alert is as a result of a specimen that was brought into our lab, and the material could be up to 36 hours old. So what we are not getting is we are not getting that near-real-time alert that would be an advance to what we get in rather robust systems from our labs and from our emergency rooms.

So right now we see a near-real-time what goes on every day in Maryland's emergency rooms and gives us chief complaints, the leading edge. But I think what is being described with this new technology is an opportunity to get ahead of that by several hours, which would then really be an advance in terms of our ability to muster a response.

Mr. BILIRAKIS. Very good. Thank you very much.

Anything further from the panel?

Well, thank you so much. Thanks for your patience. I want to thank the witnesses for your valuable testimony; of course, the Members for their questions. The Members of the subcommittee may have some additional questions, and we ask that you respond in writing, please. The hearing record will be open for 10 days.

Without objection, the subcommittee stands adjourned. Thanks so much.

[Whereupon, at 4:28 p.m., the subcommittees were adjourned.]

A P P E N D I X

QUESTIONS FROM CHAIRMAN GUS M. BILIRAKIS FOR ALEXANDER G. GARZA

Question 1. Please provide the amount of funding spent on BioWatch Generation 1/2 since its inception. Please include all relevant costs, such as research and development, unit costs, operational and maintenance costs, etc.

Answer. Response was not received at the time of publication.

Question 2. Please provide the amount of funds spent on the development of the Autonomous Pathogen Detection System (APDS).

Answer. Response was not received at the time of publication.

Question 3. Please provide all data, and a detailed description of the experimental methods used to generate these data, pertaining to system sensitivity for Generation 1/2. Please indicate when these tests were undertaken.

Answer. Response was not received at the time of publication.

Question 4. Please provide a list of all BioWatch Actionable Results since the deployment of BioWatch, to include which agents were detected, the method of testing performed to confirm the findings, and any other data and supporting evidence utilized to determine whether a positive result was due to an attack versus natural persistence of the organism in the environment.

Answer. Response was not received at the time of publication.

Question 5. You mentioned in your testimony that you are working on improving the Generation 2 assays. Please describe in detail what steps are being undertaken to ensure that deployed assays are meeting the mission need, where the work is occurring, when it was initiated, how much it is costing, what the end goal is, and when you expect to have the improved assays finished and fielded.

Answer. Response was not received at the time of publication.

Question 6. Please provide all of the data associated with BioWatch Generation 3 systems in development to date, including those for the Chicago field test.

Answer. Response was not received at the time of publication.

Question 7. Please provide all supporting documentation provided to Department of Homeland Security management (including for Acquisition Review Board decisions) pertaining to the Generation 3 system test, evaluation, and acquisition activities.

Answer. Response was not received at the time of publication.

Question 8. Please indicate how much money has been spent to date on Generation 3, and how much remains unspent from prior year funds.

Answer. Response was not received at the time of publication.

Question 9. Please explain what the difference is between the Autonomous Pathogen Detection System (APDS), which was pulled from indoor testing in New York City, and the more recent Automated Detection System that has undergone testing by the Office of Health Affairs. Are there any differences in the assay chemistry, sample capture process, sample processing process, or sample analysis process? Please provide details.

Answer. Response was not received at the time of publication.

Question 10. Please provide funding levels and rationale for such funding provided to performers to upgrade Generation 3/advanced systems to fulfill Generation 3 requirements.

Answer. Response was not received at the time of publication.

Question 11. Is the Department of Homeland Security Science and Technology Directorate undertaking any activities to support or optimize a BioWatch Generation 3 system at the current time? If so, what are they? What is the funding associated with the project to date, which system is it for, and what is the time line for the deliverable?

Answer. Response was not received at the time of publication.

Question 12. When do you plan to complete the new Analysis of Alternatives?

Answer. Response was not received at the time of publication.

QUESTIONS FROM CHAIRMAN DANIEL E. LUNGREN FOR ALEXANDER G. GARZA

Question 1. In your testimony you mentioned that two independent studies have supported your claim that the work you are doing on BioWatch Generation 3 is not research and development. Please provide these studies.

Answer. Response was not received at the time of publication.

Question 2a. The Department of Homeland Security Science and Technology (S&T) Directorate is working on a number of advanced biodetection efforts. One of these, Detect to Protect, a “triggers and confirmers” type of system, is undergoing testing in the Boston subway system.

What is the difference between Detect to Protect and BioWatch Generation 3?

Answer. Response was not received at the time of publication.

Question 2b. When was the Detect to Protect project initiated, and how much has been spent on it? How do the anticipated procurement, operations, and maintenance costs compare to BioWatch Generation 3?

Answer. Response was not received at the time of publication.

Question 2c. What testing, evaluation, and validation have been conducted to date? What have these tests told us about the system sensitivity, specificity, and reproducibility?

Answer. Response was not received at the time of publication.

Question 2d. When will this project be completed and transition to the Office of Health Affairs (OHA), and how will OHA use this technology?

Answer. Response was not received at the time of publication.

Question 3. Please describe the ways in which you coordinate with Under Secretary O’Toole on the S&T biodetection portfolio generally, to ensure prevention of redundancy and optimization of acquisition of biodetection technology that will be most useful for end users.

Answer. Response was not received at the time of publication.

Question 4a. Your position with regard to recent press claims about false positives in the BioWatch Generation 1/2 system is that such claims are inaccurate and that, in fact, any hits have always been true positives. You have also argued that the BioWatch program has never had any false positives and all positives are associated with background environmental persistence of the organisms, not actual attacks.

Can you please tell us how these were confirmed to be true positives? What gold standard test was performed to reach this conclusion in each case?

Answer. Response was not received at the time of publication.

Question 4b. Were the hits on the DNA of bacteria that were very closely related to those we were looking for? But they weren’t actually what we were looking for?

Answer. Response was not received at the time of publication.

Question 4c. If these bacteria are setting off the sensors, why hasn’t anyone gotten sick from them?

Answer. Response was not received at the time of publication.

Question 5. Many agencies employ some form of biodetection. Who is designated to look across the board at all of these different programs, and assess them for redundancy, overlap, gaps, and potential for cost-savings?

Answer. Response was not received at the time of publication.

QUESTION FROM CHAIRMAN GUS M. BILIRAKIS FOR RAFAEL BORRAS

Question. Your testimony states that the Department of Homeland Security Science and Technology Directorate is working closely with the Office of Health Affairs on the technical strategy for Generation 3. Please provide evidence of this.

Answer. Response was not received at the time of publication.

