

CONTINUING CONCERNS OVER BIOWATCH AND
THE SURVEILLANCE OF BIOTERRORISM

HEARING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JUNE 18, 2013

Serial No. 113-56



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CONTINUING CONCERNS OVER BIOWATCH AND THE SURVEILLANCE OF BIOTERRORISM

TUESDAY, JUNE 18, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10 a.m., in room 2322 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Present: Representatives Murphy, Burgess, Blackburn, Scalise, Harper, Olson, Gardner, Johnson, Long, Ellmers, Bilirakis, DeGette, Butterfield, Tonko, Green, and Waxman (ex officio).

Staff present: Carl Anderson, Counsel, Oversight; Sean Bonyun, Communications Director; Karen Christian, Chief Counsel, Oversight; Andy Duberstein, Deputy Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Brittany Havens, Legislative Clerk; Sean Hayes, Counsel, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Phil Barnett, Democratic Staff Director; Stacia Cardille, Democratic Deputy Chief Counsel; Kiren Gopal, Democratic Counsel; Hannah Green, Democratic Staff Assistant; Elizabeth Letter, Democratic Assistant Press Secretary; Stephen Salsbury, Democratic Special Assistant; and Roger Sherman, Democratic Chief Counsel.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Good morning. I convene this hearing of the Subcommittee on Oversight and Investigations on Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism. We will be examining the effectiveness and efficiency of BioWatch, a Department of Homeland Security program that relies heavily on the Centers for Disease Control and Prevention, and the State and local public health laboratories that are members of the CDC Laboratory Response Network.

BioWatch is an early warning system designed to detect a large-scale, covert attack that releases anthrax or other agents of bioterrorism into the air. The program was launched in January 2003 as this country was preparing for war against Iraq when many believed that state-actor programs had stockpiles of anthrax, smallpox, and botulinum.

BioWatch deploys collectors in 34 of the largest U.S. metropolitan areas in outdoor locations, with indoor deployments in three

sites, and special event capacity. These collectors hold filters that gather air samples. Every 24 hours, a government worker goes to these collectors, manually retrieves the filters, and takes them to a State or local laboratory for analysis and testing. If the lab testing shows a positive result, called a BioWatch Actionable Result, or BAR for short, government officials review other evidence and information to decide if it is an actual attack, or just the detection of a bacteria in the environment that has a similar DNA to the pathogen of concern. Since the program started, there have been 149 BARs, none of them being an actual attack. BioWatch costs about \$85 million a year to operate, and over \$1 billion spent since 2003.

For 9 years BioWatch has sought to develop and deploy a more advanced type of technology that would include air sampling and analysis of the samples in the same device, a so-called lab-in-a-box. This technology, known as Generation 3, is estimated by GAO to cost \$5.8 billion over 10 years. According to a senior CDC official, the cost is “an abomination.”

Unfortunately, after much hype, versions of the lab-in-a-box technology have failed. One version, BioWatch Generation 2.5, was actually deployed for 2 years and then halted because it was ineffective. The latest version of technologies for Generation 3 failed testing. About \$300 million has already been spent on these failed detection technologies. Last year, the Senate and House Appropriations Committees removed the \$40 million requested by the Administration for Generation 3, and no procurement of this technology can proceed until after the Secretary of Homeland Security certifies that the science is proven.

Almost a year ago, this committee opened this investigation after a National Academy of Sciences report in 2011 and an article in the Los Angeles Times in July 2012 noted that the BioWatch system was generating false positives or indicating the “the potential occurrence of a terrorist attack when none has occurred.” A DHS official responded, stating that the reports of false positives were incorrect and unsubstantiated, and that there “has never been a false positive result.”

However, the committee’s investigation found other serious problems with the BioWatch program besides the BAR false positives. Most troubling is whether we are better prepared to respond to bioterrorism than we were 5 years ago. Unfortunately, the answer would seem to be no.

The public health workforce has been reduced by 21 percent over the last 5 years, with emergency preparedness being hardest hit. Several of the bioterrorism threats we thought we faced in 2003 no longer apply or have been lessened. According to the DHS experts interviewed by committee staff, recent threat assessments show that a large-scale catastrophic attack is less likely. However, the threat is still dangerous because of certain technological advances and the greater likelihood of smaller-scale attacks that would probably not be detected by BioWatch.

Yet, if the science of Generation 3 is proven, DHS would be expected to pursue the multibillion-dollar Generation 3. We cannot afford another DHS boondoggle. This costly approach is unbalanced and misdirected. It makes no sense to expand outdoor monitoring

for a less likely large-scale attack, while not addressing the declining number of public health responders who are needed in any kind of attack. If public health authorities lack the capability to respond, BioWatch will not produce a benefit.

The committee's investigation did not find a strategy reflecting changes in the threat and the reduced resources in the public health workforce. Last July, the President put out a National Strategy for Biosurveillance. He directed that a strategic implementation plan be completed within 120 days, but there is no strategic implementation plan that has been publicly released, and the committee staff have been unable to confirm if this plan even exists.

Once the role of BioWatch is appropriately analyzed in the context of an overarching biodefense strategy, tough questions need to be examined. After 10 years of operation, we still don't know if the current BioWatch technology can detect an aerosolized bioterrorism agent in a real-world environment. DHS expects to have this data this fall. We don't know if past management problems have been corrected. Bipartisan committee staff asked DHS to produce documents from an internal DHS investigation of a DHS official's conduct related to BioWatch, but DHS has not done so.

There has been bipartisan and non-partisan concern over BioWatch, including the ranking member of the House Homeland Security Committee, Bennie Thompson, the GAO, the National Academies of Science, Congressman David Price, Democrats and Republicans on the Senate and House Appropriations Committees, House Homeland Security Committee Republicans, Congressman Gus Bilirakis, now a member of the House Energy and Commerce Committee, and Congressman Dan Lungren. Let us work together to get the right solution.

We want to thank the witnesses for being here today. I would now like to give the ranking member, my good friend from Colorado, Ms. DeGette, an opportunity to give her opening statement for 5 minutes.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

I convene this hearing of the Subcommittee on Oversight and Investigations on "Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism." We will be examining the effectiveness and efficiency of BioWatch, a Department of Homeland Security (DHS) program that relies heavily on the Centers for Disease Control and Prevention (CDC), and the state and local public health laboratories that are members of the CDC Laboratory Response Network.

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OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, very much, Mr. Chairman.

Mr. Chairman, I am so glad we are here talking about this BioWatch surveillance program. Bioterrorism remains a threat to our nation, and BioWatch's detection capabilities are critical, and I agree with you, that is why we need to make sure that the program is operating efficiently.

After the anthrax mailings of 2001, the federal government needed to act fast. In September 2001, the New York Times reported that the government's bioterrorism planning was so disjointed that the agencies involved could not even agree on which biological agents posed the biggest threat. Boy, we have come a long way since then, in large part because of the BioWatch program.

BioWatch has been monitoring the air for potential bioterror agents like anthrax for the last decade. It is a valuable tool because it provides us with advanced warning of a biological attack. If a release of anthrax was detected before it began to adversely affect people, for example, public health officials could take action to mitigate its impact and prevent it from being spread. Local hospitals could be told to be on the lookout for certain symptoms and ensure victims weren't being misdiagnosed. Any time that we can buy through early detection could mean many lives saved.

With this kind of biosurveillance system in place, the likelihood of a biological attack inflicting mass casualties and overwhelming our public health system would be greatly reduced. That is why biosurveillance is an essential activity and a national priority, and that is BioWatch is a beneficial program that helps meet our national security needs. But, Mr. Chairman, there is a big "if", and I agree with you: those facts only hold true if we can be confident that the BioWatch program works the way it says it should.

Experts have in recent years raised a number of technical and management concerns with the BioWatch program. Mr. Chairman, you talked about some of those in your opening statement. This committee's job is to hear about those concerns so we can make sure that the program is on the right path forward. Is the federal, state, and local collaboration running smoothly? Are constructive recommendations being implemented? Is the program now being effectively managed? Is the current generation of BioWatch technology meeting appropriate standards, and is the next generation of BioWatch technology fiscally and technically feasible.

I appreciate both of our witnesses today, and I hope they can help us answer these questions. We have heard from officials that Generation 3 that you discussed, which is the proposed new BioWatch technology, could provide more timely threat detection. Before we expend considerable resources on that, though, I think we can be in agreement, we have got to be confident that this technology works. If it can be tested and proven, Generation 3 holds the potential to provide continuous and autonomous detection and expanded population coverage. Unfortunately, the acquisition proc-

ess for BioWatch Generation 3 has been married with difficulties, and serious questions remain about whether Generation 3 is a viable advance.

Last September, GAO reported that decisions were made to go forward with this automation detection technology without the proper due diligence and without justifying the mission need. DHS didn't develop a complete and reliable performance schedule and cost information before approving the acquisition, and if there is one thing we have learned since September 11th, let us just stop throwing money around willy-nilly. Let us make sure that we target it to programs that work.

Generation 3 acquisition is currently on hold as DHS tries to resolve these issues, and that seems like the prudent course of action to me. The delays and mismanagement that led us to this point, however, are unacceptable, and DHS must do better. I am looking forward to hearing from Dr. Walter about what has been done to rectify these deficiencies so that we can move forward.

The BioWatch program is only a small part of our efforts to detect and to deter bioterrorism. That is why part of our discussion about BioWatch must also ask about broader biosurveillance activities and where this picture fits into the large picture. We obviously can't protect against every potential threat but we should be figuring out what the likeliest threats are, and if our current infrastructure meets the challenges of today as well as the future, given the limited resources.

I look forward again to hearing from the witnesses about BioWatch, and I know we will be able to have a constructive discussion about where we go from here, and I yield back, Mr. Chairman.

Mr. MURPHY. The gentlelady yields back, and now I turn towards the vice chairman of the committee, Dr. Burgess, for 5 minutes.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for the recognition.

We have already heard this morning the result of the 9/11 attacks, the anthrax letters in 2001 of escalated bioterrorism from a concept to a reality. In response, the BioWatch program was launched as an early-detection warning system for bioterrorist attacks. Unfortunately, in the rush to launch BioWatch, the government failed to ensure the proper role for the program in the greater United States biosurveillance strategy.

Public health is best administered at the local and community level. While BioWatch has the potential to provide valuable data to federal, State and local officials, the promise continues to remain one in theory.

The Centers for Disease Control requires reliable, high-quality evidence in order to decide to respond to a bioterrorism event. The Department of Homeland Security, who is in charge of the BioWatch system, has failed to utilize BioWatch to gather the information necessary to guide the decisions of public health authorities.

We have another problem. Since 2003, BioWatch has produced 56 false alarms. This unfortunately has the effect of destroying

public confidence that public health officials may have had in the system. Federal, state, and local agencies already operate and maintain a wide variety of outdoor air monitoring systems across the United States. The 26th district of Texas, which produces a lot of natural gas through a process known as fracking, maintains a number of air quality sensors, both from the Texas Commission for Environmental Quality as well as the private sector as well. If private companies have the ability to capture real-time air quality data through remote sensing, why do we still lack the ability to detect that that came from a bioterrorism attack?

Terrorist threats have changed since 2001. The enemies are developing new strategies that will circumvent our surveillance. Our surveillance and response strategy must improve at an even faster pace. We should identify and address the evidence gaps in our public health surveillance system, ensuring that all United States surveillance systems cooperate to achieve our biosurveillance strategy and prevent those threats before they become a reality.

And then lastly, I feel obligated just to mention that back in the early 1950s, the United States Navy undertook a series of exercises that were famously declassified in the mid-1970s that provided evidence that yes, indeed there can be a problem. The dispersal of what was thought to be a harmless bacteria along the coastline in the United States ended up causing illness in a limited number of individuals but nevertheless illness all the same. So it certainly underscores the importance of undertaking this work but it is also important that we get it right.

Mr. Chairman, I thank you for the consideration and I will yield back to you.

Mr. MURPHY. The gentleman yields back. I now recognize the ranking member of the committee, Mr. Waxman, for his opening statement for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman, and my comments are going to be similar to my colleagues because we all understand what we are facing today.

The history of this is that in 2003 in his State of the Union address, President Bush announced the deployment of “the Nation’s first early warning network of sensors to detect biological attack.” Just months after this announcement, the BioWatch program was up and running. We have since learned that BioWatch, like other post-September 11 programs, was implemented too hastily and without appropriate long-term planning.

But that doesn’t mean that the program cannot be repaired. In fact, progress is already being made. In recent years, Government Accountability Office and other analysts have identified legitimate concerns with the management of the BioWatch program that should be addressed, particularly with respect to the acquisition of new early-detection Generation 3 technology. This new technology is promising because it could lead to faster detection in the event of a bioterror attack.

According to GAO, however, the Department of Homeland Security approved the Gen-3 acquisition “without fully developing critical knowledge that would help ensure sound investment, decision making, pursuit of optimal solutions, and reliable performance, cost, and schedule information.” To protect taxpayers, DHS officials have now put the acquisition on hold until all the necessary steps are taken to ensure we are making a wise investment decision that is grounded in the facts, and that of course is a prudent approach.

The L.A. Times, however, has brought other issues to light. In its reporting, the Los Angeles Times exposed a series of false positives identified by BioWatch sensors. As the Times documented, BioWatch sensors have repeatedly indicated the detection of possible bioterror agents that were later found to be harmless, naturally occurring organisms. Fortunately, all of these false positives were identified before the public was needlessly alarmed. When the sensors went off, scientists were alerted to determine if these were legitimate bioterror agents or detections of benign agents. The Department is now working to lower the incidence of false positives, and this seems to be improving. There have been none so far this year.

We have also heard about scientific disagreements within the program. Much of the debate about the program’s path forward and particularly the acquisition of new Generation 3 technology revolves around complex scientific questions. These types of scientific questions are not surprising in a highly technical program like this. We can’t answer the questions ourselves, but we can listen to the experts in biology, epidemiology and detection technology to become better informed, and I hope today’s hearing will help in this area.

While we hear criticism of the BioWatch program, especially today, we also need to bear in mind its important public safety objectives. BioWatch’s early-detection capabilities and its role in facilitating communication between key state and local decision makers can help protect our communities. We should use this hearing as an opportunity to strengthen the program. That is why I am glad that Dr. Walter is here today to discuss the history of the BioWatch program and how the Administration is learning from past mistakes to make the program even more effective in the future. It shouldn’t be all that hard, but if we are going to keep this program, let us make sure it is effective.

Mr. Chairman, I thank you for calling this hearing, and I thank our witnesses for being with us today to help us answer these questions about this important Homeland Security program.

I want to apologize to the witnesses in advance. We have another hearing going on simultaneously, and I am going to have to be going back and forth, but I will have a chance to review the record and my staff is here to learn all the information that will be brought out at this hearing. I yield back the balance of my time, and thank you for calling on me.

Mr. MURPHY. The gentleman yields back, and thank you for your opening statement.

I would like to note and state that all those who just had opening statements agree that this is an area we are unified on in purpose, so now to our witnesses.

First let me introduce the witnesses so everybody knows who you are. First, Dr. Michael Walter, welcome here. He is the Detection Branch Chief and BioWatch Program Manager with the Office of Health Affairs at the Department of Homeland Security. He works with labs, public health, law enforcement, and emergency management personnel to assist federal, state, and local governments in developing and testing response measures to biological attacks. In addition to directing operations of the current BioWatch system, Dr. Walter also oversees the testing, acquisition, and deployment of the newer technology referred to as Generation 3. Welcome. Our second witness is Dr. Toby Merlin. He has been with the Centers for Disease Control and Prevention since 2003. He is the Director of the Center for Disease Control and Prevention's Division of Preparedness and Emerging Infections and has been the CDC's main interface with the BioWatch program since 2011. Prior to his current role, Dr. Merlin served as the Deputy Director of the Influenza Coordination Unit during the 2009 H1N1 pandemic.

I will now swear in the witnesses, and you are that the committee is holding an investigative hearing, and when doing so has the practice of taking testimony under oath. Do you have any objections to testifying under oath?

Mr. WALTER. No.

Dr. MERLIN. No.

Mr. MURPHY. So now the Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today? Both witnesses indicated no. In that case, if you would please rise and raise your right hand and I will swear you in?

[Witnesses sworn.]

Mr. MURPHY. Both of the witnesses are now under oath and subject to the penalties set forth in Title XVIII, Section 1001 of the United States Code. You may now each give a 5-minute summary of your written statement. Dr. Walter, you may begin.

TESTIMONY OF MICHAEL WALTER, PH.D., BIOWATCH PROGRAM MANAGER, U.S. DEPARTMENT OF HOMELAND SECURITY, OFFICE OF HEALTH AFFAIRS; AND TOBY L. MERLIN, MD., DIRECTOR, DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS, NATIONAL CENTER FOR EMERGING AND ZOO NOTIC INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION

TESTIMONY OF MICHAEL WALTER

Mr. WALTER. Chairman Murphy, Ranking Member DeGette, and distinguished members of the subcommittee, thank you for inviting me to speak with you today. I appreciate the opportunity to testify on the Office of Health Affairs' BioWatch program, and I am honored to testify alongside my distinguished colleague from the Centers for Disease Control and Prevention, Dr. Toby Merlin. My name is Dr. Michael Walter. I am the Program Manager for the DHS Office of Health Affairs' BioWatch program.

Bioterrorism remains a continuing threat to the security of our Nation. A biological attack would impact every sector of our society

and place enormous burdens on our Nation's public health with rippling effects on critical infrastructure. Biological attacks are particularly challenging because they can be so difficult to detect. Early detection is critical to the successful treatment of affected populations and provides public health decision makers more time and thereby more options in responding to, mitigating and recovering from a bioterrorism event. If a bioagent is detected and confirmed to be a threat to the public health, prophylactic treatment could be started prior to the widespread onset of symptoms resulting in a more cohesive response and more lives saved.

The BioWatch program is the country's only nationwide program whose goal is to continuously monitor for aerosolized environmental agents. The program consists of planning, preparedness, exercising, training and early-detection capabilities. Deployed throughout the country, the system is a collaborative effort of health professionals at all levels of government. The program is operated by a team comprised of field operators, laboratory technicians, and public health officials from city, county, state, and federal organizations. The current detection capabilities used by the BioWatch program consist of aerosol collectors whose filters are manually collected and retrieved for subsequent analysis in BioWatch laboratories that are located in state or county public health laboratories that are members of the CDC laboratory response network.

When a detection of a positive signal occurs, a BAR, or a BioWatch Actionable Result, is declared. A BAR is declared by the Director of the Public Health Laboratory or their designee, not by the federal government. 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 threat to the public health. A BAR simply means that DNA of a select organism is present. Each BioWatch jurisdiction across the country has a BioWatch Advisory Committee, or BAC, made up of state, local, and federal partners who operate the program and are responsible for planning and leading response efforts.

The BioWatch program has succeeded in bringing together state and local public health first responders and law enforcement personnel along with locally deployed federal officials, resulting in communities that are better prepared not only for a biological attack but for an all-hazards response. The BioWatch program relies heavily on our federal partners for expertise in public health, law enforcement, intelligence and technical support to ensure optimum operations throughout the program.

To that end, the BioWatch is supported by federal partners including the CDC, the Federal Bureau of Investigations, the Department of Defense and the Environmental Protection Agency, and I would like to take this opportunity to thank Dr. Merlin and the CDC for their continued engagement in support of the program.

Consistent with the National Strategy for Biosurveillance, we have been looking at new technologies that could shorten the time to detect including autonomous detection technology. The BioWatch program understands the importance of providing public health officials the timeliest information possible to help them make high-

consequence decisions. Automated detection would reduce the time to detect significantly, handing back precious time to our public health officials faced with responding to a potential bioterrorism event. In addition, it would reduce cost of operations while providing continuous collection and analysis capability. The Department is currently conducting an analysis of alternatives consistent with Government Accountability Office recommendations prior to moving forward with a potential acquisition of advanced automated detection technologies.

I appreciate the committee's interest in the BioWatch program and your continued partnership as we work to improve our Nation's biopreparedness. The Office of Health Affairs believes strongly in a comprehensive surveillance approach that includes environmental and clinical surveillance as well as point-of-care diagnostics.

Thank you for the opportunity to appear today, and I look forward to your questions.

[The prepared statement of Mr. Walter follows:]

Written Statement of Michael Walter, PhD
BioWatch Program Manager
U.S. Department of Homeland Security
Before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
June 12, 2013

Chairman Murphy, Ranking Member DeGette, and distinguished members of the Subcommittee, thank you for inviting me to speak with you today. I appreciate the opportunity to testify on the Office of Health Affairs (OHA) BioWatch Program and I'm honored to testify alongside my distinguished colleague from the Centers for Disease Control and Prevention (CDC), Dr. Toby Merlin.

Bioterrorism remains a continuing threat to the security of our nation. A biological attack could impact any sector of our society and place enormous burdens on our nation's public health, with a rippling effect on critical infrastructure. Biological attacks are particularly challenging because they can be difficult to detect. Detecting a biological attack as soon as it occurs and identifying the biological agent helps save lives.

The early detection, planning, preparedness, exercising and training capabilities provided by the BioWatch Program are essential parts of a biodefense posture. Early detection is critical to the successful treatment of affected populations and provides public health decision makers more time – and thereby more options – in responding to, mitigating, and recovering from a bioterrorist event. If a bioagent is detected and assessed to be the result of an act of bioterrorism and/or a threat to public health, prophylactic treatment can be started prior to the widespread onset of symptoms resulting in more lives saved.

Overview of the BioWatch System

The BioWatch Program is the nation's only federally-managed, locally-operated nationwide 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 between preparedness and public health personnel at all levels of government. The program is operated by a team comprised of field operators, laboratory technicians, and public health officials from city, county, state, and federal organizations. This coordinated team is responsible for installing bio-collectors, collecting daily samples, analyzing and reporting laboratory results, and responding to the detection of a positive signal, known as a BioWatch Actionable Result (BAR).

The current detection capabilities used by the BioWatch Program consist of outdoor and select indoor aerosol collectors whose filters are retrieved for subsequent analysis in state or county public health laboratories that are members of the CDC Laboratory Response Network (LRN). BioWatch works with jurisdictional personnel to determine collector locations, and has an initiative that looks at optimizing locations. A BAR is declared by the director of that public health laboratory or their designee. A BAR simply means that DNA of a selected agent is present. 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 analysis is needed to determine if a release has occurred and if there is a risk to public health.

Federal-State-Local Partnership

BioWatch is the only program that exercises and evaluates our national collective abilities to provide a detect-to-treat notification system alerting the U.S. population to an aerosolized biological attack. While OHA oversees, coordinates, and provides technical support to the BioWatch Program at the federal level, state and local public health authorities manage the day-to-day program. These state and local partners use the information generated by the detection system as an important tool in deciding whether a biological event of public health significance has occurred.

The BioWatch Program relies heavily upon our federal partners for expertise in public health, law enforcement, intelligence, and technical support to ensure optimum operations throughout the program. To that end, BioWatch is supported by federal partners including the CDC, the Federal Bureau of Investigation, the Department of Defense and the Environmental Protection Agency. For example, the CDC provides public health perspectives on BioWatch guidance documents, as well as technical expertise to state and local public health laboratories within the BioWatch Program.

While federal interagency support is critical, because the BioWatch Program is operated by state and local officials, partnerships nationwide are especially important. Each BioWatch jurisdiction has a BioWatch Advisory Committee (BAC) made up of state, local and federal partners who are responsible for leading response efforts. In the case of a BAR, the BAC is informed within one hour of the declaration, followed within two hours by a National Conference Call. The National Conference Call brings together all the necessary state, local and federal response partners to determine whether the occurrence of a BAR is due to a potential act of bioterrorism, constitutes a threat to public health, or both. The National Conference Call also provides the federal government with situational awareness of potential resources that will be requested by the affected jurisdiction.

Further, the BioWatch Program complements the existing public health surveillance systems, allowing information to be shared with health care providers. This system of systems approach is valuable even in the absence of a BAR. The BioWatch Program has succeeded in bringing together state and local public health, first responders, and law enforcement personnel, along with locally-deployed federal officials, who continue to foster relationships beyond the BioWatch Program, resulting in communities that are better prepared not only for a biological attack, but also for an all-hazards response.

Providing Tools for Preparedness

The BioWatch Program recognizes that, while the Federal government and private sector partners have an important role to play, state and local jurisdictions are on the front lines of responding to bioterrorism events. To this end, the BioWatch Program utilizes Jurisdictional Coordinators (JCs) to assist in the operation of the BACs, facilitate communications among state and local partners, assist in preparedness and response plan development, and to help coordinate exercise and special event planning (e.g., political conventions, major sporting events, and significant local events such as parades). This locally-embedded network of JCs provides jurisdictions and the BioWatch Program leadership with information regarding challenges encountered across jurisdictions serving to inform operational and programmatic directions.

Additionally, the BioWatch Program manages the national notification process and offers laboratory support, environmental sampling, and event modeling.

Robust Quality Assurance

To ensure that end users have confidence in the analysis and laboratory detection methods, the BioWatch Program developed and implemented a formal and robust BioWatch quality assurance (QA) program in 2010. Key objectives of the QA program include: ensuring standardization across the program; characterizing performance capabilities; rapidly identifying quality issues; and supporting effective root-cause analyses, corrective actions, and continuous improvement.

BioWatch developed a laboratory Quality Assurance Program Plan in close collaboration with the state and local public health laboratory partners. In addition, the BioWatch QA program conducts audits and proficiency tests of each laboratory and tracks performance of all analysis on a daily basis.

Innovation for the Future

As the President's 2012 *National Strategy for Biosurveillance* states, we must foster innovation to facilitate new biosurveillance activities, including new detection technologies. We have been assessing new technologies that could shorten detection time, including autonomous biodetection

technology. The Department has considered automated detection because of the potential for this type of technology to shorten the time to detect by eliminating the need for manual filter retrieval and analysis through continuous collection and analysis capability. The results of this automated analysis would be transmitted virtually to public health officials. With automated detection, the time to detect could be reduced from 12-36 hours to 4-6 hours. The Department is currently conducting an Analysis of Alternatives (AoA), consistent with recommendations by the Government Accountability Office. The AoA will assess several possible alternative strategies based on technical feasibility, manageable risk and cost. Based on the results of the AoA, DHS will determine the most appropriate course of action.

Conclusion

I appreciate the Committee's interest in the BioWatch Program and your continued partnership as we work to improve our nation's biopreparedness. The Office of Health Affairs believes strongly that a comprehensive surveillance approach includes environmental and clinical surveillance, as well as point-of-care diagnostics. Thank you for the opportunity to appear before you today. I look forward to your questions.

Mr. MURPHY. Thank you.

Dr. Merlin, you are recognized for 5 minutes.

TESTIMONY OF TOBY MERLIN

Dr. MERLIN. Thank you, Mr. Chairman.

Chairman Murphy, Ranking Member DeGette and members of the subcommittee, I want to thank you for the opportunity to speak to you today about the Department of Homeland Security's BioWatch program. I am Dr. Toby Merlin, Director of CDC's Division of Preparedness and Emerging Infections in the National Center for Emerging and Zoonotic Infectious Diseases. I am honored to testify alongside my distinguished colleague from DHS, Dr. Michael Walter, with whom I regularly work.

CDC works 24/7 to save lives and protect Americans from health threats. Throughout its history, CDC and its local, national, and international partners have worked to detect, respond to and prevent health security threats. My remarks today will describe how CDC collaborates with DHS on the BioWatch program, explain the related role that CDC's Laboratory Response Network plays in this program, and discuss CDC's broader role in outbreak detection and response. All of these efforts are designed to protect Americans from infectious public health threats including threats of bioterrorism.

In 2003, DHS initially launched the BioWatch program, which is a nationwide biosurveillance system designed to detect the intentional aerosolized release of selected biologic agents. At that time, CDC helped establish and staff BioWatch laboratories and develop and validate laboratory methods for detection of targeted biologic agents. Since the establishment of the BioWatch program, CDC has provided technical assistance to DHS by ensuring that scientific experts are available for consultations with the BioWatch laboratories and conducting additional laboratory testing at CDC when requested. CDC provides BioWatch laboratories with specialized reagents used in the testing and a system for secure electronic messaging of results.

CDC also provides scientific expertise and guidance, especially as it pertains to laboratory methodology and analyses to DHS and states and localities that participate in the BioWatch program. In the event that a biological threat agent is detected through the BioWatch program and it is determined that a response is needed, CDC would coordinate any needed federal public health response.

CDC's Laboratory Response Network, or LRN, has 150 member facilities and provides support to DHS's BioWatch program. The LRN is a network of local, state, and federal public health and other laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical threats and other public health emergencies. Participation in the network is voluntary, and all member laboratories work under a single operational plan and adhere to strict policies of safety, biocontainment and security. Laboratories also perform testing using LRN procedures and reagents provided by CDC, which allows for rapid testing, reproducible results and standard reporting. BioWatch laboratories are usually collocated with LRN sites in the states and they use LRN procedures and reagents in the second phase of testing of

material collected from air samples. CDC and the LRN provide support to the BioWatch program by participating in this BioWatch testing and the review steps which are designed to detect a possible release of a biological agent into the air.

Laboratory detection and epidemiological response to disease are the foundation of CDC's activities. In addition to managing the LRN and providing support to DHS's BioWatch program, CDC plays a broader, critical role in the detection of and response to local, state, national and international outbreaks of infectious diseases whether naturally occurring or manmade. CDC is home to the country's leading experts and gold-standard laboratories in infectious disease prevention and control. CDC's laboratories serve as an early warning system to rapidly identify, confirm and characterize new infectious disease threats. CDC often serves as a resource for our state and local partners during outbreaks and plays a critical role in identifying disease patterns and linkages across state and local lines.

In closing, CDC and LRN laboratories are critical and unique laboratory-based assets to ensure that our Nation is prepared to detect and respond to biological and chemical terrorism. CDC and LRN laboratories are essential to assuring rapid detection of these threat agents and other infectious diseases that pose a threat to the public. The BioWatch program is an important component of this national effort at early detection of biological threats. CDC will continue to work closely with DHS to support the BioWatch program whenever requested specifically in the areas of laboratory testing and public health response.

Thank you, Mr. Chairman, and I would be pleased to answer any questions.

[The prepared statement of Dr. Merlin follows:]



Testimony before the
Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce
U.S. House of Representatives

**Continuing Concerns Over BioWatch and
the Surveillance of Bioterrorism**

Toby Merlin, M.D.

Director, Division of Preparedness and Emerging Infection
National Center for Emerging and Zoonotic Infectious
Diseases
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

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Good morning Chairman Murphy, Ranking Member DeGette, and distinguished Members of the Subcommittee.

Thank you for the opportunity to testify today on the Department of Homeland Security's (DHS) BioWatch program. It is a pleasure to appear before you representing the U.S. Centers for Disease Control and Prevention (CDC), the Nation's leading health protection agency. Throughout its history, CDC and its local, national, and international partners have worked to detect, respond to, and prevent health security threats. CDC works 24-7 to save lives and protect people from threats.

I am Dr. Toby Merlin, Director of CDC's Division of Preparedness and Emerging Infections in the National Center for Emerging Zoonotic and Infectious Diseases. Since the beginning of the BioWatch program, CDC has assisted DHS with several aspects of the program, including in the areas of laboratory testing and public health response. Today, I would like to describe how CDC collaborates with DHS on the BioWatch program, explain the related role that CDC's Laboratory Response Network (LRN) plays in this program, and discuss CDC's broader role in outbreak detection and response. All of these efforts are designed to protect Americans from infectious public health threats, including threats of bioterrorism.

CDC's Role in the BioWatch Program

Since the beginning of the BioWatch program, CDC has provided technical assistance to DHS when requested. In this capacity, CDC currently supplies BioWatch LRN verification reagent panels and also provides technical support for interpretation of laboratory results, process troubleshooting, and an electronic application, Results Messenger, for securely messaging laboratory results to CDC. In some instances, CDC evaluates and validates the best available testing technology for use in the BioWatch program. CDC also provides technical support in quality control testing and assurance of LRN reagents used as verification panels in BioWatch testing.

CDC provides scientific expertise and guidance — especially as it pertains to laboratory methodology and analyses — to DHS and states and localities that participate in the BioWatch program. When DHS initially launched the BioWatch program, CDC helped establish and staff BioWatch laboratories and developed and validated laboratory methods for detection of targeted biological threat agents. Since establishment of the BioWatch program, CDC has provided scientific experts on-call for consultations with BioWatch laboratories and additional laboratory testing at CDC, if requested. CDC coordinates the Federal Government's public health response to the possible detection of a biological threat agent as well.

CDC subject matter experts routinely provide technical advice on preparedness planning documents with DHS and partners to represent the public health perspective.

Ensuring Effective Laboratory Response to Bioterrorism

LRN Overview

The LRN is a CDC-managed network of local, state, and Federal public health and other laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical threats and other public health emergencies. DHS BioWatch laboratories work closely with these LRN laboratories to conduct tests and interpret their results. The LRN became operational in 1999 following the two Presidential Directives, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. CDC, in partnership with the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories (APHL), launched the LRN to strengthen the Nation's ability to respond quickly to biological, chemical, and radiological threats and other high priority public health emergencies through rapid testing, timely notification, and secure electronic submission of laboratory results. The network began with just 17 laboratories and, as of May 24, 2013, has expanded to 150 member facilities, including facilities in Australia, Canada, Germany, Japan, Mexico, South Korea, and the United Kingdom. Using 2000 census data, it has been determined that approximately 90 percent of the United States population lives within 100 miles of an LRN member laboratory. The LRN laboratories are not only geographically diverse, but they include public health, military, veterinary, environmental, and food laboratories. These laboratories provide reference testing for agents, such as *Bacillus anthracis* (anthrax), *Francisella tularensis* (tularemia), *Yersinia pestis* (plague), *Variola major* (smallpox) and *Clostridium botulinum* toxins (botulism), as well as cyanide, nerve agents, and other toxic chemicals. The different member laboratories can also identify agents in different types of samples, like clinical, environmental, food, and water samples. The LRN can be used to detect traditional biological threat agents, novel agents, or emerging infections. Just in the past few weeks, CDC developed and deployed through the LRN tests for two new health threats, influenza A H7N9, which has emerged in China, and MERS-CoV from the Middle East.

Participation in the network is voluntary and all member laboratories work under a single operational plan and adhere to strict policies of safety, bio-containment, and security. Laboratories also agree to perform testing using LRN procedures and reagents provided by CDC which allows for rapid testing, reproducible results, and standard reporting. The foundation of the LRN is a unified operational plan and standardization of laboratory testing, where a test result generated from one LRN member laboratory is the same as a result generated from another network laboratory. Some of the other key elements of the LRNs include highly-trained laboratory workers, common laboratory equipment, safe facilities, rapid detection capabilities, and fast and secure notification of results that allow for more efficient medical countermeasure deployment. As I will discuss in more detail later, CDC's investment in epidemiology and laboratory capacity at the Federal, state and local level enables an integrated response to public health threats, whether natural or man-made.

The LRN links state and local public health laboratories with veterinary, agriculture, military, and water- and food-testing laboratories, and the LRN also provides laboratory services to evaluate threat letters containing so-called "white powders."

LRN and BioWatch

BioWatch laboratories are usually co-located with LRN sites and they use LRN procedures and reagents in the second phase of their serial testing of material collected from air samples to detect biological threat agents. CDC and the LRN provide support to the BioWatch program by participating in their serial testing and review strategy, which is designed to determine when there might be a bioterrorism threat to the public from release of a biological threat agent into the air. The serial testing strategy minimizes the number of false positive laboratory test results that would indicate a bioterrorism threat.

Specifically, the BioWatch serial testing strategy entails at least two separate laboratory tests, the first of which is called the BioWatch screening test. This test is performed by BioWatch laboratories, is a very sensitive test, and can produce preliminary positive results that indicate that the specimen should undergo further testing for confirmation of the presence of material from a biological threat agent. The verification testing utilizes a panel of LRN DNA signatures for each biological agent threat, with an algorithm that has to be met to make a final call decision. The approach of using a sensitive and specific screening assay, coupled with rigorous verification testing, is consistent with Good Laboratory Practices, reduces probability of false positives, and enhances confidence in results. LRN-trained personnel use unified operational plans and standardized laboratory testing approaches to interpret these test results to determine if additional review is needed when there is a positive test result in either of these testing stages.

Outbreak Detection and Response

Laboratory detection and epidemiologic response to disease are the foundation of CDC's activities. In addition to managing the LRN and providing support to DHS' BioWatch program, CDC plays a broader, critical role in the detection of and response to local, state, national, and international outbreaks of infectious diseases caused by naturally occurring or man-made threats.

CDC Laboratories

CDC is home to the country's leading experts and gold-standard laboratories in infectious disease prevention and control. These state-of-the-art laboratories are critical to our Nation's safety and health, and are staffed and equipped to detect, track, and respond to a range of microbes and respond to outbreaks, such as the 2012 fungal meningitis outbreak. They serve as an early warning system to rapidly identify, confirm, and characterize new infectious disease threats. CDC laboratories maintain unique and critical capacities, including evaluating pathogens from outbreaks of infectious disease,

...serving as reference laboratories, conducting tests on or identifying pathogens in samples from around the world, developing diagnostic tests to more quickly and easily identify new diseases, and researching a wide range of pathogens to understand better the nature of significant and emerging pathogens.

Federal, state, local, tribal, and territorial public health departments and their laboratories are our Nation's first line of defense against public health threats. These critical partners form a national disease detection tracking network, which is essential to identifying, tracking and responding to disease outbreaks and other health threats as quickly as possible. For this reason, CDC invests in and provides training for state and local laboratories to strengthen detection of and response to infectious diseases, including those caused by influenza, healthcare-associated infections, mosquito-borne diseases (e.g., West Nile virus), foodborne pathogens, and bioterrorism threats. State health department and other laboratories rely on CDC laboratories for further assistance with rare and complex pathogens or when outbreaks are large or widely distributed geographically.

The enormous diversity of microbes—combined with their ability to evolve and adapt to changing populations, environments, practices, and technologies—creates potential threats to health and continually challenges CDC's ability to prevent and control disease. CDC must always be prepared for the unexpected. That means continuing to build state and local public health laboratory capacity throughout the United States and strengthening CDC's core infectious disease laboratories.

Outbreak Response

State and local public health departments are on the front line in detecting and responding to outbreaks, but they rely on CDC to provide laboratory and epidemiologic training and standards, and often CDC funding, to carry out their responsibility at the local level. CDC invests in state and local public health detection and response activities through the Epidemiology and Laboratory Capacity (ELC) mechanism and the Emerging Infections Program (EIP). These platforms bolster state and local capacity to detect and respond to existing and emerging infectious disease threats. Specifically, these investments support state and local public health laboratories, surveillance, outbreak investigations and response, and health tracking systems, and the training to develop the next generation of public health leaders, laboratorians, and disease detectives.

The Public Health Emergency Preparedness cooperative agreement (PHEP) complements the ELC and EIP funding and focuses on all-hazards capability development in 62 state and local public health departments and provides emergency preparedness funding to advance work on 15 key public health preparedness capabilities. These 15 capabilities include public health laboratory testing and public health surveillance and epidemiological investigation, which are tied to the LRN.

The ELC, EIP, and PHEP cooperative agreements allow state and local partners to hire and train staff, buy laboratory equipment and supplies for detecting emerging pathogens, and invest in information technology to improve disease reporting and tracking. These platforms support well over 4,800 full- and part-time positions in the state, territorial, local, and tribal health departments, including epidemiologists, laboratorians, and health information systems experts, to ensure basic capacity at the local level where many infectious diseases are first identified.

CDC often serves as a resource for our state and local partners, when requested, during outbreaks and plays a critical role in identifying disease patterns and linkages across state and local lines. We work in close collaboration with health departments to ensure a rapid and coordinated investigation and response. CDC routinely augments varied state and local capacity by providing scientific guidance to them, assisting with the epidemiologic investigation, and providing laboratory support, when needed. CDC experts also engage in outbreak investigations when the source of infection is very uncommon, new, or complex, or the outbreak occurs in more than one state.

CDC's response to an outbreak does not end once the source of the outbreak has been identified and stopped. CDC uses the information gathered during outbreak investigations to work with health departments, partners, other federal agencies, and policymakers to implement strategies to prevent future outbreaks. CDC's response to outbreaks of infectious disease, along with a thoughtful evaluation of strategies to prevent further outbreaks, continues to improve public health. The crucial laboratory and epidemiological data that CDC and its state and local partners gather allows the public, clinicians, health plans, and policy-makers to make rapid decisions based on objective evidence. CDC's systems help identify our Nation's health priorities, providing hard evidence of what works and what does not work. As a science-based agency, CDC data are used to guide decisions that protect Americans and prevent illness.

Conclusion

CDC works 24 hours a day, 7 days a week protecting Americans from health threats by providing laboratory and outbreak response assistance to federal, state and local partners. CDC helps save lives by preventing, detecting, and controlling the growing risks of infectious disease outbreaks, emerging infectious diseases, drug resistant bacteria, and natural and man-made hazards and disasters.

CDC and LRN laboratories are critical and unique assets to ensuring the Nation's preparedness to detect and respond to biological and chemical terrorism. CDC and LRN laboratories are essential to ensuring rapid detection of these threat agents and other infectious disease that could pose a threat to the public. The BioWatch program, and CDC and state and local public health laboratories that support it, contribute to this effort. CDC will continue to work closely with DHS to support the BioWatch program, as requested, specifically in the areas of laboratory testing and public health response.

I appreciate the opportunity to discuss CDC's collaboration with BioWatch program, describe our LRN program, and our critical role in infectious disease outbreak detection and response.

Mr. MURPHY. I thank both the witnesses here. We want to find out if this BioWatch system actually works, and I guess this speaks to the old adage, we want to know what time it is and we are told how a clock is made, so help us. I respect both of your experience and your intelligence, so help us walk through this. Dr. Walter, this question is for you. In yesterday's Los Angeles Times, former Homeland Security Secretary Tom Ridge, who oversaw the start of BioWatch, stated, "Everyone knew it"—that is, the BioWatch program—"was a primitive, labor-intensive, fairly unsophisticated attempt." That same technology for BioWatch is still out in the field. Do you agree with former Homeland Security Secretary Ridge that BioWatch is a primitive, labor-intensive and fairly unsophisticated tool?

Mr. WALTER. Thank you for that question, sir. With respect to Mr. Ridge, no, I do not agree with his assessment, and I think it lacks the insight of where the program has come from since the beginning of the program's origin. BioWatch uses the same collector technology that was deployed in 2003, that is true, and BioWatch is a labor-intensive process; that is also true. In the areas of laboratory analysis, our preparedness, our response and our training, Mr. Ridge is unaware of those advances to the BioWatch program and I think they have taken the BioWatch program to the next level and made it more effective.

Mr. MURPHY. Let me ask you, the BioWatch is designed to detect a catastrophic, covert bioterrorism attack. Is that correct?

Mr. WALTER. Yes, sir.

Mr. MURPHY. And for BioWatch to meet its mission, the DHS is supported especially by the state and public health laboratories, correct?

Mr. WALTER. That is correct, sir.

Mr. MURPHY. And do you agree that state and local health departments need to have the capability to respond with public health or medical measures to minimize illness and death?

Mr. WALTER. It is essential, sir.

Mr. MURPHY. OK. Well, the threat that BioWatch is detecting is a large-scale covert bioterrorism attack, so when BioWatch was launched in 2003, the threat assessment was concerned with large-scale threats posed by state actor programs or terrorists getting possession of biological weapons from state actor programs. Do you agree that there was a large-scale threat in 2003?

Mr. WALTER. There was a perceived threat, yes, sir.

Mr. MURPHY. And isn't it correct that the DHS official who conducts the bioterrorism risk assessment has found that under the current threat assessment, a large-scale bioterrorism attack is less likely and small-scale bioterrorism attacks are more likely?

Mr. WALTER. That is possible, but "less likely" doesn't mean impossible, and "less likely" means there is still a threat.

Mr. MURPHY. Let me go on to this. Dr. Merlin, if you could turn to tab 48 of that binder, and I will note while you are looking at that, in a May 23, 2012, email, you wrote, and I will quote it here, "The Material Threat Assessment, or MTA, which DHS is required to perform by statute, these drive the downstream decisions about medical countermeasure acquisition, diagnostic test development, BioWatch testing and preparedness plans. But the MTAs seem to

be developed without input from people who really understand the agents, the diseases or practical implications of these decisions.” Do you still have these concerns about CDC having input in DHS threat assessment, sir?

Dr. MERLIN. Mr. Chairman, the answer is no. My concerns have been diminished. The Department of Homeland Security has been working with the Department of Health and Human Services to have a more inclusive process for developing the Material Threat Assessments, and this process is designed to address some of the concerns I addressed so that experts from Health and Human Services are more actively engaged in developing the Material Threat Assessments and Material Threat Determination.

Mr. MURPHY. Let me try to understand. So you are saying that you don’t agree with that statement anymore or you do agree with that statement?

Dr. MERLIN. I believe steps have been taken to address my concerns. I believe what I said was true, and the existing Material Threat Assessments were performed by the Department of Homeland Security without the desired level of consultation with individuals from Department of Health and Human Services who have more knowledge of the agents. I believe this has been corrected by DHS.

Mr. MURPHY. Well, let me add a couple levels here and/or concerns. Dr. Merlin, isn’t it true that more than 46,000 state and local health department jobs have been lost since 2008, representing nearly 21 percent of the total state and local health department workforce?

Dr. MERLIN. Yes, that is my understanding.

Mr. MURPHY. And Dr. Merlin, if you go to tab 34, this document is a presentation to the CDC Director on the quarterly performance review of NCEZID May 25, 2011. Is this your presentation?

Dr. MERLIN. Yes, it is.

Mr. MURPHY. And according to this internal CDC document, CDC has concerns about Gen-3 because of potential workload impact on LRN, or the Laboratory Response Network, from an increased number of devices that are continuously sampling and reporting. Do you agree that there would be concerns about Gen-3 from the potential workload impact on the LRN?

Dr. MERLIN. Yes.

Mr. MURPHY. Well, I see I am out of time. I may have to come back to some of these, but I will turn to my ranking member, Ms. DeGette, for 5 minutes.

Ms. DEGETTE. Thank you very much, Mr. Chairman. Well, let us keep talking about this Gen-3 for a while.

As I noted in my opening statement, what we were told was this Gen-3 was supposed to provide automated biological threat detections so it would be sort of like a lab in the box, and there have been a number of issues around that. So I am wondering, Dr. Walter, first, can you describe briefly for us exactly what is BioWatch Generation 3?

Mr. WALTER. Yes, ma’am. I would be happy to do that. If you look at the parts that make up the BioWatch program—filter collection, laboratory analysis and reporting out the results—and you were to take all of those pieces and put them into a machine, that

is what Generation-3, the acquisition program, Generation-3, is to do.

Ms. DEGETTE. And how does that differ from the existing technology?

Mr. WALTER. The existing technology is very labor-intensive. Somebody has to go and collect the filter, somebody has to bring it to the laboratory, somebody has to analyze the filter, and somebody has to make a phone call with the result. What Generation-3 would do essentially would automate all of that.

Ms. DEGETTE. Right. So it would take the sample and it would do the test, and then if there was some abnormality, then they would notify the folks and then they would come in, right?

Mr. WALTER. That is correct, if it identified a detection, essentially it creates a BAR. The other thing that Generation-3 does, would also do, is it continuously collects and analyzes, whereas now we have got one sample—

Ms. DEGETTE. You don't have to go in and collect it?

Mr. WALTER. Right.

Ms. DEGETTE. Right. So how much do you think it will cost to implement Generation-3?

Mr. WALTER. I currently don't know because the acquisition program has been on hold, and that would depend on what technologies are eventually selected for deployment.

Ms. DEGETTE. Well, before it was on hold, did you get any kind of bids for it, any estimates?

Mr. WALTER. We had a lifecycle cost estimate that was done as part of the acquisition process.

Ms. DEGETTE. And what did that show?

Mr. WALTER. That showed a 20-year lifecycle of \$5.8 billion, and the lifecycle cost estimate number goes from initial testing all the way through disposal.

Ms. DEGETTE. Of the 20 years?

Mr. WALTER. Yes, ma'am.

Ms. DEGETTE. Now, the benefits of a system like this are obvious from your description but do you think that it would be worth the cost, given the fact that we haven't really found any—I mean, I agree, we need to have systems in place but given the fact over 10 years we haven't really had any large-scale bioterrorism, do you think it is worth the cost?

Mr. WALTER. I think it is. I think the advantages that we would gain from such a system would make the cost worthwhile. I think the increased flexibility that we would get from such a system would make the cost worthwhile. I think the ability to take the system indoors would make the cost worthwhile. And I believe that it would actually reduce the workload on state and local public health laboratories because currently we get a sample every day. With that system, we would only get a sample if something is seen.

Ms. DEGETTE. So it might be really cost-effective over the long run even though there would be a big initial investment?

Mr. WALTER. Yes, ma'am.

Ms. DEGETTE. Now, you mentioned that the program has been stopped for now. Why, and how did we get to that point?

Mr. WALTER. There was a Government Accountability Office review of the acquisition methods used as part of the acquisition pro-

gram, and what they found was essential the Gen-3 acquisition program straddled the implementation of MD-102, which is, I believe, the acquisition directive that garners how the Department does its acquisitions. When BioWatch Gen-3, the acquisition program, was started, they weren't being deployed or they were just being implemented, so we kind of started in the middle, if you will, and when the GAO came in and did its assessment, they said well, you followed the acquisition processes that were in place at the time but really it is a big program, you probably want to be careful and go back and kind of dot the i's and cross the t's.

Ms. DEGETTE. Are you going back and dotting the i's and crossing the t's? What steps are you taking now to evaluate and develop Gen-3 in a way that will not just satisfy the GAO but will also satisfy the budget hawks on this committee?

Mr. WALTER. We have instituted an analysis of alternatives. That is being conducted independently of the Department. We have rewritten the mission needs statement and we have formulated what we call an acquisition con ops, which is part of the formal acquisition process, which essentially says if you had this technology, how would you use it.

Ms. DEGETTE. And what kind of a timeline are you on?

Mr. WALTER. We are expecting the final briefing for the analysis of alternatives in the August-September time frame with a final report in September-October.

Ms. DEGETTE. Super. Mr. Chairman, I would suggest we bring these folks back to talk to us about that timeline and see what they have looked at, see if they have looked at the alternatives, and see if they are planning to go forward with Gen-3. I yield back.

Mr. MURPHY. Thank you. I now recognize Dr. Burgess of Texas for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Merlin, let me just start out by thanking you and your organization. The CDC has unfailingly been helpful on not just this issue but any time there has been an issue that has affected the public health and welfare of the United States, and your director, Dr. Frieden, has of course come to this committee and discussed with us the nature of novel flu, called me personally when West Nile virus was a problem in north Texas, and then the fungal meningitis outbreak occurred, CDC was in fact the only federal agency that would talk to me and answer the telephone, so I thank you for that. It is good to know that you are there and on the job.

Dr. Walter, let me just ask you, you referenced something called the BioWatch Actionable Result and the role of the DHS. Could you kind of define for us what constitutes a BioWatch Actionable Result?

Mr. WALTER. That is an excellent question, sir. A BioWatch Actionable Result is an analytical result, a laboratory result, and what we do is, we conduct—we don't look for the actual bacteria, we actually look for the DNA of the bacteria and we look for very specific pieces of DNA that we do a two-step process. The first essentially is kind of a screen. We look for signs of the agent, and if it shows up, then we run additional—look for additional pieces of DNA using the Laboratory Response Network agents or reagents that we get from the CDC. And then—

Mr. BURGESS. So you do some confirmational activity?

Mr. WALTER. Oh, absolutely, sir.

Mr. BURGESS. Now, just from that, you can't confirm or deny that a terrorist attack has taken place, correct?

Mr. WALTER. No, sir, and that is never the purpose of the BAR. The BAR is simply the detection of the DNA from the agent.

Mr. BURGESS. And will it show whether or not people have actually been exposed or it just detects the presence of the sentinel DNA in the environment?

Mr. WALTER. It just detects the DNA, and we have modeling that we can look at to go back and look at where would this plume have gone. But the assessment as far as whether there is a threat to the public health, whether this is a terrorism attack or whether this is something that naturally exists in the environment is made following the BAR, and that is during the national conference call which brings a host of agencies together including the CDC that essentially discusses what the context of this detection is.

Mr. BURGESS. So I guess that leads to my next question. What process is then put in place? Poor Dr. Merlin is sitting there at the CDC. You give him this information that oh, my gosh, we have got a real problem here, so Dr. Merlin is then looped in through a conference call? Is that what—

Mr. WALTER. That is correct. Dr. Merlin or his designee is part of the conference call, and that discussion is, what do we have, where was it found, have we ever seen it before, is there a lot of it, is there a little of it. It includes the FBI and local and state and federal law enforcement and emergency responders.

Mr. BURGESS. Now, you referenced in your testimony the preventive measures that might be instituted. At what juncture at those triggered? You referenced the prophylaxis that might need to be administered. Where does that come in?

Mr. WALTER. That would take place after this national conference call if the decision is made that we think this is a bioterrorism attack and/or there is a threat to the public health because they don't necessarily have to be linked.

Mr. BURGESS. Then Dr. Merlin, when at the CDC level, I mean, you referenced the Laboratory Research Networks. Is this what you do to confirm or to gain additional knowledge about the information that you are given from DHS? Because at some point you have got to tell the doctors yes or no. I mean, DHS can't tell the doctors to prescribe something. You all have to play a role. Is that correct?

Dr. MERLIN. Yes. We work with DHS and the local jurisdiction that has made the detection as well as other federal agencies to try to gather as much additional information as possible to determine whether the BAR represents an anomaly or a threat, and the sorts of things we will do is, we will ask the local jurisdiction to do additional testing on the sample that they have. We may ask them to go out and perform environmental sampling in the area where the detector was located. We will query intelligence agencies to find out whether there is any indication that there might be a threat with this agent. We will ask subject-matter experts in the field if there are other things they think might be causing this positive, and we will try to quickly gather the information we need to sort of make an informed decision.

Mr. BURGESS. Very good. In my opening statement, I referenced the data that was generated back in the early 1950s. No one wants to see that type of testing go on again but I think it does—the lesson from that is, there is a vulnerability here from a biologic agent, and certainly the work—we want you to get it right, and I was called a budget hawk a minute ago. Yes, I am guilty as charged but at the same time, the primary role, my role defined in the Constitution is the defense of my Nation. I want you all to get it right. It is critically important that you do, and I agree with Ranking Member DeGette that we will need to hear from you again in the fall. So thank you.

Mr. MURPHY. Thank you. The gentleman's time is expired. We will now go to the gentleman from New York, Mr. Tonko, for 5 minutes. You are recognized.

Mr. TONKO. Thank you, Mr. Chair.

The whole issue of relationship between DHS and CDC and local public health partners is critical because the BioWatch program depends on local officials in order to execute many of these programs. In the very early days of BioWatch, as has been discussed, the relationship between federal agencies and local public health partners did not work as well as it should. Dr. Merlin, what would you cite as examples of improved communications amongst DHS, CDC and local officials over recent years?

Dr. MERLIN. There are several things. I think DHS has made a concerted effort to include public health officials and public health responders in their national BioWatch meetings. They hold regular webinars that I believe are monthly for all stakeholders including public health, and whenever they have working groups, they reach out to public health participants, and I am impressed they reach out to public health participants including those whom they know are not their fans. So they try to have those voices at the table. There is an IOM meeting scheduled, Institute of Medicine meeting scheduled next week to go over some BioWatch questions, and I notice there is a panel with a diverse range of public health officials on it. So I do think they actively reach out to include public health.

Mr. TONKO. And Dr. Walter, in terms of the overview of DHS's communication efforts with local public health officials, can you give us a sense of how that collaboration has been improved on a day-to-day basis?

Mr. WALTER. I believe that it has improved in our routine communications because it does take place on a day-to-day basis. We spend a lot of time talking to our state and local partners, and it has been my business since coming into the program in 2009 to arrange the relationship that we have with our state and local public health community as partners in this program. I don't command the BioWatch program and they are not a subordinate command. We work in partnership with them. We have done our utmost to include them in all of the testing and evaluation that we have conducted so far in the acquisition program, the Gen-3 acquisition. We hold focus groups because we have noticed that when we get a large group of them on the phone, they don't say a lot, but when we bring them into a small room with a select group, they are very opinionated and there is a wealth of expertise that we can tap into there. We have brought their laboratories into the program. Prior

to my coming into the program, there was—if technology improvements were put in, they were done at a national lab and handed to the state and local labs. Now we work with the laboratories themselves to bring those in. So we have done our utmost to make sure that they are part of the program and that communication is there.

Mr. TONKO. Thank you very much.

Last July, I believe it was, the President released a National Strategy for Biosurveillance, which outlined guiding principles for strengthening our capabilities, and it called for focusing on core functions, increasing integration and improving information sharing. To each of you, my question would be, how does BioWatch fit into the Nation's larger biosurveillance strategy?

Mr. WALTER. BioWatch complements the national strategy. There is nothing about environmental surveillance that precludes doing any other surveillance. BioWatch, I believe, complements medical surveillance, it complements syndromic surveillance, it complements point-of-care diagnostics, and it also provides the early detection that we would need because the downside of medical surveillance is, people have to get sick for us to be able to detect them using those methods. BioWatch provides us the opportunity to detect them before they show symptoms so that we get medicines to them before they are sick and start to overwhelm the public health infrastructure, integration as far as the exercising, but the big part of what we do too is the planning and preparedness side, and we know we are not going to be able to—or it is going to be very difficult to respond to a bioterrorism event on the fly. All of that has to be worked out in advance, and a big part of what the program does is work with our state and local jurisdictions to get them prepared, provide them exercises so we know their plans make sense.

Mr. TONKO. Dr. Merlin, would you add to any of that?

Dr. MERLIN. Yes. I basically agree with Dr. Walter. When you look at the biosurveillance strategy, it addresses the spectrum of biological threats to the American population, and the threats can range from small threats that threaten a small number of people to very large threats. The BioWatch system addresses really the very far end of the threat spectrum. It addresses the catastrophic aerosol released, the sort of thing that would be really sort of an act of war, a nation-state type of action. And that is part of the threat spectrum that needs to be addressed. There are of course other things in there, and much smaller attacks like the anthrax letters of 2001, which were a much smaller attack, are a high risk and also need to be addressed in our strategy.

Mr. TONKO. Thank you very much. Mr. Chair, I yield back.

Mr. MURPHY. Thank you. We will now go to the gentleman from Louisiana, Mr. Scalise. You are recognized for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman. I appreciate you having this hearing. Thank you to our panelists.

I want to really get into the BioWatch program, Mr. Walter. It is my understanding from the reports I have read that somewhere in the neighborhood of a billion taxpayer dollars has been spent on developing BioWatch since it started in, I think, 2003. Is that correct?

Mr. WALTER. I think a little less than a billion dollars has been invested in running the BioWatch program, not developing it.

Mr. SCALISE. How much total between both developing and running?

Mr. WALTER. Oh, I don't think a lot was put into developing it because the technologies that we use are developed technologies. So—

Mr. SCALISE. Developed by whom, and how much money? Who gets the money? Where does that money come from?

Mr. WALTER. Most of the technologies we use were developed by the Department of Defense, the Centers for Disease Control and Prevention, the technical aspects. We are an operational program. We don't conduct research and development. I take what is available to accomplish the mission and use that. So most of the funding that—

Mr. SCALISE. When I read that the Department of Homeland Security spent about \$300 million developing this technology, you just said you don't develop technology.

Mr. WALTER. The BioWatch program doesn't develop it. A lot of that developmental work was done by the Science and Technology Group, which does do research and development and does develop.

Mr. SCALISE. So for a billion dollars, whether some of it was spent by the Department of Defense, I am sure you all coordinate because ultimately you are implementing it, the bottom line is, it hasn't worked yet. At least it hasn't worked the way it was supposed to. Is that accurate?

Mr. WALTER. I would respectfully disagree with that, sir. I think everything that we have shows that the process does work. We have instituted an extremely robust quality assurance program that tracks the ability of our laboratories to detect any agent that may be on a filter.

Mr. SCALISE. Do you get a lot of false positive tests?

Mr. WALTER. No, sir. What we get—what we have—what we detect are naturally occurring agents. All of the agents that we look for are naturally occurring somewhere in the environment. Most of them are out there endemic, and it stands to reason that we will occasionally detect one or two of them.

Mr. SCALISE. So I am looking at this report again. It says Department of Homeland Security spent about \$300 million developing this technology as well as on Gen-2.5, which was deployed for 2 years and then pulled. Was it pulled because it was working so well or was it pulled because it wasn't working?

Mr. WALTER. That was before my time, sir.

Mr. SCALISE. Are you familiar with what the status is and why it was pulled?

Mr. WALTER. Everything I got was secondhand. My understanding, and this is just my understanding, was that it was pulled because it was expensive, it was pulled because of preparation for the acquisition program, the Gen-3 program.

Mr. SCALISE. Do you know how much we have spent on it?

Mr. WALTER. I do not, sir. I am sorry.

Mr. SCALISE. If you could get the committee that information?

Mr. WALTER. Sure thing, sir.

Mr. SCALISE. I wanted to ask you about the internal investigation. It is our understanding that there has been an internal investigation into BioWatch. First of all, are you familiar? Did you all do an internal—maybe before you were there, but I mean, are you aware of an internal investigation?

Mr. WALTER. I am not aware of an internal investigation into BioWatch itself.

Mr. SCALISE. Or an employee at BioWatch that may have been removed for mismanagement?

Mr. WALTER. It may have been but that is before my time, sir, and I can't comment on that.

Mr. SCALISE. OK, but I mean, you are there now, you are heading this up. We are trying to get more details. Again, a lot of taxpayer money is involved in this. If there was mismanagement by an employee, by many employees, if someone was removed and maybe somebody that was removed is now back working on the program, we are hearing about all this secondhand but supposedly there is an internal investigation that was done and some documentation about this that we don't have. I think it is real important that this committee get that information. Can you, number one, go and find out if there was an investigation done by your agency, and if so, can we get a copy of that information?

Mr. WALTER. I am aware of an investigation that was undertaken. I don't know really the details of why it was undertaken.

Mr. SCALISE. Can you at least assure us that you will get us a copy of that investigation?

Mr. WALTER. I give you my word, I will try, sir.

Mr. SCALISE. Why would you not be able to get it to us?

Mr. WALTER. I don't know.

Mr. SCALISE. If you tried, it would happen, so I am just asking if you can make it happen.

Mr. WALTER. I will make it happen, sir.

Mr. SCALISE. I appreciate that very much because, I mean, when we are hearing about all this and we are hearing that maybe there was an employee involved in mismanagement and that the employee was maybe removed but now the employee is back over there, I mean, that raises a lot of questions that we have about the program.

Mr. WALTER. I can tell you that no one currently on the BioWatch program was removed and then brought back into the program.

Mr. SCALISE. So as long as you are going to get us that information, that will at least help answer a lot of these questions. We shouldn't have to wonder and speculate about it if you have got an investigation somewhere in your agency, you can get that to us and then that will remove the cloud of speculation and we will know exactly what is going on to be able to proceed from there. So I appreciate that, and I thank the chairman for his discretion and yield back the balance of my time.

Mr. MURPHY. The gentleman yields back. We will now go to the gentleman from North Carolina, Mr. Butterfield.

Mr. BUTTERFIELD. Thank you very much, Mr. Chairman, and let me thank both of the witnesses for their testimony today.

Mr. Chairman, I always begin whenever I can asking witnesses questions about the impact of sequestration is having on their agency because so many of our constituents really don't fully understand the full impact that sequestration is having on the functions of government, and so let me just start with sequestration and start with you, Dr. Walter. It is my understanding that many DHS programs are exempt from the impact of sequester but certain programs related to the implementation of the BioWatch program may be impacted. What impact has sequester had on DHS programs related to the BioWatch program?

Mr. WALTER. The BioWatch program was not exempt from sequestration. It has decreased our contact with our state and local jurisdictions in that our travel budgets have been reduced. It has decreased our ability to bring state and local public health and emergency responders in for focus groups and discussions with them. And it has decreased our ability to carry out certain improvements to the program that we had planned.

Mr. BUTTERFIELD. Can you quantify this by percentage? Is it 8 percent, 6 percent?

Mr. WALTER. We are looking at around—I think we are looking at around 5 to 10 percent, in that range.

Mr. BUTTERFIELD. And you do realize that unless sequestration is reversed or repealed, this is a 10-year proposition? It is not a 1-year deal.

Mr. WALTER. I understand.

Mr. BUTTERFIELD. And does it have long-range implications for the program?

Mr. WALTER. Yes, sir, it does. As we move over time, obviously we have contracts that have inflation clauses built in that we will have to cover, and we will basically have to pare the program down to doing just the basics of what we need to do and not improve the program as we would like to.

Mr. BUTTERFIELD. And I understand the GAO has made some recommendations to you that you would like to implement that this may impact. Has the GAO made any recommendations?

Mr. WALTER. Not that I am aware of, not relative to sequestration that I am aware of, sir.

Mr. BUTTERFIELD. I mean to the actual programmatic part of your work.

Mr. WALTER. They have done that, and we have implemented them. This primarily was geared towards the acquisition program, the so-called Gen-3 program, and we have implemented those recommendations.

Mr. BUTTERFIELD. And Dr. Merlin, can you speak to it from the CDC aspect?

Dr. MERLIN. Yes, Congressman. I can tell you about the immediate impacts it has on the work in my division. We have decreased the number of proficiency testing challenges that we provide to the members of our Laboratory Response Network because those are—each one has a cost associated with it. We have also had to decrease the amount of reagents that we keep for surge, a potential surge in demand in reagents that we would need in a large-scale event, and in terms of the funding that we provide to state and local health departments through my division and other parts of

CDC that contribute to the ability of those health departments to respond to outbreaks in bioterrorism, the amount of money has gone down. It has gone down through our budget constraints because most of the money that CDC receives goes out to state and locals. The response of the cut to us passed on to state and locals.

Mr. BUTTERFIELD. Are we talking between 5 and 10 percent as DHS has experienced?

Dr. MERLIN. For us, the number is around 5 percent.

Mr. BUTTERFIELD. All right. Back to you, Dr. Walter. Is it possible that newer and more efficient biosurveillance technologies could reduce costs enough to enable the expansion of the BioWatch program to new municipalities?

Mr. WALTER. Yes, sir, it is.

Mr. BUTTERFIELD. And Dr. Merlin, the number of false positive BAR results in 2013 has decreased to zero, and that is probably good. Can you explain the CDC's role in eliminating false positives and elaborate on the success of the serial testing strategy?

Dr. MERLIN. We worked closely with Department of Homeland Security to try to effectively reduce the number of false positives that were being caused by an organism related to one of the target organisms, *Francisella tularensis*, and together we have implemented three changes in the testing protocol that have caused a reduction in false positives. One is that we reduced the number of cycles of reaction that is used for detection. Another thing we have done is, we have—DHS has actually implemented use of another reagent for screening. They have used the Critical Reagents program reagent rather than a CDC reagent for screening. And the third thing and importantly—

Mr. BUTTERFIELD. I think the chairman is tapping on the table there. Can you just give us the last sentence?

Dr. MERLIN. They have put in a test that distinguishes this near neighbor from the target, which enables us to say no, that is a near neighbor, and we know it is not a target, and to not react to it.

Mr. BUTTERFIELD. Thank you. Yield back.

Mr. MURPHY. The gentleman yields back. Now we will recognize the gentleman from Texas, Mr. Olson, for 5 minutes.

Mr. OLSON. I thank the chair, and welcome to the witnesses. Dr. Walter, Dr. Merlin, welcome. I am concerned like we all are about an attack by a biological weapon. I am a Member of Congress from Houston, Texas, about to be the third largest city in America. There is no better target for biological attack than Houston, Texas. We are the largest foreign tonnage port in America lined by the largest petrochemical complex in the world. We have the largest medical center, the Texas Medical Center, just south of downtown. There is no better target for biological attack by terrorists either with conventional bombs, sort of dirty nuclear weapon, chemical weapons or a biological weapon, and the scariest of these may be a biological attack. Say let us go to the Texas Medical Center and launch that weapon in the air conditioning system and disappear, long gone before anybody realizes that you have been attacked. The biological weapon flows through the air conditioning system all over the Texas Medical Center. Within hours, days, weeks, people are becoming infected, and that is a big problem. Most importantly,

it is not just people being infected but the people that are infected are the professionals that are needed to recover from this attack.

And so one other point for my colleagues: If you want to lose some sleep, come down to Galveston, Texas, to the Galveston National Laboratory on the campus of the University of Texas medical branch. It is one of two bio 4 labs in America, a very, very secure place with all sorts of very dangerous chemical and biological weapons, mostly biological. I have been down there on a tour. I put on this pressure suit, negative pressure, went through a couple of locked doors and watched these men and women working on agents that if they got out in this room right now, many of us would not walk out of here alive within minutes. So this is a very, very scary proposition, and we need—it is so important that we spend our limited resources on products that work. I am concerned about Gen-2, more importantly, Gen-3.

And my first question is for you, Dr. Walter. Is there a concern that the BioWatch program doesn't fully understand how the current generation Gen-2 works, that these concerns are real? How can we be confident that Gen-3 will work?

Mr. WALTER. No, we are very confident in the way the Generation-2 system works, sir. We track our performance under our laboratory analysis. We know what we can detect at what concentrations and with what statistical confidence. We have recently actually just completed another test of our collection and analysis operations out at Dugway, Utah, where we looked at what is the minimum number of bacteria we could collect in the atmosphere using chambers, of course, and then how would we—how does that number translate through our analysis. So we have a very good understanding of what our technology is capable of doing.

Mr. OLSON. And you mentioned Dugway, sir. The analysis on alternative testing done by this fall includes a cost-benefit comparison between Gen-2 and Gen-3 but DHS won't have the data from Dugway until sometime in the fall of this year so you are bringing up online before you actually have the data.

Mr. WALTER. No, the data that will be produced from Dugway will be the technical performance of the technology. That will be done in the July-August time frame. We expect the analysis of alternatives that is going to include the Gen-2 system to be done about the same time, and any information that the performer for the AOA is requesting, we are making sure that they get it as quickly as we can get it to them.

Mr. OLSON. Dr. Merlin, how about your concerns about Gen-3?

Dr. MERLIN. Congressman, my concerns about Gen-3 have primarily to do with lack of information about the performance of the assays, and Dr. Walter and I have had and his staff have had exchanges about a number of concerns that my colleagues at CDC had about particular technical aspects of what was in the phase I of Gen-3, and we are just concerned that the technology be right and that we know what the limits of detection are likely to be and that we know what the limits of detection are going to be in a performing area. So my concerns are basically about the availability of data on the performance and an appropriate review of the data on the performance.

Mr. OLSON. I share those concerns. I am out of time. I yield back.

Mr. MURPHY. I thank the gentleman from Texas. Now to the other gentleman from Texas, Mr. Green, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman, and again, I thank our witnesses for being here. I also have a district just north of Galveston, and I have been to the bio lab. I was impressed in watching it being built, and in 2008 when Hurricane Ike literally went over that area, that was the one building at the University of Texas Medical Branch that was not damaged, and there was no issue because we have learned in Texas, you don't put your generating equipment on the bottom floor when you have four or five foot of water. So you put it on top.

But again, I am pleased that we are taking the time to examine BioWatch because of how importance it is. Last Congress, I worked with colleagues on this committee on the legislation, the Pandemic and All Hazards Preparedness Act. We worked together to make sure the relevant agencies had the tools to identify threats including those originating from terrorists and address those threats effectively, and I know at the bio lab, as my colleague and my neighbor talked about, the National Lab there in Galveston, does tests and working on developing vaccines for SARS, West Nile encephalitis, avian flu, influenza as well as microbes that are being deployed by terrorists. That topic is important to me.

The relationship between DHS, CDC, and local public health partners is critical because BioWatch programs depend on our local officials. They execute many of the program's most important functions. But in the early days of BioWatch, the relationship between federal agencies and local public health partners did not work as well as it should have.

Dr. Merlin, have communications between DHS, CDC, and local officials improved in the last few years?

Dr. MERLIN. Congressman, I have been with this program at CDC for 2 years, and I personally think there has been substantial improvement in the communications. I believe that we now regularly have very candid discussions about concerns from local public health and that we have very candid discussions about concerns that my colleagues at CDC have about technical aspects of the BioWatch assays. I admire the fact that Dr. Walter includes, as I mentioned earlier, includes people in these discussions that he knows are critical to the program, and I think that is a good thing.

Mr. GREEN. Do local public health labs have proper federal guidance on what to do in the event of what appears to be initial positive test result known as a BioWatch Actionable Result?

Dr. MERLIN. Congressman, I think the answer to that is both a yes and a no. The BioWatch program recently released a new version of its outdoor guidance, which is guidance to the BioWatch jurisdictions on how to respond to an outdoor release. There is—and Dr. Walter is aware of this, there is no indoor guidance, which means that there is no formal guidance on how jurisdictions should respond to an indoor release, and I know the program is working on that.

There are also a number of important issues related to environmental sampling and how to conduct the appropriate environmental sampling that had been worked on collaborative by DHS

and EPA and CDC for a number of years but there is no formal guidance out there that I think the locals really need.

Mr. GREEN. I only have another minute. Obviously the partnership between the CDC and locals is very important. In fact, just as we came up, welcome to the Gulf Coast in summer, we have some our mosquitoes that have been tested and found to have West Nile encephalitis, not in the Galveston area but further north, and so this is important. And I know from your testimony you have had to cut back some of your public health meetings with local officials because of the budget constraints but I know you also do conference calls. Have you all increased that since you can't do the physical presence?

Mr. WALTER. That is correct, sir. We have increased our conference calls. We have started a webinar series. And we are doing our best to keep our communications open. We also have a number of liaisons, we call them jurisdictional coordinators, who are in all of our BioWatch jurisdictions who also serve to keep us informed and keep the program and our state and locals informed as to what is happening.

Mr. GREEN. And again, from a military perspective, the troops on the ground are those public health agencies, so obviously the more we can relate from what we do here and CDC and what you all do. Thank you.

Mr. MURPHY. The gentleman's time is expired. Now we will go to the gentleman from Ohio, Mr. Johnson, for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman.

Dr. Walter, I will try to look around you here and still get to my microphone. According to the information provided by DHS, there have been 149 BioWatch Actionable Results, or BARs, since the BioWatch program started in 2003. is that correct?

Mr. WALTER. That is correct, sir.

Mr. JOHNSON. And these BARs represent naturally occurring biological pathogens detected from environmental sources. Is that correct?

Mr. WALTER. Yes, sir.

Mr. JOHNSON. In a July 12, 2012, DHS blog posting, DHS Assistant Secretary for Health Affairs, Alexander Garza, wrote this. He said, "Out of these more than 7 million tests, BioWatch has reported 37 instances in which naturally occurring biological pathogens were detected from environmental sources." Given the figure of 149 BARs reported to the committee, the 37 instances was an incorrect number. Is that correct?

Mr. WALTER. That is correct, sir.

Mr. JOHNSON. OK. Were you involved in writing the blog posting for Dr. Garza?

Mr. WALTER. I reviewed it, and I missed that.

Mr. JOHNSON. OK. Were you the one that provided him with those statistics?

Mr. WALTER. No, I don't know where those statistics came from but I should have caught it, and I didn't.

Mr. JOHNSON. As the BioWatch program manager, didn't you know you had over 149 BARs by July 2012?

Mr. WALTER. Yes, sir.

Mr. JOHNSON. You got any thoughts if you reviewed it, how did we miss it? I mean, this is an important system.

Mr. WALTER. I missed that number in his blog. I am very aware of the performance of the system, and I am very aware of any issues that come up with the system that impact its performance.

Mr. JOHNSON. Did you provide the correct statistics—or let me go back. When did you find the error? When did you realize that there was an error?

Mr. WALTER. It was shortly after the blog was posted.

Mr. JOHNSON. Did you provide the correct statistics to Dr. Garza?

Mr. WALTER. Yes, sir, I did.

Mr. JOHNSON. Do you know if they corrected the record?

Mr. WALTER. I believe they did.

Mr. JOHNSON. Dr. Merlin, would you please go to tab 36 in your material? In this June 24, 2011, e-mail, you discussed, and I quote, “the squishy definition of a BAR.” You go on to write, “What is the action here? Who has made the final determination of the action to take? What is that determination? There seem to be different definitions of a BAR according to the jurisdiction, e.g., New York City versus Houston.” How do definitions differ between New York City and Houston?

Dr. MERLIN. Congressman, the primary source of the problem, I believe, is use of the word “actionable” because without defining specifically what actions are taken on the basis of this, it leaves it to the mind of the jurisdiction on to what the appropriate action is, and I personally believe that we should do a better job of defining of what an appropriate action is and based on concerns like this, the Department of Homeland Security in this most recent outdoor guidance has become much more specific about what they mean by an action. In the absence of a definition of an action, some jurisdictions may feel that this means that the area where the BAR is detected should be cordoned off and evacuated. Other jurisdictions may simply feel that it means that they send in a team to do sampling, and I think because we know technically what testing is being done, I think we need to tell people what we think is appropriate.

Mr. JOHNSON. Are there still different definitions of BARs today based on your concerns about “actionable”?

Dr. MERLIN. I will defer to Dr. Walter. He may know better than I do. I think we have gotten closer with the most recent outdoor guidance in terms of situational assessment but I am sure that all of the BioWatch jurisdiction committees are on the same page.

Mr. JOHNSON. Mr. Chairman, I yield back.

Mr. MURPHY. The gentleman yields back, and now to the ranking member of the full committee, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman.

Last October, the Los Angeles Times reported on the failed deployment of BioWatch Generation 2.5, which was supposed to provide interim automated detection capability before the deployment of Generation 3. The technology suffered from delays and issues related to scientific validation and I would like to hear from our witnesses today about how this happened and what steps have been taken to ensure that it won’t happen again. The Los Angeles Times reported that the BioWatch program put new testing assays called

multiplex assays into use without adequately validating them. According to the article, the tests were used for 2 years from 2007 to 2009 before it became clear that they were so insensitive to the presence of bioterror agents that they were unsuitable for BioWatch.

Dr. Walter, I know these programs occurred before you became the head of the BioWatch program. Still, I would like to get your views on the allegations of the L.A. Times story. Was the BioWatch program relying on inadequate tests for two full years?

Mr. WALTER. I honestly can't answer that question. I would like to think they are not, but what I can tell you is that before we deploy assays now, we have a very robust testing and evaluation process in place. We track the performance of those assays on a daily basis. We conduct proficiency tests of our laboratories periodically throughout the year and we conduct independent audits of our laboratories periodically throughout the year.

Mr. WAXMAN. And what actions were taken when the program officials discovered these problems?

Mr. WALTER. I believe the system was withdrawn but, like I said, this is before my time and I really can't speak to it.

Mr. WAXMAN. Well, this is an important development, and it is like being told that the salesperson that defrauded you was no longer here and therefore you don't know anything about it, but you are the head of the program and you ought to know what happened not that long ago, 2007 to 2009. Well, there was a problem. What corrective measures were taken to ensure that something like this won't happen again?

Mr. WALTER. For the Gen-3 program, which is the acquisition program, which is the technology that would be deployed in place of the Gen-2.5, we have instituted a multiple-phase process that has an enormous amount of testing and evaluation attached to it. That testing and evaluation is decided upon in a committee that includes our interagency partners including the CDC. Those results are made available to all of the members of that group, and nothing goes forward unless it meets the requirements that we have set forward for the deployment of this technology.

Mr. WAXMAN. Can Americans have confidence now that the tests used in the BioWatch programs are capable of detecting a bioterror attack so public health officials can act quickly?

Mr. WALTER. I believe they can, sir. We have done our best to make that happen.

Mr. WAXMAN. You have done your best to make sure that doesn't happen but you don't know what happened in the past.

Mr. WALTER. I mean, I am hesitant to speculate on what happened to the program before I was here. I understand that the technology was deployed. My understanding was that it was essentially initially thought to be kind of a pilot to look at developing con ops. It was then actually deployed, from what I understand, and then there were issues that developed relative to some of the assays that were used. I am sorry I don't have the details of that.

Mr. WAXMAN. Well, the BioWatch program has been plagued by technical and management problems, and I hope you and your team have put these problems behind us so that the program can move forward.

Mr. WALTER. We are doing our best.

Mr. WAXMAN. Thank you. Mr. Chairman, I yield back my time.

Mr. MURPHY. The gentleman yields back. Now to Mr. Harper for 5 minutes.

Mr. HARPER. Thank you, Mr. Chairman, and thank you, gentlemen, for being here, and Dr. Merlin, I know we have had a lot of concerns obviously and work done on the state and local level as they try to look through this, and I would ask if you would go to tab 35 in your notebook there. In a May 26, 2011, email, CDC scientist Michael Farrell wrote this in part in that email that you are looking at: "Bottom line for me is that despite whatever changes they have done or assay or systems validation that they performed, the Gen-3 system with these assays is going to be dead on arrival at the public health service labs, especially and importantly at NYC. This will be simply because of a lack of confidence due to previous experience with environmental cross-reactivity and the problematic APDS, or Gen 2.5 deployment. Confidence in the system is going to be paramount with the current actionable nature of the signal that is intended. I just don't see how this is going to be possible."

Now, Dr. Merlin, do you agree with that statement or disagree?

Dr. MERLIN. It is difficult to give a yes or no answer. My colleague, Dr. Farrell, was talking about what he knew about the development of Gen-3, the basis of the testing and the signatures that were being used, and the similarities of that system to the multiplex system that was just referenced that had been withdrawn, and because that previous system had failed, Dr. Farrell was very concerned that this was going down the same line. What Dr. Farrell didn't know at the time and we found out subsequently was that this system was the first phase of a multi-phase development for Gen-3 and was not intended to be the final product, and that is what we found out in a meeting with Dr. Walter and his staff. I am benefited by having people who report to me who are quite candid about their concerns, and I take them forward to the BioWatch program.

Mr. HARPER. Dr. Merlin, let me ask you this. Has prior mismanagement by DHS and extended scientific disputes with DHS negatively impacted the confidence the CDC and the public health laboratories in working with BioWatch Gen-3?

Dr. MERLIN. I think the scientific community wants to see data. They want to see data, and it needs to be conveyed in a fashion that isn't "trust me, I have the data, it supports that this works." They really want to see the data.

Mr. HARPER. Can you go to tab 46 and let us look at that for a moment? And this is a May 2012 email where you stated about the historical tensions in the BioWatch program, and you said, in part, "I think the bottom line is that NYC public health feels that public health is struggling to be heard in a program that is dominated by DHS and law enforcement but which has huge implications for public health departments." Is this still the case?

Dr. MERLIN. This references the particular situation in New York City and the New York City jurisdictional BioWatch Advisory Committee, and I know that both Dr. Walter and I have struggled with this. New York City specifically asked me to become personally en-

gaged and to go there as a CDC representative because they thought there wasn't a sufficient scientific voice at the table of these discussions. It is the nature of the constitution of these individual BioWatch Advisory Committees and I think they vary from jurisdiction to jurisdiction.

Mr. HARPER. So is this still the case?

Dr. MERLIN. I think it is still the case.

Mr. HARPER. Thank you. I will yield back the balance of my time.

Mr. MURPHY. The gentleman yields back. Now to the gentlelady from North Carolina, Ms. Ellmers, for 5 minutes.

Mrs. ELLMERS. Thank you, Mr. Chairman, and thank you to our two gentlemen who are with us today.

I am listening to the testimony, and I am listening to the questioning, and you know, sometimes I end up with more questions after I hear the discussion. I am concerned about some of the issues with false positives or no false positives, what has been detected in the past, what has not, and you know, basically is this an effective system, and are we, you know, developing a system for future use but not necessarily taking into account things that have happened in the past and making it the most effective plan as possible.

Going back to some of the discussion that has already taken place in association with Assistant Secretary of Health Affairs, Dr. Alexander Garza, Dr. Merlin, do you agree with the way that Dr. Garza articulated the performance record of BioWatch by stating that BioWatch has never had a false positive result?

Dr. MERLIN. No, Congresswoman, I do not agree with that characterization.

Mrs. ELLMERS. OK. Great.

Dr. Walter, according to the GAO, in order to build user confidence in the system, BioWatch has established a stringent threshold of one in 10 million for the false positive rate. That is the rate at which the system is allowed to indicate a pathogen is present when one is not. Is that still the threshold and is that correct?

Dr. MERLIN. I believe it is, yes, ma'am.

Mrs. ELLMERS. OK. Moving on, in that thinking, a pathogen, we mean the threat agent to be detected, not the near neighbor background organism?

Dr. MERLIN. That is correct, ma'am.

Mrs. ELLMERS. OK. That is two yeses. Wonderful. So keeping that in mind with the development of Generation-3, DHS has changed the definition of false positive from the one used in Generation-2 in which the definition of false positive means the system indicated the DNA of the bacteria including those of the near neighbor. Is that correct? Is that the change—has that change occurred in relation to the Generation-3 or is that yet to be determined?

Dr. MERLIN. No, I think that has yet to be determined but when we look at a detection, we believe we are detecting the actual organism, not the near neighbor. With *Francisella tularensis*, the DNA assays we had deployed weren't specific enough to go down into what are known in—and I am sorry I am going to throw microbiology at you but the subtypes of these organisms that actually cause the disease, and so what we were detecting was actually

there. It was *Francisella tularensis*. It is not a near neighbor. It is potentially not the pathogenic form, that subtype of *Francisella tularensis*.

Mrs. ELLMERS. I guess that brings me to the question of specificity. So the Generation-3 operational requirement document defines specificity as the ability to detect strains of the target species without detecting near neighbor or background organisms. So under that definition, the BioWatch systems detection of near neighbors would be false positives?

Dr. MERLIN. That is correct.

Mrs. ELLMERS. That is correct? OK. And then one last question, I have about a minute left.

Dr. Merlin, during the interview with the committee staff, you compared BioWatch to the Magna Line. What did you mean by that?

Dr. MERLIN. I compared it to the Maginot Line, which was a French defensive line built prior to World War II to protect against a German invasion where the French general staff believed that the Germans were most likely to invade.

Ms. ELLMERS. Right.

Dr. MERLIN. And it was a wonderful defensive mechanism. The problem was, it wasn't where the Germans chose to invade; they invaded through Belgium and the Netherlands into northern France. And I made the comparison because we need to be careful that we build our defenses across the entire spectrum of where attacks might come, not where we think, you know, this is going to be, and that is what—in reference to the earlier strategy, bio-surveillance strategy, we need to a strategy that cuts across a spectrum of threats.

Mrs. ELLMERS. Right, not just where we might assume something would happen.

Dr. MERLIN. Or we most fear.

Mrs. ELLMERS. OK. Thank you very much. Thank you both very much. I yield back the remainder of my time.

Mr. MURPHY. On your time, I want to ask a follow-up question to what she said. Do we have actual numbers on the specificity and sensitivity of the Gen-2 and the Gen-2.5 and Gen-3 in term of these, you know, similar to other medical tests that we have some sense of, is it 20 percent, 50 percent, 80 percent? Where are we with those?

Mr. WALTER. We conducted—as part of the first phase of the Gen-3 acquisition, we conducted a number of assay evaluations using the CDC assays and the critical reagent assays that we employ operationally to test the assays that were being proposed for the first phase of the Gen-3 systems that we were testing, and that data essentially looked at the specificity and the sensitivity of the assays that we employ under laboratory conditions, and that information was compiled and actually transferred to the CDC for their use as well.

Mr. MURPHY. Well, do we have those numbers?

Dr. MERLIN. Yes. We have turned over to the committee staff information related to the testing we performed on the LRN assays that are used in the Generation-2 system, and you can certainly—if you don't have it—

Mr. MURPHY. We will put it out then. Thank you.

I now recognize the gentleman from Florida, Mr. Bilirakis from the full committee, for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much. Thank you for allowing me to sit on this panel. I have been actively interested and involved in oversight over BioWatch, the program, for a couple years now.

We all wish to ensure a comprehensive biosurveillance capability. However, we must be smart about how we accomplish that goal. I think we all agree, this capability must be reached in the most effective and efficient manner, must be based on sound science and must ensure an appropriate return on taxpayers' investment. We must not lose sight of the greater goal of overall preparedness by harnessing all of our resources toward a single static technology.

I have a question for Dr. Walter. When it used this report on BioWatch last year, the GAO confirmed that there has been no comprehensive cost-benefit analysis done to ensure that the \$5.8 billion that have been spent over BioWatch's lifecycle will buy down risk sufficient to justify such a large expenditure. Doctor, can you please update the subcommittee on any efforts to measure the cost-effectiveness of the BioWatch program?

Mr. WALTER. We are currently conducting an analysis of alternatives relative to the Gen-3 acquisition, and part of that analysis of all alternatives will include a cost-benefit analysis.

Mr. BILIRAKIS. OK. When are we going to have any—

Mr. WALTER. We should be getting the final briefing on that in August. We expect that with a final report in the September-October time frame.

Mr. BILIRAKIS. And you will report back to us?

Mr. WALTER. I will do that, sir.

Mr. BILIRAKIS. OK. How much more certainty is gained from Generation-3 machines? Do we know the decrease in human morbidity and mortality? I know most of the members have touched on this, but if you can expand.

Mr. WALTER. Currently, there is no Gen-3 program, acquisition program. It has all been placed on hold. So that would depend on the acquisition, the technology that would be eventually deployed. As originally advertised, we would be increasing the number of systems that were deployed and actually increasing the number of cities to which the systems were also deployed in and then also taking the system indoors. Based on all of that, you would expect that our resolution of where the attack took place would be better because we have more sensors out. We would be getting more frequent analysis during the day. We would be getting up to eight analyses as opposed to one, so our timeliness would be improved and we can take the system indoors so we would know a lot more a lot faster and able to reduce morbidity and mortality if we can respond appropriately.

Mr. BILIRAKIS. Dr. Merlin, do you want to comment on that?

Dr. MERLIN. I agree with Dr. Walter's assessment that the transition from Generation 2 to Generation 3 would increase the testing frequency and increase the number of testing sites, and would decrease the amount of time available, and those are essential features. What we need to know is how sensitive the system would be,

what its lower limits of detection would be, and how specific it would, how many false positives it would give in an operating environment in order to know how it truly performs. There are a number of determinants of performance. One is how many you have, how often you do it, and the other is how well it works, and what we don't know is how well it would work.

Mr. BILIRAKIS. OK. Thank you. Next question. BioWatch comprises about 80 percent of the Office of Health Affairs' budget but constitutes just a single niche of the very broad mandate that is biosurveillance. Aside from BioWatch, are there other things we need to be doing to fill other capability gaps, Dr. Walter?

Mr. WALTER. I think we need to make sure that BioWatch is not mutually exclusive of other surveillance systems. BioWatch needs to complement medical surveillance. BioWatch needs to complement syndromic surveillance. BioWatch needs to complement point-of-care diagnostics. Also, out of the detection realm but into the preparedness and training realm, we need to make sure that our jurisdictions, our state and locals, know what they are going to do in the event of a biological attack, which is a major part of what the BioWatch program spends its time doing. It is not our responsibility nor do we want to develop their response cutoffs but we do provide them with guidance documents, points to consider, and we do provide them with a robust exercise program to see if those plans they put in place make sense. All of that together is a big part of how we are going to—what we need to do improve bio-defense in the country.

Mr. BILIRAKIS. Very good. I understand that Gen-3 BioWatch system uses local laboratories to manually analyze filter samples for the presence of suspicious bacteria. I can imagine that there are likely several hundreds of scientists and laboratory technicians involved in this activity across the United States. If Gen-3 technology works as planned, then the need for manual analysis would be most likely eliminated. Would this result in reduction of BioWatch laboratory workforce and thereby saving taxpayer dollars, or does it not save money because the system is so expensive? Either one of you.

Mr. WALTER. I think that is probably mine. You are correct in that as we envision it, the only laboratory analysis that would need to be done is in the event of an automated system detecting something, and either going forward and collecting additional samples or getting an archived sample from the unit or units that have shown a positive in doing that analysis. So we would actually need less support on our field operations and also less support in our laboratory operations. We would still need to support state and local public health because we would basically be trading the manual part in for interpretation of results. What is the machine telling us? Who do I need to make sense of that. So there wouldn't be a wholesale—we couldn't subtract off the funding that we need to support the field and laboratories but I believe that would be reduced.

Mr. BILIRAKIS. What do you think, Dr. Merlin? Do you think we will save some money?

Dr. MERLIN. I think the jury is out on that. I think almost invariably new technology programs are offered with the promise that

they are going to save money by saving labor and decreasing costs, and often that doesn't turn out to be the case. One question will be the actual acquisition costs, and from the numbers I have heard, the actual acquisition costs and operating costs are greater than the current Gen-2 costs. I don't see how there could be a net savings of money. There is going to be an increase anyhow. And then there is a question in the rollout period once it is rolled out what the implications are of the downstream effects on public health departments and the need to support it. I think it is just very hard in a program like this to speculate what the operating costs are truly going to be.

Mr. BILIRAKIS. I appreciate that. Thank you very much. I yield back, Mr. Chairman.

Mr. MURPHY. Thank you. Just a quick question. The President in July 2012 released the National Strategy for Biosurveillance. He said he would have a strategic implementation plan in 120 days. Do either of you gentlemen know if we have one yet?

Dr. MERLIN. On the way here yesterday from Atlanta, I got an email saying that the implementation plan had been posted. I didn't have a chance to look but it should be—if it is there, it should be on the Executive Office of the President Web site.

Mr. MURPHY. Would you please help make sure we see that too? And also about the costs. On July 16, 2008, the GAO testified at the House Homeland Security Subcommittee hearing that the Generation-2.5 lab-in-a-box units would cost \$120,000 per unit and \$65,000 to \$72,000 annually per unit to operate and maintain. According to a slide from DHS scientists in December of 2011, the cost estimates for Gen-3 showed \$117,000 per unit, which is comparable to Gen-2.5, but a much higher \$174,000 per unit for operation and maintenance for Gen-3 lab-in-a-box services. So Dr. Walter, why is the operation and maintenance for Gen-3 devices more than \$100,000 higher per unit than the Gen-2.5? Do you know?

Mr. WALTER. I do not know that. Like I said, Gen-2.5 predates me. I know Gen-2.5 was a fairly expensive system to maintain but we are also looking as part of the acquisition to reduce the costs of maintaining those systems. Most of the costs in maintaining or fielding an automated detection system is going to be in operations and maintenance, and anything we can do to reduce those costs is going to work in our favor.

Mr. MURPHY. Well, thank you. I think we heard today on both sides of the aisle the concern about these costs, the effectiveness, the sensitivity and specificity, and we will want to continue to work with you to make sure that we have that information.

I ask for unanimous consent that the written opening statements of members be introduced into the record, and without objection, the documents will be entered into the record.

I also ask unanimous consent that the contents of the document binder be introduced into the record and authorize staff to make any appropriate redactions. So without objection—

Mr. TONKO. Without objection.

Mr. MURPHY. The documents will be entered into the record with any redactions staff determines are appropriate.

I also ask for unanimous consent to put the majority staff's supplemental memorandum into the record, so without objection, this memorandum will be put into the record.

So in conclusion, I would like to thank the witnesses and the members for their hard work and thoughtful participation in today's hearing. I remind members they have 10 business days to submit questions for the record, and I ask that the witnesses all agree to respond promptly to the questions.

So with that, the subcommittee is adjourned.

[Whereupon, at 11:49 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
DOCUMENT BINDER INDEX**

June 18, 2013

"Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism"

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3	Appendix C: Glossary
4	Glossary of Acronyms
5	Table of Biological Threat Agents
6	June 7, 2103 Congressional Research Service Memorandum: Information for a hearing on the Department on the Homeland Security BioWatch program
7	July 8, 2012 Los Angeles Times Article, by David Willman, "The biodefender that cries wolf"
8	October 22, 2012 Los Angeles Times Article, by David Willman, "BioWatch technology couldn't detect lethal germs, tests found"
9	December 21, 2012 Los Angeles Times Article, by David Willman, "Troubled BioWatch program at a crossroads"
10	June 16, 2013 Los Angeles Times Article, by David Willman, BioWatch faces congressional hearing this week"
11	July 19, 2012 Letter to Centers for Disease Control Prevention Director Thomas Frieden
12	November 16, 2012 Response to our July 19, 2012 Letter to Centers for Disease Control and Prevention Director Thomas Frieden
13	July 19, 2012 Letter to Department of Homeland Security Secretary Janet Napolitano
14	November 13, 2012 Letter to Centers for Disease Control Prevention Director Thomas Frieden
15	January 25, 2012 Response to our November 13, 2012 Letter to Centers for Disease Control and Prevention Director Thomas Frieden
16	November 13, 2012 Letter to Department of Homeland Security Secretary Janet Napolitano
17	January 25, 2012 Response to our November 13, 2012 Letter to Department of Homeland Security Secretary Janet Napolitano
18	January 31, 2013 Letter to Department of Health and Human Services Secretary Kathleen Sebelius
19	June 10, 2013 Email From: DHS; To: Committee Staff; Subject: Number of BARS
20	June 14, 2013 Email From: DHS; To: Committee Staff; Subject: Jurisdictions

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21	October 9, 2012 Email From: Jasmine Chaitran, CDC; To: Toby Merlin; Subject: Total Number of BARS since BioWatch inception
22	May 29, 2013 Email From: Shana Bevin, CDC; To: Committee Staff; Subject: Breakdown of the number of BARS
23	August 13, 2011 Email From: Segaran Pillai (DHS); To: Toby Merlin; Subject: Signatures on Current PHAA Document
24	December 8, 2011 Email From: Robert Hooks; To: Michael Walter (DHS); Subject: Update on Program
25	
26	January 3, 2012 Email From: Cristin Willner (CTR); To: Segaran Pillai (DHS); Subject: BioWatch Read Ahead Material, attachment of background included
27	April 23, 2012 Email From: Douglas Drabkowski (DHS); To: Segaran Pillai (DHS); Subject: TEMP from OHA
28	June 14, 2012 Science & Technology Directorate Chem-Bio Division Review and Comment BioWatch Documents-“Acquisition Program Baseline (APB) for BioWatch Gen-3 Autonomous Detection System”
29	July 12, 2012 Email From: Wendy Hall; To: Douglas Drabkowski and Segaran Pillai; Subject: Gen-3 IRT Outbrief
30	June 19, 2012 Email From: Tara O’Toole; To: Brian DeVallance; Subject: Bio Meeting
31	June 25, 2012 Email From: Erin O’Connor; To: Tara O’Toole; Subject: BioWatch IRB
32	August 6, 2012 Email From: Douglas Drabkowski; To: Segaran Pillai; Subject: BioWatch Gen-2 Data
33	September 7, 2012 DHS Acquisition Decision Memorandum, Subject: BioWatch Generation-3 Acquisition; From: Doctor Alexander Garza, Assistant Secretary for Health Affairs; To: Rafael Borrás, Under Secretary for Management
34	May 22, 2011 Email From: Toby Merlin (CDC); To: Beth Bell (CDC) and Thomas Hearn (CDC); Subject: OPR on LRN-Draft Outline of Presentation
35	May 26, 2011 Email From: Michael Farrell; To: Toby Merlin (CDC); Subject: Private Conversation with Mike Walter and Ulana Bodnar and email chain
36	June 24, 2011 Email From: Toby Merlin (CDC); To: Michael Farrell, Richard Kellogg, Harvey Holmes; Subject: Incident Notice-BioWatch Notification-F. Tularensis, Houston, TX CLOSED
37	June 9, 2011 Email From: Toby Merlin (CDC); To: Richard Kellogg (CDC); Subject: LRN Comment on Proposed Email to Ranhofer about BioWatch Gen-3 Signature Concern
38	August 10, 2011 Email From: Harvey T. Holmes; To: Toby Merlin (CDC); Subject: Multiplex
39	September 9, 2011 Email From: Richard Kellogg; To: Dan Sosin, Joanne

Exhibit Number	Document
	Andreadis, Toby Merlin (all CDC); Subject: Feedback on Tara O'Toole Discussion
40	September 9, 2011 Email From: Toby Merlin (CDC); To: Dan Sosin (CDC); Subject: Feedback on Tara O'Toole Discussion
41	October 13, 2011 Email From: Toby Merlin (CDC); To: Segaran Pillai (DHS); Subject: Signatures on Current PHAA Document
42	October 19, 2011 Email From: James Hayslett (CDC); To: Toby Merlin (CDC); Subject: Conflict Between OHA and S&T
43	November 17, 2011 Email From: Toby Merlin (CDC); To: James Hayslett (CDC); Subject: Follow-Up from Toby Merlin to NYC DOH
44	November 17, 2011 Email From: Toby Merlin (CDC); To: James Hayslett (CDC); Subject: Letter We/DPEI are Sending to DHS-OHA About Our Concerns on Gen-3 ORD
45	November 17, 2011 Email From: Beth Maldin (Health.NYC.Gov); To: Toby Merlin (CDC), Colin Stimmler, Issac Weisfuse (CDC) and Stephen Papagiotas (CDC); Subject: Draft DHS OT&E Guidance
46	May 6, 2012 Email From: Toby Merlin (CDC); To: Beth Bell (CDC); Subject: Follow-Up on NYC BioWatch Concerns
47	May 16, 2012 Email From: Toby Merlin (CDC); To: Jasmine Chaitram (CDC); Subject: Question to Follow-Up BioWatch Indoor Working Group
48	May 23, 2012 Email From: Toby Merlin (CDC); To: Beth Bell (CDC) and Tracee Treadwell (CDC); Subject: Thoughts for 11:30 Call about Beth's Upcoming Meeting with Tara O'Toole
49	June 20, 2012 Email From: Beth Bell (CDC); To: Ali S. Khan (CDC); Subject: BioWatch Story
50	June 21, 2012 Email From: Ali S. Khan (CDC); To: Beth Bell (CDC); Subject: BioWatch Story
51	June 29, 2012 Email From: Toby Merlin (CDC); To: James Hayslett (CDC); Subject: Life, Liberty and the Pursuit of Assays
52	July 25, 2012 Email From: Toby Merlin (CDC); To: Stephen A. Morse (CDC); Subject: Garza's Statement
53	July 26, 2012 Email From: Stephen A. Morse (CDC); To: Toby Merlin (CDC); Subject: Gen-3
54	July 26, 2012 Email From: Angela Webber (CDC); To: Toby Merlin (CDC) and Stephen A. Morse (CDC); Subject: Congressional Letter and Mention of "Trace" Detection
55	August 16, 2012 Email From: Angela Webber (CDC); To: Stephen A. Morse (CDC); Subject: Trace Amounts
56	October 22, 2012 Email From: Michael Farrell (CDC); To: Toby Merlin (CDC); Subject: Question #3 About the LOD Summaries
57	July 9, 2012 Letter; From: Bennie G. Thompson; To: Secretary Janet Napolitano; Subject: LA Times Article on BioWatch Gen-3 Technology

Document 1

**THE COMMITTEE ON ENERGY AND COMMERCE**

Memorandum

June 14, 2013

TO: Members, Subcommittee on Oversight and Investigations
FROM: Majority Committee Staff
RE: Hearing on BioWatch and Public Health Surveillance

On Tuesday, June 18, 2013, at 10:00 a.m. in room 2322 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism." This hearing is an examination of the effectiveness and efficiency of BioWatch, a Department of Homeland Security (DHS) program, and its relationship with the Centers for Disease Control and Prevention (CDC) and state and local public health authorities.

I. WITNESSES

Michael Walter, Ph.D.
BioWatch Program Manager
U.S. Department of Homeland Security
Office of Health Affairs

Toby L. Merlin, M.D.
Director
Division of Preparedness & Emerging Infections
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

II. BACKGROUND

The BioWatch program was started in 2003, and is managed by the DHS Office of Health Affairs. BioWatch is an early warning system for detection of a large-scale, bioterrorist attack using pathogens that have been covertly released into the air.

BioWatch deploys collectors in 34 of the largest U.S. metropolitan areas in outdoor locations to detect the possible aerosol release of a bioterrorism pathogen. This program also includes three indoor deployments and special event capacity. By detecting a biological attack much earlier than through public health surveillance, BioWatch could save more lives because medications would be distributed to the population before many exposed individuals became ill. BioWatch uses polymerase chain reaction (PCR) laboratory testing designed to detect an

aerosolized biological attack from several specific biological agents considered high-risk for use as biological weapons, such as anthrax. BioWatch has three main elements coordinated by different agencies: sampling, analysis, and response. The sampling component involves collectors with filters collecting air samples. These filters are manually collected, usually at 24-hour intervals. The CDC coordinates analysis, and the laboratory testing of the samples, though the testing is carried out in state and local public health laboratories. Local jurisdictions are responsible for the public health response to positive findings.

The detection of biological agent DNA by the BioWatch program is referred to as a BioWatch Actionable Result (BAR). A BAR is defined as one or more PCR-verified positive result(s) from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents. If there are positive findings, federal, state, and local officials review findings from other collectors, conduct additional tests on samples, and review additional relevant information. If it is determined that an actual attack has occurred, several public safety and health measures take place, including potential mass prophylaxis of exposed populations and requesting vaccines or anti-viral medications from the Strategic National Stockpile.

Under the current BioWatch system called Generation 2 (Gen-2), the detection process can take 12 to 36 hours and entails labor costs for manual collection and analysis. Because prompt treatment may minimize casualties in a bioterrorism event, federal efforts have aimed to reduce the inherent delay in daily BioWatch filter collection by developing autonomous detection systems. Unlike the current BioWatch system, these autonomous systems would not only collect the samples, also identify the specific agent.

Since 2004, DHS has been pursuing a technology – which is to be the third generation of deployed BioWatch technology, called BioWatch Generation-3 (Gen-3). The goal of Gen-3 is to improve upon existing technology by enabling autonomous collection and analysis of air samples using the same laboratory science that is carried out in manual processes in the current system. The new technology would operate as a self-contained “laboratory-in-a-box” that would reduce the time to six hours between potential exposure and confirmation of the presence of biological pathogens and eliminate manual collection and analysis costs. In addition to this technological enhancement, DHS has aimed to widen deployment of the Gen-3 collectors to more cities, and to add collectors to each of these cities to widen population coverage for each area.

BioWatch currently costs about \$85 million a year to operate, with over \$1 billion spent since 2003. However, an internal DHS document from December 2011 projected the anticipated future cost for operating Generation 3 at \$7.7 billion for 15 years. According to the Government Accountability Office (GAO), the cost of Gen-3 without risk adjustments is estimated to be about \$5.8 billion over 10 years. These cost estimates were based on technologies that failed to meeting operational requirements in testing. There is no current cost estimate for Gen-3 because the BioWatch program is completing an Analysis of Alternatives (AoA), and will update the cost estimate to reflect any changes in the program.

Acquisition Status

The BioWatch Gen-3 acquisition process has had difficulties maintaining target costs goals and meeting technical requirements. The estimated lifecycle costs of the Gen-3 program

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increased between 2009 and 2011 from \$2.1 billion to \$5.8 billion. The GAO questioned the prior cost estimates and concluded that they “did not account for risk and uncertainty, and it was not based on the work breakdown structure for Gen-3 and as such, DHS did not have assurance that it captured all relevant costs.”¹

The competing technologies for Gen-3 have also failed to meet requirements, leading DHS and the Congress to put Gen-3 on pause.

Last September, Congress cut approximately \$40 million that DHS had requested for Gen-3. Congress in effect also required the Secretary of DHS to certify that the science of Gen-3 is proven before procurement can be permitted. During the passage of the Consolidated and Further Continuing Appropriations Act of 2013² (the CR), the House and Senate appropriators issued the following explanatory statement that instructs DHS with respect to the Gen-3 program:

The Committees have consistently demonstrated strong support for the development of an early warning network to detect biological agents to speed response and recovery from a terrorist attack. While the Committees support OHA's ongoing efforts to improve the Nation's biological detection capabilities, serious concerns have been raised about the Biowatch Generation 3 program, to include scientific validity and delays in execution that have created large carryover balances. The Department is encouraged to continue with Phase II, Stage I activities, as currently planned with available carryover funding, to ensure candidate systems meet entry criteria through performance testing. However, prior to entering Phase II, Stage 2 that includes down-selection for a single solution and entering operational testing and evaluation, the Secretary shall certify to the Committees that the science used to develop the technology is proven and warrants operational testing and evaluation.

It is unclear what will be required to show that the science is proven. At a minimum, the acquisition process will impose certain requirements before Gen-3 can be certified. In September 2012, DHS revised its acquisition strategy and ordered an AoA, and re-evaluated the mission and goals of Gen-3. The AoA must include a Cost-Benefit Analysis of the deployed Bio-Watch Gen-2 performance versus the proposed Gen-3 performance. The AoA is underway and is expected to conclude in the fall of 2013.

In addition, other studies and information-gathering efforts may further delay possible certification of Gen-3. Recently, Dr. Walter, the DHS BioWatch program manager, asked the National Academies of Science (NAS) to convene an ad hoc committee to conduct a study and prepare a report that will evaluate and provide guidance on appropriate standards for the validation and verification of PCR tests and assays used by the BioWatch program. The efforts are expected to make adequate performance data available to public health and other key decision makers so that they have a sufficient confidence level to facilitate the public health response to a BAR. The requested report is not expected to be issued until the latter part of 2014. In addition, DHS is also funding a June 25-26, 2013, NAS workshop to explore alternative biodetection systems to Gen-3.

¹ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 30.

² Explanatory Statement of Managers associated with Public Law 113-6, March 26, 2013.

Committee investigation

On July 19, 2012, Chairman Upton and O&I Subcommittee Chairman Stearns opened an investigation into the BioWatch program, to examine its performance and its impact on the nation's public health system. Request letters were sent to both DHS and CDC. The investigation followed up on a July 8, 2012, *Los Angeles Times* article, which reported that BioWatch had been plagued by false alarms and other failures. In addition, state and local health officials reportedly expressed their lack of confidence in BioWatch.

DHS disputed the *Los Angeles Times* article. On July 12, 2012, Dr. Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS), posted a blog on the DHS website entitled "The Truth About Biowatch: The Importance of Early Detection of a Potential Biological Attack." In his posting, Dr. Garza wrote: "Recent media reports have incorrectly claimed that BioWatch is prone to 'false positives' or 'false alarms' that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result."

On November 13, 2012, Chairman Upton and Subcommittee Chairman Stearns sent request letters to DHS and CDC concerning the BioWatch program. The Committee was following up on an October 23, 2012 *Los Angeles Times* article, which reported that a BioWatch system was operating with defective components. In addition, the requests were reaffirmed and expanded because of inadequate responses to the July 12, 2012, request letters.

On January 31, 2013, Chairman Upton and O&I Subcommittee Chairman Murphy sent a request letter to HHS Secretary Kathleen Sebelius reaffirming the November 13, 2012, document request sent to CDC and asking that the document production be expedited.

Both DHS and CDC have provided documents. Committee staff has also conducted interviews with officials from DHS and CDC.

III. ISSUES

Do state and local authorities in BioWatch jurisdictions have adequate guidance from DHS on what response actions to take following a BioWatch Actionable Result?

Before making a certification on the science of Gen-3, will the Secretary of DHS rely on information from the study and report by the National Academies of Science that is to be conducted over the next year?

What factors led to the delays in the Gen-3 acquisition timeline?

What improvements have been made to Gen-2, the current BioWatch program technology?

What additional type of information will CDC look for before taking public health actions with the distribution and dispensing of medical counter-measures?

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IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin or Carl Anderson at (202) 225-2927.

Document 2

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U.S. Bioterror Detection Program Comes Under Scrutiny

A national air sampling system tasked with picking up terrorist biological attacks faces scrutiny

By Dina Fine Maron | Monday, June 17, 2013 | 2 comments

A cutting-edge biological terror alert system detected a potential threat in the air one morning back in 2008, threatening to derail then-Sen. Barack Obama's acceptance speech in Denver for his party's presidential nomination at the Democratic National Convention. Initial results from a pricey national air sampling system suggested that bacteria that could cause tularemia had been detected. The microbe, *Francisella tularensis*, might have been weaponized to cause the infectious disease.

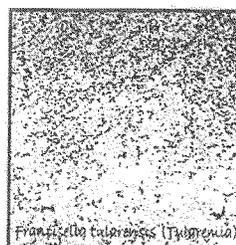
Public health officials sprang into action and tested further samples from the area that triggered the system, but turned up negative results. The alert, like others issued by the system in the past decade, was ruled to be a false alarm. Obama still made his acceptance speech that night, of course, in an open-air stadium as planned. But the system's critics say BioWatch has repeatedly triggered an alarm when no threat has existed. Now the program faces the scrutiny of Congress.

BioWatch, an alert system designed to be an early detection system for airborne threats such as anthrax and smallpox, was unveiled in 2003 by Pres. George W. Bush. In his State of the Union address, he talked about the system, saying he was "deploying the nation's first early warning network of sensors to detect biological attack." Since then the system has cost \$1 billion and been met with mixed reviews. A committee convened by the Institute of Medicine (IOM) and the National Research Council (NRC) said in a 2011 report no expansion of the program should be made without better collaboration with the existing public health system. The panel also called for further analysis of the program and how it could be used to reduce mortality and morbidity.

The network of outdoor and select indoor air samplers was installed, under the aegis of the U.S. Department of Homeland Security (DHS), in more than 30 U.S. metropolitan areas to sniff the air for potential threats. The filters from those aerosol collectors are retrieved for analysis in state or county public health laboratories.

Whereas technically the potential threats detected by the system in the past were not false positives—they did accurately pick up tiny, background amounts of DNA from organisms naturally present in the environment—in effect, they were false alarms because they signaled the potential occurrence of a terrorist attack when none had occurred. Some public health officials have said they are hesitant to rely on the program. Others say it is an important piece of the bioterror response puzzle.

"The way I look at BioWatch is that it is a tool," says Umair A. Shah, executive director of the Harris County Public Health and Environmental Services Department in Texas. "It is one of many tools that are available to public health decision-makers and needs to be kept in the context of that paradigm. The sum of all those tools is really how we go about making sound public health decisions." Sensors in area around Houston and Harris County had the first-ever positive result through BioWatch in 2003. Like the later DNC incident, BioWatch picked up indications of *F. tularensis*. Those readings also turned out to be a false alarm; BioWatch again had detected organisms naturally present in the environment.



Francisella tularensis.
Image: Missouri Department of Health and Senior Services



The value of the system, even with its false alarms, is that it could give public health officials the first clues of a bioterror attack. "You don't necessarily want to make [BioWatch] less sensitive to avoid false positives," says Seth Foldy, a physician who works on public health informatics and served on the NRC-IOM panel looking at the program. The tricky part, he says, is finding a way to make the system sensitive enough so that it would pick up actual disease-causing agents in the event of a bioterror threat, but specific enough to be able to distinguish them from very closely related bacteria that may exist in the environment but do not lead to human disease.

A House subcommittee is set to examine the program Tuesday, with representatives from the DHS and the U.S. Centers for Disease Control set to discuss the system's future. "The BioWatch Program is the only federally—managed, locally—operated nationwide bio—surveillance system designed to detect select aerosolized biological agents," says DHS spokesman SY Lee. "BioWatch provides public health officials with a warning of a biological agent release, before potentially exposed individuals develop symptoms of illness."

Against the backdrop of lukewarm reviews, however, a planned expansion of BioWatch, Generation 2.5, was canceled in fall 2008. The next proposed stage of the system, Generation 3, will be under discussion at the hearing. The system as it stands now is designed so that the time between sample collection and laboratory results indicating potential biological aerosol release is between 10 to 36 hours. With future iterations of the program the hope is to get initial analysis of the samples wrapped up within six hours. For Generation 3, DHS is looking into including autonomous biodetection technology to help eliminate the need for manual filter retrieval and analysis. Still, confirmatory tests would still be required raising questions about how much time would be saved and if it would result in faster response times and disbursement of emergency drugs that could help avoid human sickness or death.

At the very least it may help preliminary results get out faster. "The difference it would make," says Bob England, director of the Maricopa County Department of Public Health, which covers the Phoenix metropolitan area, "is you would get your first inkling that something might be going on hours earlier. That would give you that much more time to get people together and ready to evaluate the confirmatory results when they do come back so it does make the response earlier."

In the current fiscal environment there is also concern from some public health offices that dollars allocated to detecting biological threats through BioWatch may be competing with the ones needed to provide complementary information to help detect threats—such as picking up any uptick in certain symptoms at hospitals through robust health surveillance. According to National Association of County and City Health Officials (NACCHO), 59 percent of local health departments rely exclusively on federal funding to support their emergency preparedness programs. As cuts have been made to public health emergency response in recent years, says Jack Herrmann, senior advisor and chief of public health preparedness at NACCHO, that makes it more difficult to conduct consistent public health monitoring and create optimal response plans.

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Document 3

For Official Use Only**Appendix C: Glossary**

Acquisition Decision Authority: The individual designated in accordance with criteria established by the Department Chief Acquisition Officer to approve entry of an acquisition program into the next phase of the acquisition process. Formerly known as a Milestone Decision Authority (MDA).

Acquisition Decision Event: A predetermined point within the acquisition phases at which the investment will undergo a review prior to commencement of the next phase. Formerly known as a Key Decision Point (KDP).

Agent Data: Data containing sample analysis or results.

BioWatch Actionable Result (BAR): One or more PCR-verified positive results from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents (i.e., three of three signatures). If PCR-verified positive results are obtained for two BioWatch agents on a single collector, this is considered one BAR. See below for PCR-verified definition.

BioWatch Autonomous detector: The BioWatch Autonomous Detector is a networked device capable of achieving the following: (1) Rapidly process and accurately analyze aerosol samples with a high level of confidence (2) Automate and integrate the major system functions into the detector including aerosol sample collection, preparation, analysis, and analytical results reporting (3) Operate in its intended outdoor and indoor environments (4) Disseminate and archive analysis results and system operational data.

BioWatch Collector: Collector is the generic term used to describe the devices used to extract particulate matter from the air and deposit it onto a filter that is subsequently analyzed at a laboratory.

BioWatch Jurisdiction: For purposes of this document, the term "BioWatch Jurisdiction" will be used to describe each of the BioWatch program metropolitan areas. BioWatch is operational in more than 30 of the largest metropolitan areas in the United States. These areas may be composed of one or more city, county, state, and/or regional BioWatch Jurisdictions or decision making bodies. Officials in each BioWatch Jurisdiction should interpret this term to reflect their unique decision-making and communications structure.

BioWatch Signal: A BioWatch Signal is defined to mean detector analysis results that exceed specified thresholds. This enables a means of filtering high frequency data to assure that results that may contain significant content are automatically brought to the user's attention.

Data centers: High-availability Information Technology facilities where G3BOSS is hosted. These data centers provide data processing, backup, storage, and dissemination of information in a secure environment.

DNA signature: A region of a DNA sequence that is specific to a certain organism or genus.

Function Cycle: A function cycle refers to each function's (sub-system) unique cycle of operation thus requiring a level of detail that includes independent monitoring/reporting for each function.

Gen-3 BioWatch Operations Support System (G3BOSS): The Gen-3 BioWatch Operational Support System consists of the information and data management technology required to deliver high-availability data services to the Gen-3 user.

Jamming: Emitting a signal from a communications device that creates constant or partial blockage of an established telecommunications channel, e.g. Creating collisions on a wired network to interrupt normal data communication; generating random radio signals on a known frequency to disrupt normal data transmission on that frequency.

Key Performance Parameter (KPP): Those attributes or characteristics of a system/program/project that are considered critical or essential parts of an effective system/program/project capability.

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██████████ The average biological agent air concentration over the collection period, assuming a probability of detection equal to or greater than 98%. The average air concentration of agents over the collection period includes flow rate, collection efficiency, collection duration, and limit of detection (LOD) of the analysis subsystem. For example, if the LOD of the analysis subsystem is 900 organisms, the collection duration is 3 hours, the collection efficiency is 90%, and the flow rate is 100 liters per minutes, the system-level sensitivity of the detector is 56 organisms per cubic meters.

System: ██████████ System specificity is defined as the ability of the Gen-3 BioWatch System to detect strains of the target species without detecting near-neighbors or background organisms.

Time to Detect: The elapsed time between intake of the agent and generation and transmission of the analytical results.

Document 4

Glossary of Acronyms

BAR	A BioWatch actionable result (BAR) is defined as one or more PCR-verified positive results from a single BioWatch collector that meets the algorithm for one or more specific BioWatch agents (i.e. three of three signatures). If PCR-verified positive results are obtained for two BioWatch agents on a single collector, this is considered one BAR. See below for PCR-verified definition.
BioWatch Collector	Collector is the generic term used to describe the devices used to extract particulate matter from the air and deposit it onto a filter that is subsequently analyzed at a laboratory.
BRRAT Laboratory	Bioterrorism Rapid Response and Advanced Technology Laboratory. This is the primary bioterrorism laboratory located at the CDC. It is a state-of-the-art facility that develops and validates new Laboratory Response Networks (LRN) assays, processes suspicious samples, and provides 24-hour diagnostic support to bioterrorism response teams.
BTRA	Bioterrorism Risk Assessment. This is an evaluation conducted by The Department of Homeland Security Science and Technology Directorate every two years and it began in 2006. It provides a mechanism for assessments and reprioritization of federal capabilities in response to changing adversary capabilities.
ConOps	Concept of Operations. A term used to describe the characteristics of a proposed system from the viewpoint of an individual who will use that system. It is used to communicate the quantitative and qualitative system characteristics to all stakeholders. It may include the goals and objectives of the system, strategies, tactics, policies, and constraints, specific operational processes for fielding the system and processes for initiating, developing, maintaining, and retiring a system.
Ct	Cycle threshold. A term used in real-time PCR describing the cycle number at which fluorescence intensity exceeds threshold baseline.
LRN	Laboratory Response Network of the Department of Health and Human Services, Centers for Disease Control and Prevention. The LRN maintains a

	national and international network of laboratories fully equipped to respond to acts of biological or chemical terrorism, emerging infectious disease, or other public health threats and emergencies.
ORD	Operational Requirements Document. This document describes what intended role the system will be used for and therefore determines what requirements the system must have.
PCR	Polymerase chain reaction is a laboratory technique used to amplify a DNA fragment present in BioWatch samples as part of the process of detecting genetic fingerprints of intentionally released aerosolized biological agents.
PCR-verified positive test	First event that triggers an initial BioWatch response. A PCR-verified positive result is defined as a result that meets a particular threshold and algorithm (i.e. three of three signatures are reactive) for a specific BioWatch agent. When a sample is deemed reactive during the screening assay (one agent signature crosses the threshold), a verification panel for that particular agent is tested.
PSU	Portable Sampling Unit (PSU) is a type of sample collector. The PSU is designed for use as a constant flow air sampler. It is used to pull air through a filter for the collection of airborne pathogens for analysis. A unique feature of the PSU sampling system is that the sample inlet is adjustable between 48 and 72 inches above the ground. The PSU has been custom designed to enclose and provide chain of custody for the pump, flow controller, flow meter, filter holder, and all electronics inside two individual, lockable, weather-resistant boxes.
SNS	Strategic National Stockpile. This is the national repository of antibiotics, vaccines, chemical antidotes, antitoxins and other critical medical equipment and supplies. In the event of a national emergency involving bioterrorism or a natural pandemic, the SNS has the capability to supplement and re-supply local health authorities that may be overwhelmed by the crisis, with response time as little as 12 hours. The SNS is managed by the Centers for Disease Control and Prevention with support from other agencies in the Department of Health and Human Services and the U.S. Government.

Document 5

Table of Biological Threat Agents		
Common Name	Species & Sub-Species	Description
Anthrax	<i>Bacillus anthracis</i>	Anthrax is an infectious disease caused by <i>B. anthracis</i> spores that are ingested by grazing animals. ¹ Humans are infected through inhalation of spores or ingestion of infected animals. Anthrax leads to skin infection, respiratory infection, and gastrointestinal infection. Inhalation of anthrax is fatal (90% of identified cases led to death). Skin infection and gastrointestinal infection may be treated with antibiotics, unless the infection leads to the bloodstream resulting in death.
Brucellosis Malta Fever Undulant Fever Mediterranean Fever Rock Fever Gibraltar Fever	<i>Brucella melitensis</i> <i>Brucella suis</i> <i>Brucella abortus</i> <i>Brucella canis</i> <i>Brucella pinnipediae</i> <i>Brucella cetaceae</i>	Brucellosis is a disease that infects cattle, goats, camels, pigs, and dogs. ² Humans contract the disease from eating infected food products. Infection is rare in the U.S., roughly 100-200 cases per year. Symptoms include on/off fever persisting for months, headaches, muscle/back pain, swelling of heart, and fatigue. Mortality rate is low (<2%) with appropriate treatment of antibiotics.
Plague Bubonic Pneumonic Septicemic Pneumonic	<i>Yersinia pestis</i>	Plague is a deadly infectious disease, popularized as the bubonic plague from the Middle Ages. ³ The three most common forms of plague are Bubonic, Pneumonic, and Septicemic. Human contraction comes from flea bites or inhalation of bacteria. Fleas contract the disease from rabbits, squirrels, prairie dogs, and cats. Symptoms typically occur after 2-5 days of bacterial exposure. Mortality rate is high if treatment is not received in 24-hours after symptoms appear. Without treatment 50% of bubonic plague patients die and nearly all pneumonic plague patients die. Treatment can only reduce mortality rate to 50%.
Q Fever	<i>Coxiella burnetii</i>	Q Fever is a global infectious disease that infects sheep, goats, cattle, dogs, cats, birds, rodents, and ticks. ⁴ Humans contract the disease by inhaling or ingesting milk, urine particles, and fecal particles of infected animals. Humans can be infected by a single bacterium. Treatment with antibiotics is very effective leading to low mortality rates.
Tularemia Deerfly Fever Rabbit Fever Charr Disease Lemning Fever Pahvant Valley Plague	<i>Francisella tularensis tularensis</i> (Type A) <i>Francisella tularensis holarctica</i> (Type B) <i>Francisella novicida</i> <i>Francisella philomiragia</i>	Tularemia is an infectious disease caused by the species <i>Francisella</i> . The bacterium is carried by small rodents (rabbits, beavers, muskrats, rats, squirrels, raccoons, and skunks). ^{5,6} Ticks, flies, and mosquitoes spread the disease to humans through bites. Tularemia can easily be aerosolized and spread as a bioterror agent. Treatment of Tularemia is very effective with antibiotics. Mortality rate is ~5% in untreated cases.
Smallpox	Variola major (Virus) Variola minor (Virus)	Smallpox is a deadly virus that has been eradicated by the WHO in the 1970s. ⁷ Variola major causes life threatening symptoms to those not vaccinated with the smallpox vaccine. Variola minor causes a mild infection that rarely leads to death. Contraction of Smallpox without vaccination has a mortality rate of nearly 30%. The virus is contracted through human-to-human contact and contact with contaminated objects. The virus can be aerosolized and distributed easily as a bioterror agent.

<p>Viral Encephalitis</p>	<p>Poliovirus Echovirus Cytomegalovirus Adenovirus Measles/Rubella Epstein-Barr Virus Herpes Simplex Virus Varicella-Zoster Virus</p>	<p>Encephalitis can be caused by diverse viral infections. It is a rare infection that is more susceptible in the first year of life or with the elderly.⁸ Encephalitis is characterized as inflammation and irritation of the brain due to viral infections. Humans contract the virus through airborne infection, insect bites, and ingesting contaminated food. Symptoms lead to fever, vomiting, headache, light sensitivity, seizures, paralysis/body stiffness, coma, amnesia, rash, and pneumonia.</p>
<p>Viral Hemorrhagic Fever Lassa Fever Crimson-Congo Fever Hantavirus Fever Ebola Fever Marburg Fever</p>	<p>Arenaviridae (Virus) Bunyaviridae (Virus) Filoviridae (Virus) Flaviviridae (Virus)</p>	<p>Viral Hemorrhagic Fevers are caused by a diverse array of viruses. Clinical symptoms range from mild to severe. The most popularly characterized VHF is the Ebola virus. Ebola is a deadly illness that affects humans and primates.⁹ Mortality rate of Ebola is as high as 90%. There is no known treatment for Ebola. All the viruses are carried by small rodents and insects. Humans contract the virus via insect bites, ingesting contaminated food, and inhaling particles.</p>
<p>Botulism Botulinum Toxin (Types A-G)</p>	<p><i>Clostridium botulinum</i></p>	<p><i>C. botulinum</i> is found globally in the soil and untreated water.¹⁰ The bacterium produces hardy spores that create a neurotoxin. The toxin is highly infectious and in small dosages can cause severe poisoning. The toxin is noted for its ability to paralyze muscles. Around 110 cases of botulism occur in the U.S. yearly. A derivative of the neurotoxin is commonly used for Botox Therapy.</p>
<p>Staphylococcal Enterotoxin B (SEB)</p>	<p><i>Staphylococcus aureus</i></p>	<p>Staphylococcus bacteria thrive in unrefrigerated meats and dairy products.¹¹ The bacterium will excrete SEB toxins that lead to toxic shock syndrome. SEB is very stable and is easy to aerosolize. SEB inhalation leads to high levels of incapacitation and even death. <i>S. aureus</i> is a common source for food poisoning leading to diarrhea, nausea, intestinal cramping, fever, sore throat, chest pain, and vomiting.¹²</p>
<p>Melioidosis Whitmore's Disease</p>	<p><i>Burkholderia pseudomallei</i></p>	<p>Melioidosis is an infectious disease that affects humans and animals.¹³ The bacteria causing the disease is predominately found in soil and contaminated water. The disease is global, but commonly found in the tropics. Human contraction comes from contamination of wounds, ingestion, and inhalation.¹⁴ Incubation period may last from one day to many years. Symptoms can include ulcers, skin abscess, pulmonary infection, fever, headache, and septic shock. Animal species susceptible to Melioidosis are sheep, goats, swine, horses, cats, dogs, and cattle.¹⁵ Treatment requires antibiotics from weeks to months. Mortality rate has been observed to be around 20-50%.¹⁶</p>
<p>Glanders</p>	<p><i>Burkholderia mallei</i></p>	<p>Glanders is a disease that affects horses, donkeys, and mules. It is mostly seen in parts of Asia, Africa, the Middle East, as well as Central and South America.¹⁷ Humans can contract the disease via contact with infected animals. Glanders can easily be aerosolized and spread out. If inhaled can lead to severe disease. The bacteria can cause rashes, opening of wounds, fever, diarrhea, and lung abscesses. Treatment for Glanders is directed toward antibiotics, as there is no vaccine available.</p>

⁸ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2029242/>
⁹ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1006422/>
¹⁰ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005182/>
¹¹ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005117/>
¹² <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005154/>

¹³ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005154/>
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¹⁷ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005154/>
¹⁸ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005154/>
¹⁹ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005154/>
²⁰ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1005154/>

Document 6



MEMORANDUM

June 7, 2013

To: House Committee on Energy and Commerce
Attention: Alan Slobodin

From: Dana A. Shea, Specialist in Science and Technology Policy, 7-6844
Frank Gottron, Specialist in Science and Technology Policy, 7-5854
Sarah Lister, Specialist in Public Health and Epidemiology, 7-7320

Subject: Information for a hearing on the Department of Homeland Security BioWatch program

This memorandum responds to your request for an overview of the Department of Homeland Security (DHS) BioWatch program. You requested information about the history of the BioWatch program; funding appropriated for its development, operation, and maintenance; and policy issues of potential interest to the Committee.

Information in this memorandum is of general interest to Congress. As such, this information may be, or may have been, provided to other congressional requesters, and may be published in CRS products for general distribution to Congress at a later date. Your confidentiality as a requester would be preserved in any case. Please contact us with any questions.

History and Background of the BioWatch Program

The BioWatch program, started in 2003, is responsible for oversight of a system of biological agent or pathogen detectors deployed in order to provide early warning, detection, or recognition of a biological attack. It is located within the DHS Office of Health Affairs (OHA). The BioWatch program is also responsible for acquiring the next-generation of pathogen detectors in order to provide detection continuity and increased technical capabilities.

The BioWatch program has located current-generation BioWatch systems in more than 30 cities. President Bush announced the existence of the BioWatch program during the 2003 State of the Union address.¹ The DHS Science and Technology (S&T) Directorate deployed and oversaw the BioWatch systems from the program's inception until the creation of OHA late in 2007. The DHS then transferred responsibility for the BioWatch program to OHA. The S&T Directorate performed and continues to perform research and development (R&D) into biological detection technologies. The OHA does not have R&D responsibilities.

¹ Executive Office of the President, The White House, *State of the Union Address*, January 28, 2003.

The BioWatch system is composed of biological detectors that monitor the air for the presence of specific pathogens.² These detectors collect airborne particles onto filters, which are subsequently transported to laboratories for analysis. It is expected that this system will provide early warning of a pathogen release, alerting authorities of the bioterrorism event before victims begin to show symptoms and providing the opportunity to deliver medical intervention earlier. Computer models constructed by the Department of Health and Human Services and other experts suggest that early response to an airborne biological attack may lead to fewer casualties and fatalities.³ The DHS used a technology developed at the Department of Energy national laboratories, the Biological Aerosol Sentry and Information System (BASIS), to develop the initial BioWatch systems, known as BioWatch Generation 1, or Gen-1. In 2005, DHS expanded the BioWatch deployment. This expanded deployment included the addition of indoor monitoring capabilities. These systems, which are currently in place, are known as BioWatch Generation 2, or Gen-2. In recent years, DHS has deployed few new Gen-2 BioWatch systems, except for temporary use associated with National Special Security Events. However, DHS requires annual funding to operate and maintain existing Gen-2 systems.

Positive findings from BioWatch samples are termed “BioWatch Actionable Results” (BARs). When this occurs, federal, state, and local officials take steps to determine the appropriate response. They may review findings from adjacent devices, conduct additional tests on samples, and review additional relevant information to determine next steps. In the event of a suspected mass exposure to a bioterrorism agent, state and local public health officials, with federal assistance, are responsible for the public health response.⁴ These officials may decide to begin mass prophylaxis of exposed populations and may request medical countermeasures (e.g., drugs and vaccines) from the Strategic National Stockpile (SNS), managed by the Centers for Disease Control and Prevention (CDC).⁵ State and local health officials are responsible for mass distribution and dispensing. Through its Cities Readiness Initiative, CDC provides grant funds to 72 major metropolitan areas to strengthen their ability to respond to a large-scale bioterrorist event within 48 hours.⁶

The BioWatch program has not detected a bioterrorism incident since its inception, although it has detected pathogens of concern. Scientists believe that natural airborne “background” levels of these pathogens, or close relatives of them, exist in certain regions. In 2012, the *Los Angeles Times* published a series of investigative articles criticizing the performance of BioWatch.⁷ These articles echoed in part the concerns of the Government Accountability Office (GAO)⁸ and the National Research Council.⁹ The *Los*

² The identities of these pathogens are classified. The GAO has identified that the BioWatch system detects at least five pathogens (Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012).

³ See, for example, Prasith Baccam and Michael Boechler, “Public Health Response to An Anthrax Attack: An Evaluation of Vaccination Policy Options,” *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, Vol. 5, 2007, pp. 26-34; and Lawrence M. Wein, David L. Craft, and Edward H. Kaplan, “Emergency Response to an Anthrax Attack,” *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 100, 2003, pp. 4346-4351.

⁴ The Federal Bureau of Investigation is responsible for the law enforcement response to a bioterrorism incident.

⁵ Centers for Disease Control and Prevention, Strategic National Stockpile, <http://www.cdc.gov/phpr/stockpile/stockpile.htm>.

⁶ Centers for Disease Control and Prevention, Cities Readiness Initiative (CRI), <http://www.cdc.gov/phpr/stockpile/cri/index.htm>. BioWatch jurisdictions may be among the CRI cities, but CRS cannot confirm this with publicly available information.

⁷ David Willman, “The Biodefender that Cries Wolf,” *Los Angeles Times*, July 8, 2012.

⁸ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012.

⁹ National Research Council, 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: Abbreviated Version*, National Academies Press, Washington, DC, 2011.

Angeles Times articles claimed that the BioWatch system is prone to false alarms and is also insufficiently sensitive to detect an actual bioterrorism incident. Dr. Alexander Garza, then the DHS Assistant Secretary for Health Affairs, disputed these claims.¹⁰ In addition, some state and local health officials defended the program, saying, among other things, that it has fostered collaboration among federal, state, and local officials who would be called upon to work together in response to an actual incident.¹¹

The systems currently deployed require technicians to collect samples periodically from the geographically distributed devices. These samples generally are brought to local public health laboratories and tested for the presence of biological agents. The lack of sample collection automation and the time required to transport and process samples at local public health laboratories create logistical challenges. In practice, samples from BioWatch systems are processed on a daily basis, though this might be done more frequently with commensurate increases in operational costs. Since soon after the initial deployment of the BioWatch Gen-2 systems, DHS has focused its attention on developing a next-generation BioWatch system with increased automation. Such increased automation might increase the number of samples processed daily and thus reduce the amount of time elapsing between a potential biological release and its detection. The concept of a next-generation BioWatch system became known as BioWatch Generation 3, or Gen-3.

BioWatch Gen-3 has been under development since 2004 by the DHS S&T Directorate.¹² The BioWatch Gen-3 system would include the air sampling and the biological agent detection in the same device. This system is to analyze samples autonomously and remotely report the results. The OHA intends the BioWatch Gen-3 systems to reduce the time to detect a biological agent release from the current 36 hours to less than 6 hours. Shortening the time to detection in this way would allow more time for public health response and a greater likelihood of success in providing medical countermeasures to exposed populations before serious illnesses ensued.

In 2007, DHS established a pilot program as an interim solution to the development of BioWatch Generation 3. Through this pilot program it deployed the Autonomous Pathogen Detection System (APDS), a prototype system developed by Lawrence Livermore National Laboratory in association with private industry. The APDS is sometimes referred to as BioWatch Gen-2.5. The DHS had identified shortcomings in the APDS, including size, efficiency, environmental robustness, and sensitivity, but believed that some of the APDS shortcomings could be minimized through deployment in indoor settings.¹³ The DHS halted the APDS pilot deployment when the APDS began malfunctioning in the field.¹⁴

The DHS has experienced multiple challenges in attempting to develop, test, and acquire the BioWatch Gen-3 system. Initially expected to be deployed in 2012,¹⁵ DHS now estimates Gen-3 deployment

¹⁰ Dr. Alexander Garza, Assistant Secretary for Health Affairs, DHS, "The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack," blog posting, July 12, 2012.

¹¹ See, for example, Robert Roos, "Public Health Officials Respond to Critique of BioWatch," *CIDRAP News*, August 17, 2012, <http://www.cidrap.umn.edu/cidrap/content/bt/bioprep/news/aug1712biowatch.html>.

¹² Department of Homeland Security, *Department of Homeland Security: Science and Technology Fiscal Year 2006 Congressional Justification*, p. 61.

¹³ Jeffery Runge, Department of Homeland Security Assistant Secretary for Health Affairs and Chief Medical Officer, Testimony before the House Committee on Appropriations Subcommittee on Homeland Security, April 1, 2008.

¹⁴ Spencer S. Hsu, "U.S. Halts Pilot Program in New York to Detect Biological Attacks," *Washington Post*, May 7, 2009.

¹⁵ National Research Council, 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: Abbreviated Version*, National Academies Press, Washington, DC, 2011, p. 52.

beginning in 2016.¹⁶ The life-cycle cost estimate¹⁷ for the program has increased from \$2.1 billion to \$5.8 billion.¹⁸ The performance of the BioWatch program has attracted the attention of Members of Congress since its inception. These challenges in acquiring a next-generation system have been the subject of congressional hearings.¹⁹ Congressional appropriators have at times sought to limit funding for program expansion and/or called for program reviews.²⁰ The BioWatch Gen-3 program is currently undertaking a new Analysis of Alternatives (AoA)²¹ for the BioWatch Gen-3 acquisition, as recommended by GAO in 2012.²² The DHS expects to complete the AoA in 2013. The DHS has stated its intention to decide the future of the BioWatch Gen-3 acquisition in late 2013 following consideration of the AoA results.²³

Appropriations for the BioWatch Program

From FY2003 through FY2007, the DHS Science and Technology Directorate (S&T) oversaw the BioWatch program. The DHS did not specifically identify funding in the S&T Directorate for BioWatch, instead incorporating it with other biological countermeasures funding. In FY2008, DHS transferred BioWatch operations and management responsibilities from S&T to the Office of Health Affairs (OHA). **Table 1** presents BioWatch funding for OHA since the transfer. BioWatch funding accounts for more than half of the OHA budget.

Table 1. Appropriations for BioWatch in Office of Health Affairs
(\$ in millions)

FY2008	FY2009	FY2010	FY2011	FY2012	FY2013 ^a	FY2014 Request
77.1	111.6	89.5	100.8	114.2	85.3	90.6

Source: CRS analysis of Department of Homeland Security appropriations acts, FY2013 operating plan, and FY2014 budget request, <http://www.dhs.gov/dhs-budget>.

a. Amount reflects across-the-board rescissions and sequestration.

¹⁶ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

¹⁷ A lifecycle cost estimate is the expected total cost to the government of acquisition and ownership of a system over its useful life. It includes the expected costs of development, acquisition, operations, and support (to include manpower), and where applicable, disposal.

¹⁸ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

¹⁹ For example, U.S. Congress, House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response and Communications, *The Fiscal Year 2013 Budget Request for the Department Homeland Security's Office of Health Affairs*, 112th Cong., 2nd sess., March 29, 2012.

²⁰ See CRS annual Homeland Security appropriations reports, sections on Office of Health Affairs, for examples. <http://crs.gov/pages/subissue.aspx?clid=2345&parentid=73&preview=False>.

²¹ An Analysis of Alternatives (AoA) provides a systematic analytic and decision making process to identify and document an optimal solution for an identified mission capability gap. An AoA involves application of analyses that evaluate effectiveness, suitability, and financial justification for each viable alternative. The AoA considers both materiel and non-materiel solutions as well as combinations of non-material and materiel solutions, such as reengineered processes supported by modernized systems.

²² Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012.

²³ Department of Homeland Security, *BioWatch Gen-3 Phase II, Stage 1 Presolicitation and Draft Request for Proposal*, HSHQDC-13-R-00026, February 8, 2013.

The DHS has not presented BioWatch funding amounts according to generation. However, for FY2007, the House Appropriations Committee urged the S&T Directorate, in report language, to proceed with Gen-3 development.²⁴ Both chambers reiterated this directive to the S&T Directorate for FY2008, although ongoing BioWatch operations were funded through OHA beginning that year.²⁵ Beginning with FY2009, congressional appropriators, in report language, expressed concerns regarding Gen-3 development and deployment.²⁶

Policy Issues

The BioWatch program faces a wide range of policy challenges. Below are selected issues of potential interest to congressional policymakers. They are organized into three broad categories: strategy, relationship with public health, and acquisition of next-generation systems.

Strategic Issues

Environmental surveillance is a key component of federal strategic planning against biological terrorism.²⁷ Within these federal biodefense efforts, the BioWatch program is intended to play a central surveillance role, complementing traditional disease reporting efforts and recently developed efforts to use health data to identify disease outbreaks, a process sometimes known as syndromic surveillance. In determining the efficacy of the BioWatch program in meeting the strategic goal of providing warning of a biological terror attack, policymakers may be interested in how the BioWatch program adapts to the changing biological terrorism threat, how DHS determines the population protected through the BioWatch program, and how DHS and other stakeholders respond to BioWatch alarms that do not arise from terrorism.

Risk Assessment and the Evolving Threat

When DHS began BioWatch in 2003, it intended the program to address a range of adversary capabilities regarding biological weapons. For example, in 2004, DHS described the deployment of first-generation BioWatch systems as part of “domestic preparedness during war with Iraq and Al Qaeda,”²⁸ implying that the program was to address both potential state-sponsored and transnational terrorism. During the existence of the BioWatch program the biological weapon threat has altered due to changing events, such as advances in technology, changes in terrorist capabilities, and changes in political regimes in various countries.

In 2004, President Bush issued Homeland Security Presidential Directive (HSPD) 10, *Biodefense for the 21st Century*, part of which required “a continuous, formal process for conducting routine capabilities assessments to guide prioritization of our on-going investments in biodefense-related research,

²⁴ H.Rept. 109-476, to accompany H.R. 5441, appropriations for the Department of Homeland Security for FY2007, p. 112, May 22, 2006.

²⁵ H.Rept. 110-181, p. 92; and S.Rept. 110-84, pp. 88-89.

²⁶ For more information, see sections on Office of Health Affairs Issues for Congress in CRS Report R42644, *Department of Homeland Security: FY2013 Appropriations*, coordinated by William L. Painter.

²⁷ White House, *National Strategy for Biosurveillance*, July 2012, p. 5, http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Biosurveillance_July_2012.pdf.

²⁸ P. L. Estacio, Senior Medical Advisor and BioSecurity Program Executive, Department of Homeland Security, *Bio-Watch Overview*, September 27, 2004.

development, planning, and preparedness.²⁹ HSPD-10 assigned responsibility for these assessments to DHS. The DHS S&T Directorate has conducted a bioterrorism risk assessment (BTRA) every two years, starting in 2006. While some experts have critiqued the risk methodology used in the BTRA and questioned its use as a planning mechanism,³⁰ many would agree that it provides a mechanism for assessment and reprioritization of federal capabilities in response to changing adversary capabilities.

In 2012, GAO found that the BioWatch program generally incorporated BTRA information and aligned its detection capabilities against the biological agents of significant concern (as identified in the BTRA). In addition, DHS has stated that the expanded number of biological threat agents to be detectable by future generations of BioWatch systems will be informed by the BTRA's risk rankings.³¹ Policymakers may be interested in the extent to which the DHS bioterrorism risk assessment has determined the technical requirements of the Gen-3 system and the capabilities of the Gen-3 system to evolve and respond to the potential changing threat.

Population Coverage

The DHS deployed the BioWatch Gen-2 systems in urban environments with high population density. Each BioWatch system provides detection capability for some fraction of the population. Deployment of BioWatch systems might be viewed as a tradeoff between the detection coverage and the costs of such deployment. More detectors provide greater population coverage but with increasing cost. However, as population density decreases (often with increasing distance from the center of a city), each additional system provides a smaller increase in coverage for the same increase in cost. The DHS goal for BioWatch Gen-2 population coverage within a BioWatch jurisdiction was 80%,³² but apparently only 65% coverage exists.³³ Assuming that DHS places existing detectors in each jurisdiction's most population-dense areas, it would be more costly to cover an additional 15% of the jurisdiction's target population (in less dense areas) than it was to provide any 15% increment of existing coverage.

The DHS set a population coverage goal for the BioWatch Gen-3 system of 90% of the population within a BioWatch jurisdiction, an increase relative to the existing BioWatch Gen-2 system. The GAO reported that the BioWatch Gen-3 system deployment would increase the number of BioWatch jurisdictions, the number of systems per jurisdiction, the total U.S. population covered, and the population coverage in BioWatch jurisdictions.³⁴ It is unknown whether BioWatch Gen-3 will have a gap between the population coverage goal and the actual coverage similar to the BioWatch Gen-2 gap, especially since DHS has not identified a final technology for the system.

²⁹ The White House, *Biodefense for the 21st Century*, Homeland Security Presidential Directive (HSPD) 10, April 28, 2004.

³⁰ National Research Council, Committee on Methodological Improvements to the Department of Homeland Security's Biological Agent Risk Analysis, *Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change*, National Academies Press, Washington, DC, 2008.

³¹ Government Accountability Office, *Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use*, GAO-12-272, January 2012, pp. 26-27.

³² Office of Inspector General, Environmental Protection Agency, *EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program*, 2005-P-00012, March 23, 2005, p. 4.

³³ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 21.

³⁴ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 22.

The population coverage in each BioWatch jurisdiction likely depends upon the number of detectors deployed and the modeling and assumptions used regarding the transport of biological agents from their point of release to the detector. As a consequence, coverage areas and populations affected likely depend on the type of pathogen released. For example, estimates of detection coverage are likely larger for a pathogen that can travel further in viable form (e.g., a spore-former such as *Bacillus anthracis*) than for a pathogen that cannot. Similarly, detector performance and pathogen transport behavior likely affect the minimum quantity of a released pathogen that can be detected. As a consequence, performance of the BioWatch system likely varies depending on the type of biological agent and expectations regarding how the adversary will use the agent.

The GAO and others have identified challenges in the use of plume modeling in urban environments, although federal agencies have attempted to consolidate and coordinate such modeling efforts.³⁵ Such plume modeling is key to predicting the likelihood that a biological release will be detected and to determine the extent of exposure and the prophylaxis distribution plan. Accurate models allow for estimates of detectable release amounts, the number of detectors needed for coverage of a given area, and subsequent response to a detection event.

Policymakers may be interested in identifying the range of threats that DHS expects the BioWatch Gen-2 and Gen-3 systems to detect. For example, policymakers may view a system able to detect only large aerosol releases as having a different value than one also able to detect small-scale attacks.

Definition of a False Positive

A system designed to detect just one type of threat can be characterized by two numbers:

- the true positive rate, or probability of detection, which is defined as the probability that the system will detect a threat when one is present; and
- the false positive rate, or false alarm rate, which is defined as the probability that the system will indicate a threat when *no* threat is present.

Each of these characteristics can also be described by its complement:

- the false negative rate, which is defined as the probability that the system will *not* detect a threat when one is present (this is 100% minus the true positive rate); and
- the true negative rate, which is defined as the probability that the system will *not* indicate a threat when no threat is present (this is 100% minus the false positive rate).

Table 2 illustrates these definitions.

³⁵ For an overview of challenges identified by GAO and interagency groups, see Government Accountability Office, *Homeland Security: First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas Is Significantly Limited*, GAO-08-180, June 2008.

Table 2. Terms Used to Describe Detector Performance for a Single Threat

Actual	Alarm	No Alarm
Threat	True Positive	False Negative
No Threat	False Positive	True Negative

Source: CRS

The use of the term *false positive* is potentially confusing when discussing the BioWatch program, as it has referred specifically to the act of detection rather than the context for the detection. The BioWatch program is intended to detect biological terrorism, but some of the pathogens under detection also naturally exist in the environment. According to the DHS, the events identified by the National Research Council and the *Los Angeles Times* as false positives were actually correct identifications of the biological agent, but these pathogens either arose from natural circumstances or are similar, naturally occurring, non-pathogenic versions of the biological agents. The National Research Council report acknowledges this difference, and identifies a new term, a “BioWatch Actionable Result (BAR) false positive,” to address false positives in the BioWatch context:

Indeed, the laboratory assays have never indicated the presence of a biological agent when it was not present, although several BARs have been declared that have been attributed to the detection of ambient DNA that was naturally present in the local environment. From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been “BAR false positives,” meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.³⁶

When one considers the number of BAR false positives relative to the number of potential detection events (samples analyzed), the false positive rate is quite low, estimated at approximately 1 in 189,000 events.³⁷ Such a false positive rate meets or exceeds requirements for other homeland security detection systems.³⁸ Some policymakers might view such a false positive rate as acceptable given the limits of comparable technology. Other policymakers might view any number of BAR false positives as unacceptable, since the desired response to a BioWatch Actionable Result is to begin early treatment of potentially exposed individuals. Such early treatment may involve activation of federal assets such as the Strategic National Stockpile; notification of the public regarding necessary treatments; and the initiation of law-enforcement activities. In contrast to the response to alarms from other detectors used for homeland security, these activities come with both a financial and social cost that some policymakers may view as too expensive for a false alarm.

³⁶ National Research Council, 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: Abbreviated Version*, National Academies Press, Washington, DC, 2011, pp. 50-51.

³⁷ CRS analysis based on data reported in Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer for DHS, “The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack,” *The Blog@Homeland Security*, July 12, 2012, <http://blog.dhs.gov/2012/07/truth-about-biowatch-importance-of.html>.

³⁸ For example, the testing and evaluation protocol for certain radiation detection systems requires a false alarm rate of less than 1 in 1,000. National Institute of Standards and Technology, *Testing and Evaluation Protocol for Spectroscopy-Based Portal Monitors Used for Homeland Security*, T&E Protocol N42.38, Version 1.02, 2010.

External Reviews

External groups have studied the BioWatch system and provided advice to DHS. These include the National Research Council of the National Academies (NRC),³⁹ GAO,⁴⁰ Sandia National Laboratories, and the Homeland Security Studies and Analysis Institute.⁴¹

In 2009, the NRC provided DHS with the findings of its study, although the final report was not published until 2011.⁴² The NRC found it difficult to determine the effectiveness of the BioWatch Gen-2 system due to insufficient testing by DHS. It also found that performance of the system could be improved through better DHS collaboration with local public health jurisdictions. Additionally, the NRC found that DHS would need to overcome significant scientific and technical hurdles to successfully develop Gen-3 detectors.

In September 2012, GAO published its report to Congress on BioWatch Gen-3 development. The GAO found deficiencies in the DHS Gen-3 acquisition process. It found some key documents used to support acquisition decisions, such as the Mission Need Statement⁴³ and the Analysis of Alternatives, appeared to have been written to fit predetermined findings rather than using objective analysis.⁴⁴ The GAO recommended that DHS reevaluate its biosurveillance needs and then complete an objective analysis of several possible solutions to address the identified capabilities gap. The DHS did not comment in the GAO report whether it planned to complete a new Mission Needs Statement.⁴⁵ However, the DHS expects the new Analysis of Alternatives to be completed in fall 2013. Some of the alternatives that DHS could consider include other technical approaches, varying the number of planned detectors and population coverage, continued use of Gen-2 systems as currently deployed or modified, or ending the BioWatch program. However, the DHS has not stated what options it has included in its analysis.

The DHS commissioned at least two studies that are not publicly available. According to GAO, Sandia National Laboratories evaluated the requirements set by DHS regarding the level of Gen-3 pathogen sensitivity. This study led DHS to relax its technical requirements regarding the Gen-3 pathogen sensitivity.⁴⁶ The Homeland Security Studies and Analysis Institute was to evaluate whether the Gen-3 technology is mature enough to proceed to acquisition or whether it needs additional development work,

³⁹ National Research Council, Committee on Effectiveness of National Biosurveillance Systems: Bio Watch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011.

⁴⁰ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012.

⁴¹ The Homeland Security Studies and Analysis Institute and Sandia National Laboratories studies are not publicly available.

⁴² National Research Council, Committee on Effectiveness of National Biosurveillance Systems: Bio Watch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version*, National Academies Press, Washington, DC, 2011, p.1.

⁴³ A Mission Need Statement is a high-level document whose primary purpose is to clearly define and articulate an identified capability need/gap. It describes the mission need in sufficient detail for reviewers to understand the need for the specific capabilities required to perform a mission. It is intended to provide the basis on which the reviewers can decide whether to initially authorize an acquisition program or project.

⁴⁴ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p.18.

⁴⁵ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 41.

⁴⁶ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 28.

as the NRC had found previously.⁴⁷ The extent to which DHS has incorporated the findings of these reports into its acquisition decision making process is difficult to assess because these reports are not publicly available.

Intersection with Public Health

The success of the BioWatch program relies heavily on its use by state and local public health officials, who have the primary authority and responsibility for public health decisions in their jurisdiction. The confidence of these officials in the performance of existing BioWatch Gen-2 and the potential autonomous Gen-3 systems relies on multiple factors, including the robustness of concepts of operation; the extent of trust and experience between federal, state, and local stakeholders; and the rigor of the detection technology underlying the BioWatch systems.

Concepts of Operation and Local Jurisdiction Participation

In the current BioWatch Gen-2 configuration, local jurisdictions, which are the principal responders to a BAR, play a key role in the program. (See **Figure 1**.) They collect and analyze BioWatch samples and determine whether a result is positive. Local officials need to have sufficient confidence in the BioWatch system to make difficult and potentially economically costly decisions following a positive BioWatch result. However, media coverage over the past year has raised questions regarding local jurisdictions' confidence in the current BioWatch Gen-2 system.⁴⁸

If a positive BioWatch result signaled an actual or potential mass exposure to a bioterrorism agent, public officials would have to consider a number of potentially high-regret decisions. Those responsible for public safety may weigh decisions to close major transportation hubs or cordon off large numbers of dwellings or businesses. It falls to public health officials to determine if mass medical treatment of potentially exposed populations should be carried out, and if they so determine, to carry out this task under substantial time pressure.

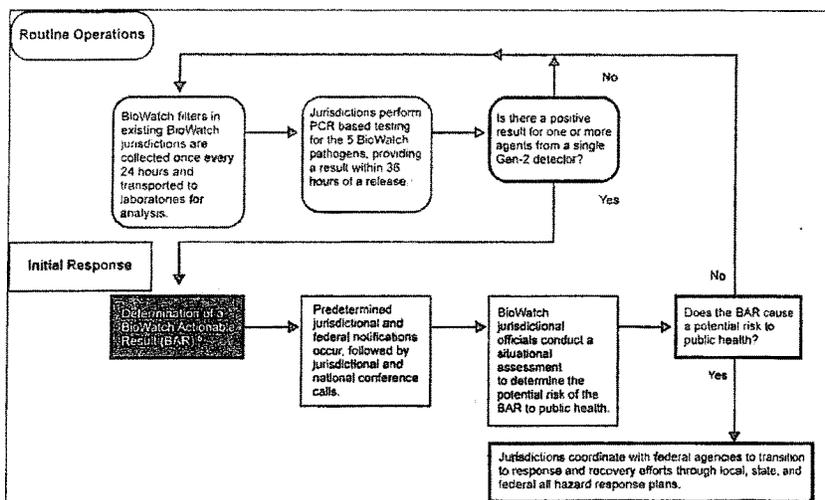
The Laboratory Response Network for Bioterrorism (LRN), coordinated by CDC, also supports testing for bioterrorism agents. Certain member laboratories (most of them governmental) test both environmental samples (e.g., white powders) and clinical samples (e.g., blood). LRN tests are non-commercial and are generally developed and delivered by CDC to network participants.⁴⁹ CDC provides ongoing technical support to LRN member laboratories conducting bioterrorism testing. Many of them are state and local public health laboratories. BioWatch Gen-2 testing is an LRN activity.

⁴⁷ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 23.

⁴⁸ For example, see David Willman, "The Biodefender That Cries Wolf," *Los Angeles Times*, July 8, 2012.

⁴⁹ Department of Health and Human Services, Centers for Disease Control and Prevention, "Facts About the Laboratory Response Network," <http://emergency.cdc.gov/lrn/factsheet.asp>.

Figure 1. Role of Jurisdictions in BioWatch (Gen-2)



Source: CRS modified from Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 11.

- a. Polymerase chain reaction (PCR) is a technique to copy DNA for laboratory testing.
- b. The BioWatch program defines a BAR as one or more PCR-verified positive results from a single BioWatch detector.

As noted, in the current BioWatch Gen-2 configuration, local public health officials are generally involved in sample analysis. They are, therefore, the first to know if a sample is positive and are actively involved in determining whether such a finding signals an actionable incident. Under an autonomous analysis system such as BioWatch Gen-3, local officials would no longer be responsible for sample analysis; such a change could affect their confidence in BioWatch results. OHA officials told GAO that they “want the jurisdictions to have enough confidence in the system that they are willing to take action based on positive results from a Gen-3 system without confirmatory laboratory testing.”⁵⁰

Some of the confidence local jurisdictions have in Gen-2 likely arises from their familiarity through extensive use of the system. To help instill local confidence in the Gen-3 system DHS told GAO

they provide guidance to jurisdictions and are in the process of developing a quality assurance process to track system performance. Furthermore, these officials anticipate running Gen-2 and Gen-3 concurrently for up to 6 months in BioWatch jurisdictions, and requiring all candidate technologies to

⁵⁰ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

archive positive samples so that the jurisdictions can run confirmatory laboratory analysis on the samples.⁵¹

One of the key possible benefits of Gen-3 technology over Gen-2 technology is the decrease in time between the biological release and the signaling of a positive result. However, local officials who lack sufficient trust in the results from the autonomous detectors may delay the politically difficult and potentially economically costly decisions until the results are confirmed by a methodology in which they have greater confidence. Such a course of action could significantly reduce the benefits from acquiring Gen-3 technology. Given the importance of local jurisdiction confidence in the new technology, it is unclear whether the confidence building efforts DHS has outlined will prove sufficient.

*Assay Performance*⁵²

The decision to conduct mass medical treatment in a potentially exposed population involves administering drugs, vaccines, and/or treatments. These are medical (i.e., clinical) decisions. In order to assure reliable performance of medical tests, the federal government regulates clinical laboratory testing in two ways. The Food and Drug Administration (FDA) requires demonstration of a test's efficacy in routine use in order for the test to be licensed for use. In addition, the Centers for Medicare and Medicaid Services (CMS), pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), certifies laboratories that conduct clinical testing as being able to do so reliably.⁵³

BioWatch assays are not required to conform to these federal standards, and it is not clear that they could conform. A key element in quality assurance, both for test method performance and laboratory performance, is assessment of an assay against a "gold standard," a rigorous test with known performance characteristics. Gold standard tests are often too costly, cumbersome, or slow for routine or screening uses. Instead they are used to assess the reliability of rapid screening tests, for example, and to confirm their findings. In clinical microbiology, testing often involves assays of microbial chemicals or genetic material (DNA or RNA) to determine the presence of the organism. The gold standard is subsequent growth of the organism ("culture confirmation"), confirming the accuracy of the positive chemical or DNA screening test. In the context of BioWatch microbial testing, confirmatory culture is often not possible; pathogens may dry out and become non-viable in the sensors. Also, the time required for culture confirmation would come at the expense of the early warning capability that is the key purpose of BioWatch.

If the BioWatch assays met an alternate set of meaningful benchmarks, public health decision-makers' trust in the assays could potentially increase, even without the benefits of FDA approval, CLIA oversight, and confirmatory testing. The DHS S&T Directorate is interested in developing consensus standards for microbial field tests that are intended to be actionable by public safety officials (i.e., guiding decisions to evacuate, close, or cordon) and actionable by public health officials (i.e., guiding decisions regarding mass prophylaxis or quarantine).⁵⁴ Such standards would include general elements, such as a concept of

⁵¹ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

⁵² An assay is an analysis used to determine the presence (and sometimes also the amount) of a chemical or substance of interest in a sample. An assay includes both physical components, such as treated filters and liquid reagents, and the procedures used in performing the assay.

⁵³ P.L. 100-578. See Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Clinical Laboratory Improvement Amendments," <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>.

⁵⁴ Department of Homeland Security, Science and Technology Directorate, *Framework for a BioThreat Field Response Mission Capability*, April 5, 2011, p. 7.

operations, and specific elements, such as characteristics (e.g., DNA sequences) that definitively identify each biothreat agent of interest.

Acquisition of Next-Generation Systems

The DHS has attempted to acquire next-generation BioWatch systems since 2009. This acquisition has had multiple challenges, including questions regarding the benefits and costs of the system. While DHS has received appropriations to acquire a next-generation system, DHS has not yet acquired such a system. Instead, most funds have been invested in testing and evaluating prototype systems that did not meet system requirements. In this context, policymakers have questioned the evolution of technical analyses and requirements and the viability of the current acquisition process.

BioWatch Gen-3 Costs and Benefits

The DHS acquisition process, as defined in DHS acquisition management directive 102-01, is a multistep process with specific associated acquisition decision events.⁵⁵ DHS acquisition policy requires development of certain analysis and documentation for programs with lifecycle costs above specified thresholds. Within these requirements are assessments of alternative approaches and estimates of the costs and benefits of the proposed acquisition. Even in cases where costs or benefits cannot be quantified, “breakeven” or threshold analysis might be performed. As described by the White House Office of Information and Regulatory Affairs:

When quantification and monetization are not possible, many agencies have found it both useful and informative to engage in threshold or “breakeven” analysis. This approach answers the question, “How large would the value of the non-quantified benefits have to be for the rule to yield positive net benefits?”⁵⁶

The GAO has reported that DHS did not fully assess the costs and benefits of the BioWatch Gen-3 program. The DHS performed a limited cost analysis and did not analyze or identify specific benefits beyond those accruing from early detection. The GAO identified that these analyses were limited because within DHS “consensus already existed that autonomous detection was the optimal solution.”⁵⁷ A key question for policymakers is whether the costs of the Gen-3 acquisition, or even the BioWatch program as a whole, are worth the benefits received.

Costs

The BioWatch Gen-3 acquisition has had challenges regarding the program’s overall costs and maintaining target cost goals. The GAO has reported that key DHS goals for the BioWatch Gen-3 program included “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.”⁵⁸ The detection

⁵⁵ Department of Homeland Security, *Acquisition Management Directive*, 102-01, undated, http://www.dhs.gov/xlibrary/assets/foia/mgmt_directive_102-01_acquisition_management_directive.pdf.

⁵⁶ Office of Information and Regulatory Affairs, The White House, *Regulatory Impact Analysis: A Primer*, undated, http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf. See also U.S. Office of Management and Budget, *Circular A-4*, September 17, 2003.

⁵⁷ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 20.

⁵⁸ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before* (continued...)

system tested by the BioWatch Gen-3 program does not reduce the operating cost per detector. Consequently, replacing BioWatch Gen-2 systems with an equivalent number of BioWatch Gen-3 systems would itself lead to a more expensive BioWatch program.

In addition, GAO reports that DHS plans to increase both the number of BioWatch jurisdictions and the number of detectors per jurisdiction. Thus, the envisioned BioWatch Gen-3 program would deploy a greater number of detectors than currently deployed under Gen-2. The GAO asserts this deployment would have a Gen-3 annual operating cost approximately four times greater than the current BioWatch Gen-2 program.⁵⁹

Further, the estimated lifecycle costs of the BioWatch Gen-3 program increased between 2009 and 2011 from \$2.1 billion to \$5.8 billion.⁶⁰ According to the GAO, prior cost estimates “did not account for risk and uncertainty, and it was not based on the work breakdown structure for Gen-3 and as such, DHS did not have assurance that it captured all relevant costs.”⁶¹ In contrast to the estimate from 2009, the 2011 estimate captures relevant costs, includes the full expected lifecycle of the Gen-3 system, and is adjusted for risk and uncertainty.⁶² The \$5.8 billion estimate in 2011 has an 80% confidence level, meaning there is an 80% likelihood that the lifecycle cost will not exceed \$5.8 billion.⁶³ For comparison purposes, DHS provides an estimate at the 28% confidence level that the lifecycle cost will not exceed \$3.8 billion.

Benefits

The GAO found that DHS planning documents for BioWatch Gen-3, specifically the Analysis of Alternatives, failed to “identify any benefits of investment beyond the assumption—inherent in its focus on increasing the number of detection cycles per day—that earlier detection has the potential to save lives and limit economic loss, a basic and accepted principle for all enhanced surveillance efforts.”⁶⁴ The GAO identified at least four metrics that DHS could include in estimates of the benefits of acquiring, deploying, and operating the BioWatch Gen-3 system:

- risk reduction per additional BioWatch jurisdiction;
- risk reduction per fraction of U.S. population covered;
- risk reduction per fraction of BioWatch jurisdiction population covered; and
- risk reduction per hour of detection time.

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Proceeding with BioWatch Generation-3 Acquisition, GAO-12-810, September 2012, p. 16.

⁵⁹ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 22.

⁶⁰ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

⁶¹ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 30.

⁶² Note the 2011 cost estimate considers costs through FY2028, while the 2009 cost estimate considers costs through FY2020 (Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 31).

⁶³ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

⁶⁴ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

The DHS might take other approaches to estimating benefits, such as determining the results from various attack scenarios, determining the beneficial impacts arising from the presence of the BioWatch system, and attempting to convert these benefits into monetary terms. The U.S. Coast Guard took such an approach, for example, when determining the benefits from mandating implementation of electronic Transportation Worker Identification Credential (TWIC) readers.⁶⁵

Another potential factor for policymaker consideration is the increasing age of the BioWatch Gen-2 systems. The DHS deployed BioWatch systems beginning in 2003, and these systems may be reaching or surpassing their expected life-span. In general, as systems approach their design life-span, operation and maintenance costs increase. Often, replacement of these systems becomes more cost-effective, over the long term, than continued maintenance of aging systems. A potential benefit from deploying a BioWatch Gen-3 system would be the avoided cost of recapitalizing BioWatch Gen-2 systems. The DHS has not publicized the contents of the program AoA to be completed in 2003, its range of costs and benefits considered, and the alternatives analyzed.

Requests for Proposals

The DHS effort to acquire a BioWatch Gen-3 system that meets the technical requirements established by OHA has relied on a series of DHS requests for information and proposals from vendors that have systems that might meet the Gen-3 technical requirements. Few vendors have participated, and Congress has expressed concern regarding the range of competition present in BioWatch Gen-3 acquisition.⁶⁶ In addition, DHS has delayed acquisition and deployment of BioWatch Gen-3 systems as the program has evolved.

Initially, DHS identified a two-phase approach to acquiring a BioWatch Gen-3 system. First, DHS would engage in independent testing of multiple bio-detectors. Then, following that testing, DHS would issue a single acquisition contract for the successful Gen-3 technology. The DHS began the first phase (Independent Testing of Bio-detectors) of the BioWatch Gen-3 acquisition in 2009.⁶⁷ Five vendors responded to the DHS request for proposals (RFP), and DHS provided contracts to two of them. Following the testing and evaluation of these candidate systems, neither system met all key performance parameters required for the Gen-3 acquisition. Only one system, the Next-Generation Automated Detection System (NG-ADS), completed the first round of testing and remains a potential candidate technology.

In February 2011, DHS issued a new request for information (RFI) regarding vendors with systems able to provide BioWatch Gen-3 capabilities.⁶⁸ According to then-DHS Assistant Secretary for Health Affairs and Chief Medical Officer Alexander Garza, replies from the RFI indicated that two vendors might have systems capable of responding to a request for proposals.⁶⁹

⁶⁵ 78 *Federal Register* 17782-17833 (March 22, 2013), at 17821-17824. See also U.S. Coast Guard, *Transportation Worker Identification Credential (TWIC) - Reader Requirements Notice of Proposed Rulemaking Preliminary Regulatory Analysis and Initial Regulatory Flexibility Analysis*, USCG-2007-28915, February 2013.

⁶⁶ House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications, "Ensuring Effective Preparedness Responses and Recovery for Events Impacting Health Security," *Serial No. 112-12*, March 17, 2011, p. 19.

⁶⁷ Department of Homeland Security, *BioWatch Gen-3 Industry Day*, March 6, 2009.

⁶⁸ Department of Homeland Security, *DHS BioWatchGen3 - Phase II*, PHASEIRFI-2172011, February 17, 2011.

⁶⁹ House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications, "Ensuring Effective Preparedness Responses and Recovery for Events Impacting Health Security," *Serial No. 112-12*, March 17, (continued...)

In August 2011, DHS issued a draft RFP for the second phase (System Production, Deployment, Operations, Supply Support, and Maintenance) of the Gen-3 acquisition. Under the draft RFP, DHS would issue a single contract for a technology that met the operation requirements for the Gen-3 system. At that time, DHS expected to issue a final Request for Proposals (RFP) in October 2011 and award acquisition contracts in May 2012.⁷⁰ The DHS testified that it considered this acquisition “low risk because of the technology maturity required to be accepted.”⁷¹

In September 2012, DHS revised its acquisition strategy to include a two-step competitive process rather than issuing a single contract. Under this two-step process, candidate technologies would undergo a round of performance testing, similar to that engaged in during 2010-2011 as part of the first acquisition phase. Following this testing, DHS would issue an acquisition contract. In January 2013, DHS issued a new draft RFP as part of the two-step competitive process. The DHS expects to release a final RFP and contract in the third quarter of FY2013.⁷² According to GAO, DHS would begin deployment of Gen-3 systems in 2016.⁷³

Some policymakers may question the appropriateness of the Gen-3 requirements given the extent of industry participation in the RFP process and the lack of successful candidate systems. Few industry participants may indicate too stringent requirements that outstrip current capabilities. Some policymakers may question the repeated delays in the Gen-3 acquisition timeline and the impacts of these changes in acquisition strategy.

Technical Requirements

The technical requirements for the Gen-3 detectors, known as Key Performance Parameters (KPPs), have changed over time. These KPPs are the threshold requirements, or the minimum standard DHS determined that candidate technologies had to meet to achieve the program goal. In the 2008 Operational Requirements Document, the minimum requirements for BioWatch Gen-3 included the detection of 6 different agents at 10 particles per cubic meter and a false positive rate of 1 in 100 million.⁷⁴ According to the GAO, in 2009 the Gen-3 KPPs included the detection of fewer agents (5), at the higher concentration, (60 particles per cubic meter) and higher false positive rate (1 in 10 million). According to GAO, OHA is making additional changes to the Gen-3 KPPs following the failure of the candidate system to meet some KPPs during testing in 2010 and 2011.⁷⁵ According to GAO, the candidate system did not meet the pathogen sensitivity requirement and required more frequent maintenance than planned.⁷⁶

(...continued)

2011, p. 19.

⁷⁰ Department of Homeland Security, *BioWatch Gen-3 Phase II Industry Day*, September 12, 2011.

⁷¹ House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response, and Communications, “Ensuring Effective Preparedness Responses and Recovery for Events Impacting Health Security,” *Serial No. 112-12*, March 17, 2011, p. 19.

⁷² Department of Homeland Security, *BioWatch Gen-3 Phase II, Stage 1 Presolicitation and Draft Request for Proposal*, HSHQDC-13-R-00026, February 8, 2013.

⁷³ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 26.

⁷⁴ Office of Health Affairs, *BioWatch Gen-3 Detection System Operational Requirements Document*, January 24, 2008.

⁷⁵ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p.48.

⁷⁶ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 48.

To date, DHS has based its acquisition decisions on analyses using technical requirements more stringent than the current ones. It is not clear how the more easily achievable standards will affect the DHS analysis. A sufficient reduction in the Gen-3 system's detection capability could reduce the benefits of the system enough that other alternative solutions become acceptable to DHS. Similarly, increased system operating costs caused by more frequent maintenance could shift cost considerations to favor other alternatives. The DHS has not stated whether the ongoing Analysis of Alternatives due in fall 2013 relies on new or preexisting requirements.

The GAO raised issues with regard to DHS testing for some of the KPPs. The GAO stated that legal restrictions prevented DHS from testing one of the BioWatch agents (GAO did not identify the particular agent in its publicly available report). Another KPP that would be difficult to test prior to acquisition decisions is the probability of false positives. To test that a detector would not signal the presence of an agent when none was present less than once per 10 million tests would require 33.5 years.⁷⁷ Policymakers may question the utility of such untestable requirements and the implications of basing acquisition decisions on them.

Coordination of R&D and Acquisition

Initially, DHS received appropriations for the BioWatch program in the S&T Directorate, which operated BioWatch systems and attempted to develop the next-generation successor to it. Following the creation of OHA, Congress provided appropriations to both the S&T Directorate, for R&D of biological detectors, and OHA, for operation of the BioWatch program and acquisition of Gen-3.

The S&T Directorate did not present BioWatch operations funding separately in its budget request. According to the DHS Office of Legislative Affairs, the S&T Directorate spent approximately \$160 million between FY2004 and FY2008 to develop potential BioWatch Gen-3 systems.⁷⁸ One technology developed by the S&T Directorate, called the Bioagent Autonomous Network Detector (BAND), competed to be a BioWatch Gen-3 candidate technology but did not meet the required performance measures.⁷⁹

The GAO estimates that OHA spent \$104 million on BioWatch Gen-3 acquisition from FY 2007 to FY2011, approximately 27% of its total BioWatch funding for that time period.⁸⁰ In addition to operating and maintaining BioWatch Gen-2 systems, the OHA also deployed an interim BioWatch solution, the Autonomous Pathogen Detection System (APDS), sometimes referred to as BioWatch Gen-2.5. The DHS halted the APDS pilot deployment when the APDS began malfunctioning in the field.⁸¹ The remaining BioWatch Gen-3 candidate technology under consideration is the Next-Generation Automated Detection System (NG-ADS), a system based upon the Autonomous Pathogen Detection System (APDS).

Policymakers may identify this situation as a problem in coordination and sharing expertise and technical knowledge between the S&T Directorate and OHA. Some policymakers may question the investments

⁷⁷ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 48.

⁷⁸ Personal communication between CRS and DHS Office of Legislative Affairs, August 13, 2012.

⁷⁹ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 46.

⁸⁰ Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, p. 38.

⁸¹ Spencer S. Hsu, "U.S. Halts Pilot Program in New York to Detect Biological Attacks," *Washington Post*, May 7, 2009.

made by the S&T Directorate regarding Gen-3 BioWatch. While the S&T Directorate attempted to develop a BioWatch replacement system, its investments did not lead to a successor system. In this light, policymakers may assess this as an R&D failure, with the S&T Directorate failing to incorporate operational requirements into its R&D activities. Similarly, policymakers may question the investments made by OHA. While the OHA has spent at least \$104 million on Gen-3 acquisition,⁸² no system has met the technical requirements established by OHA. Some policymakers might perceive this as an overly optimistic assessment by OHA of the maturity and capabilities of existing technology.

If you have further questions, please feel free to contact any of the authors directly.

⁸² Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810, September 2012, Highlights page.

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The biodefender that cries wolf

The Department of Homeland Security's BioWatch air samplers, meant to detect a terrorist biological attack, have been plagued by false alarms and other failures.

By David Willman, Los Angeles Times

July 8, 2012

DENVER — As Chris Lindley drove to work that morning in August 2008, a call set his heart pounding.

The Democratic National Convention was being held in Denver, and Barack Obama was to accept his party's presidential nomination before a crowd of 80,000 people that night.

The phone call was from one of Lindley's colleagues at Colorado's emergency preparedness agency. The deadly bacterium that causes tularemia — long feared as a possible biological weapon — had been detected at the convention site.

Should they order an evacuation, the state officials wondered? Send inspectors in moon suits? Distribute antibiotics? Delay or move Obama's speech?

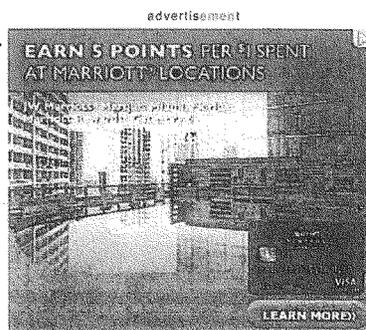
Another question loomed: Could they trust the source of the alert, a billion-dollar government system for detecting biological attacks known as BioWatch?

Six tense hours later, Lindley and his colleagues had reached a verdict: false alarm.

BioWatch had failed — again.

President George W. Bush announced the system's deployment in his 2003 State of the Union address, saying it would "protect our people and our homeland." Since then, BioWatch air samplers have been installed inconspicuously at street level and atop buildings in cities across the country — ready, in theory, to detect pathogens that cause anthrax, tularemia, smallpox, plague and other deadly diseases.

But the system has not lived up to its billing. It has repeatedly cried wolf, producing dozens of false alarms in Los Angeles, Detroit, St. Louis, Phoenix, San Diego, the San Francisco Bay Area and elsewhere, a Los Angeles Times investigation found.



Worse, BioWatch cannot be counted on to detect a real attack, according to confidential government test results and computer modeling.

The false alarms have threatened to disrupt not only the 2008 Democratic convention, but also the 2004 and 2008 Super Bowls and the 2006 National League baseball playoffs. In 2005, a false alarm in Washington prompted officials to consider closing the National Mall.

Federal agencies documented 56 BioWatch false alarms — most of them never disclosed to the public — through 2008. More followed.

The ultimate verdict on BioWatch is that state and local health officials have shown no confidence in it. Not once have they ordered evacuations or distributed emergency medicines in response to a positive reading.

Federal officials have not established the cause of the false alarms, but scientists familiar with BioWatch say they appear to stem from its inability to distinguish between dangerous pathogens and closely related but nonlethal germs.

BioWatch has yet to face an actual biological attack. Field tests and computer modeling, however, suggest it would have difficulty detecting one.

In an attack by terrorists or a rogue state, disease organisms could well be widely dispersed, at concentrations too low to trigger BioWatch but high enough to infect thousands of people, according to scientists with knowledge of the test data who spoke on condition of anonymity.

Even in a massive release, air currents would scatter the germs in unpredictable ways. Huge numbers of air samplers would have to be deployed to reliably detect an attack in a given area, the scientists said.

Many who have worked with BioWatch — from the Army general who oversaw its initial deployment to state and local health officials who have seen its repeated failures up close — call it ill-conceived or unworkable.

"I can't find anyone in my peer group who believes in BioWatch," said Dr. Ned Calonge, chief medical officer for the Colorado Department of Public Health and Environment from 2002 to 2010.

"The only times it goes off, it's wrong. I just think it's a colossal waste of money. It's a stupid program."

Officials at the Centers for Disease Control and Prevention, the federal agency that would be chiefly responsible for rushing medications to the site of an attack, told White House aides at a meeting Nov. 21 that they would not do so unless a BioWatch warning was confirmed by follow-up sampling and analysis, several attendees said in interviews.

Those extra steps would undercut BioWatch's rationale: to enable swift treatment of those exposed.

Federal officials also have shelved long-standing plans to expand the system to the nation's airports for fear that false alarms could trigger evacuations of terminals, grounding of flights and needless

panic.

BioWatch was developed by U.S. national laboratories and government contractors and is overseen by the Department of Homeland Security. Department officials insist that the system's many alerts were not false alarms. Each time, BioWatch accurately detected some organism in the environment, even if it was not the result of an attack and posed no threat to the public, officials said.

At the same time, department officials have assured Congress that newer technology will make BioWatch more reliable and cheaper to operate.

The current samplers are vacuum-powered collection devices, about the size of an office printer, that pull air through filters that trap any airborne materials. In more than 30 cities each day, technicians collect the filters and deliver them to state or local health labs for genetic analysis. Lab personnel look for DNA matches with at least half a dozen targeted pathogens.

The new, larger units would be automated labs in a box. Samples could be analyzed far more quickly and with no need for manual collection.

Buying and operating the new technology, known as Generation 3, would cost about \$3.1 billion over the next five years, on top of the roughly \$1 billion that BioWatch already has cost taxpayers. The Obama administration is weighing whether to award a multiyear contract.

Generation 3 "is imperative to saving thousands of lives," Dr. Alexander Garza, Homeland Security's chief medical officer, told a House subcommittee on March 29.

But field and lab tests of automated units have raised doubts about their effectiveness. A prototype installed in the New York subway system in 2007 and 2008 produced multiple false readings, according to interviews with scientists. Field tests last year in Chicago found that a second prototype could not operate independently for more than a week at a time.

Most worrisome, testing at the Pacific Northwest National Laboratory in Washington state and at the Army's Dugway Proving Ground in Utah found that Generation 3 units could detect a biological agent only if exposed to extremely high concentrations: hundreds of thousands of organisms per cubic meter of air over a six-hour period.

Most of the pathogens targeted by BioWatch, scientists said, can cause sickness or death at much lower levels.

A confidential Homeland Security analysis prepared in January said these "failures were so significant" that the department had proposed that Northrop Grumman Corp., the leading competitor for the Generation 3 contract, make "major engineering modifications."

A spokesman for the department, Peter Boogaard, defended the performance of BioWatch. Responding to written questions, he said the department "takes all precautions necessary to minimize the occurrence of both false positive and false negative results."

"Rigorous testing and evaluation" will guide the department's decisions about whether to buy the Generation 3 technology, he said.

Representatives of Northrop Grumman said in interviews that some test results had prompted efforts to improve the automated units' sensitivity and overall performance.

"We had an issue that affected the consistency of the performance of the system," said Dave Tilles, the company's project director. "We resolved it. We fixed it.... We feel like we're ready for the next phase of the program."

In congressional testimony, officials responsible for BioWatch in both the Bush and Obama administrations have made only fleeting references to the system's documented failures.

"BioWatch, as you know, has been an enormous success story," Jay M. Cohen, a Homeland Security undersecretary, told a House subcommittee in 2007.

In June 2009, Homeland Security's then-chief medical officer, Dr. Jon Krohmer, told a House panel: "Without these detectors, the nation has no ability to detect biological attacks until individuals start to show clinical symptoms." Without BioWatch, "needless deaths" could result, he said.

Garza, the current chief medical officer, was asked during his March 29 testimony whether Generation 3 was on track. "My professional opinion is, it's right where it needs to be," he said.

After hearing such assurances, bipartisan majorities of Congress have unfailingly supported additional spending for BioWatch.

Olympic prototype

The problems inherent in what would become BioWatch appeared early.

In February 2002, scientists and technicians from Lawrence Livermore National Laboratory deployed a prototype in and around Salt Lake City in preparation for the Winter Olympics. The scientists were aware that false alarms could "cause immense disruptions and panic" and were determined to prevent them, they later wrote in the lab's quarterly magazine.

Sixteen air samplers were positioned at Olympic venues, as well as in downtown Salt Lake City and at the airport. About 5:30 p.m. on Feb. 12, a sample from the airport's C concourse tested positive for anthrax.

Utah Gov. Mike Leavitt was at an Olympic figure skating competition when the state's public safety director, Bob Flowers, called with the news.

"He told me that they had a positive lead on anthrax at the airport," Leavitt recalled. "I asked if they'd retested it. He said they had — not just once, but four times. And each time it tested positive."

The Olympics marked the first major international gathering since the Sept. 11, 2001, airliner hijackings and the deadly anthrax mailings that fall.

"It didn't take a lot of imagination to say, 'This could be the real thing,'" Leavitt said.

But sealing off the airport would disrupt the Olympics. And "the federal government would have stopped transportation all over the country," as it had after Sept. 11, Leavitt said.

Leavitt ordered hazardous-materials crews to stand by at the airport, though without lights and sirens or conspicuous protective gear.

"He was ready to close the airport and call the National Guard," recalled Richard Meyer, then a federal scientist assisting with the detection technology at the Olympics.

After consulting Meyer and other officials, Leavitt decided to wait until a final round of testing was completed. By 9 p.m., when the results were negative, the governor decided not to order any further response.

"It was a false positive," Leavitt said. "But it was a live-fire exercise, I'll tell you that."

Pressing ahead

The implication — that BioWatch could deliver a highly disruptive false alarm — went unheeded.

After the Olympics, Meyer and others who had worked with the air samplers attended meetings at the Pentagon, where Deputy Defense Secretary Paul D. Wolfowitz was building a case for rapidly deploying the technology nationwide.

On Jan. 28, 2003, Bush unveiled BioWatch in his State of the Union address, calling it "the nation's first early-warning network of sensors to detect biological attack."

The next month, a group of science and technology advisors to the Defense Department, including Sidney Drell, the noted Stanford University physicist, expressed surprise that "no formal study has been undertaken" of the Salt Lake City incident. The cause of that false alarm has never been identified.

"It is not realistic to undertake a nationwide, blanket deployment of biosensors," the advisory panel, named the JASON group, concluded.

The warning was ignored in the rush to deploy BioWatch. Administration officials also disbanded a separate working group of prominent scientists with expertise in the pathogens.

That group, established by the Pentagon, had been working to determine how often certain germs appear in nature, members of the panel said in interviews. The answer would be key to avoiding false alarms. The idea was to establish a baseline to distinguish between the natural presence of disease organisms and an attack.

The failure to conduct that work has hobbled the system ever since, particularly in regard to tularemia, which has been involved in nearly all of BioWatch's false alarms.

The bacterium that causes tularemia, or rabbit fever, got its formal name, *Francisella tularensis*, after being found in squirrels in the early 20th century in Central California's Tulare County. About 200 naturally occurring infections in humans are reported every year in the U.S. The disease can be deadly but is readily curable when treated promptly with antibiotics.

Before BioWatch, scientists knew that the tularemia bacterium existed in soil and water. What the

scientists who designed BioWatch did not know — because the fieldwork wasn't done — that nature is rife with close cousins to it.

The false alarms for tularemia appear to have been triggered by those nonlethal cousins, according to scientists with knowledge of the system.

That BioWatch is sensitive enough to register repeated false alarms but not sensitive enough to reliably detect an attack may seem contradictory. But the two tasks involve different challenges.

Any detection system is likely to encounter naturally occurring organisms like the tularemia bacterium and its cousins. Those encounters have the potential to trigger alerts unless the system can distinguish between benign organisms and harmful ones.

Detecting an attack requires a system that is not only discriminating but also highly sensitive — to guarantee that it won't miss traces of deadly germs that might have been dispersed over a large area.

BioWatch is neither discriminating enough for the one task nor sensitive enough for the other.

The system's inherent flaws and the missing scientific work did not slow its deployment. After Bush's speech, the White House assigned Army Maj. Gen. Stephen Reeves, whose office was responsible for developing defenses against chemical and biological attacks, to get BioWatch up and running.

Over the previous year, Reeves had overseen placement of units similar to the BioWatch samplers throughout the Washington area, including the Pentagon, where several false alarms for anthrax and plague later occurred.

Based on that work and computer modeling of the technology's capabilities, Reeves did not see how BioWatch could reliably detect attacks smaller than, for example, a mass-volume spraying from a crop duster.

Nevertheless, the priority was to carry out Bush's directive, swiftly.

"In the senior-level discussions, the issue of efficacy really wasn't on the table," recalled Reeves, who has since retired from the Army. "It was get it done, tell the president we did good, tell the nation that they're protected.... I thought at the time this was good PR, to calm the nation down. But an effective system? Not a chance."

Why no illness?

It wasn't long before there was a false alarm. Over a three-day period in October 2003, three BioWatch units detected the tularemia bacterium in Houston.

Public health officials were puzzled: The region's hospitals were not reporting anyone sick with the disease.

Dr. Mary desVignes-Kendrick, the city's health director, wanted to question hospital officials in detail to make sure early symptoms of tularemia were not being missed or masked by a flu outbreak. But to desVignes-Kendrick's dismay, Homeland Security officials told her not to tell the doctors and nurses what she was looking for.

"We were hampered by how much we could share on this quote-unquote secret initiative," she said.

After a week, it was clear that the BioWatch alarm was false.

In early 2004, on the eve of the Super Bowl in Houston, BioWatch once again signaled tularemia, desVignes-Kendrick said. The sample was from a location two blocks from Reliant Stadium, where the game was to be played Feb. 1.

DesVignes-Kendrick was skeptical but she and other officials again checked with hospitals before dismissing the warning as another false alarm. The football game was played without interruption.

Nonetheless, three weeks later, Charles E. McQueary, then Homeland Security's undersecretary for science and technology, told a House subcommittee that BioWatch was performing flawlessly.

"I am very pleased with the manner in which BioWatch has worked," he said. "We've had well over half a million samples that have been taken by those sensors. We have yet to have our first false alarm."

Asked in an interview about that statement, McQueary said his denial of any false alarm was based on his belief that the tularemia bacterium had been detected in Houston, albeit not from an attack.

"You can't tell the machine, I only want you to detect the one that comes from a terrorist," he said.

Whether the Houston alarms involved actual tularemia has never been determined, but researchers later reported the presence of benign relatives of the pathogen in the metropolitan area.

Fear in the capital

In late September 2005, nearly two years after the first cluster of false alarms in Houston, analysis of filters from BioWatch units on and near the National Mall in Washington indicated the presence of tularemia. Tens of thousands of people had visited the Mall that weekend for a book festival and a protest against the Iraq War. Anyone who had been infected would need antibiotics promptly.

For days, officials from the White House and Homeland Security and other federal agencies privately discussed whether to assume the signal was another false alarm and do nothing, or quarantine the Mall and urge those who had been there to get checked for tularemia.

As they waited for further tests, federal officials decided not to alert local healthcare providers to be on the lookout for symptoms, for fear of creating a panic. Homeland Security officials now say findings from lab analysis of the filters did not meet BioWatch standards for declaring an alert.

Six days after the first results, however, CDC scientists broke ranks and began alerting hospitals and clinics. That was little help to visitors who already had left town, however.

"There were 100 people on one conference call — scientists from all over, public health officials — trying to sort out what it meant," recalled Dr. Gregg Pane, director of Washington's health department at the time.

Discussing the incident soon thereafter, Jeffrey Stiefel, then chief BioWatch administrator for Homeland Security, said agency officials were keenly aware that false alarms could damage the system's credibility.

"If I tell a city that they've got a biological event, and it's not a biological event, you no longer trust that system, and the system is useless," Stiefel said on videotape at a biodefense seminar at the National Institutes of Health on Oct. 6, 2005. "It has to have a high reliability."

Ultimately, no one turned up sick with tularemia.

Culture of silence

Homeland Security officials have said little publicly about the false positives. And, citing national security and the classification of information, they have insisted that their local counterparts remain mum as well.

Dr. Jonathan Fielding, Los Angeles County's public health director, whose department has presided over several BioWatch false positives, referred questions to Homeland Security officials.

Dr. Takashi Wada, health officer for Pasadena from 2003 to 2010, was guarded in discussing the BioWatch false positive that occurred on his watch. Wada confirmed that the detection was made, in February 2007, but would not say where in the 23-square-mile city.

"We've been told not to discuss it," he said in an interview.

Dr. Karen Relucio, medical director for the San Mateo County Health Department, acknowledged there was a false positive there in 2008, but declined to elaborate. "I'm not sure it's OK for me to talk about that," said Relucio, who referred further questions to officials in Washington.

In Arizona, officials kept quiet when BioWatch air samplers detected the anthrax pathogen at Super Bowl XLII in February 2008.

Nothing had turned up when technicians checked the enclosed University of Phoenix Stadium before kickoff. But airborne material collected during the first half of the game tested positive for anthrax, said Lt. Col. Jack W. Beasley Jr., chief of the Arizona National Guard's weapons of mass destruction unit.

The Guard rushed some of the genetic material to the state's central BioWatch lab in Phoenix for further testing. Federal and state officials convened a 2 a.m. conference call, only to be told that it was another false alarm.

Although it never made the news, the incident "caused quite a stir," Beasley said.

The director of the state lab, Victor Waddell, said he had been instructed by Homeland Security officials not to discuss the test results. "That's considered national security," he said.

The dreaded call

In the months before the 2008 Democratic National Convention, local, state and federal officials

planned for a worst-case event in Denver, including a biological attack.

Shortly before 9 a.m. on Aug. 28, the convention's final day, that frightening scenario seemed to have come true. That's when Chris Lindley, of the Colorado health department, got the phone call from a colleague, saying BioWatch had detected the tularemia pathogen at the convention site.

Lindley, an epidemiologist who had led a team of Army preventive-medicine specialists in Iraq, had faced crises, but nothing like a bioterrorism attack. Within minutes, chief medical officer Ned Calonge arrived.

Calonge had little faith in BioWatch. A couple of years earlier, the health department had been turned upside down responding to what turned out to be a false alarm for *Brucella*, a bacterium that primarily affects cattle, on Denver's western outskirts.

"The idea behind BioWatch — that you could put out these ambient air filters and they would provide you with the information to save people exposed to a biological attack — it's a concept that you could only put together in theory," Calonge said in an interview. "It's a poorly conceived strategy for doing early detection that is inherently going to pick up false positives."

Lindley and his team arranged a conference call with scores of officials, including representatives from Homeland Security, the Environmental Protection Agency, the Department of Health and Human Services, the Secret Service and the White House.

None of the BioWatch samplers operated by the state had registered a positive, and no unusual cases of infection appeared to have been diagnosed at area hospitals, Lindley said.

The alert had come from a Secret Service-installed sampler on the grounds of the arena where the convention was taking place. The unit was next to an area filled with satellite trucks broadcasting live news reports on the Democratic gathering. Soon, thousands of conventioners would be walking from Pepsi Center to nearby Invesco Field to hear Obama's acceptance speech.

Had Lindley and Calonge been asked, they said in interviews, they wouldn't have put the BioWatch unit at this spot, where foot and vehicle traffic could stir up dust and contaminants that might set off a false alarm. As it turned out, a shade tree 12 yards from the sampler had attracted squirrels, potential carriers of tularemia.

The location near the media trailers posed another problem: how to conduct additional tests without setting off a panic.

EPA officials "said on the phone, 'We have a team standing by, ready to go,'" Lindley recalled. But the technicians would have to wear elaborate protective gear.

The sight of emergency responders in moon suits "would have derailed the convention," Calonge said.

On the other hand, sending personnel in street clothes would risk exposing them to the pathogen.

"This was the biggest decision we ever had to make," Lindley said.

When the conference call resumed, Lindley said the state would collect its own samples, without

using conspicuous safety gear. "No one was willing to say, 'That's the right response, Colorado,'" Lindley recalled. "Everybody was frozen. We were on our own."

State workers discreetly gathered samples of soil, water and other items for immediate DNA analysis. No pathogen was found.

At 3 p.m., Lindley told participants in another national conference call that his agency was satisfied there was no threat. "I said: 'We are doing no more sampling. We are closing up this issue,'" Lindley recalled.

Lindley and Calonge, having staked their reputations on not believing BioWatch, were vindicated: Barack Obama gave his acceptance speech on schedule. No one turned up sick with tularemia. And, to their surprise, news of the false alarm never became public.

'An opportunity'

Officials responsible for BioWatch insist that the false alarms, which they refer to as "BioWatch actionable results," or BARs, have been beneficial.

Each incident "has provided local, state and federal government personnel an opportunity to exercise its preparedness plans and coordination activities," three senior Homeland Security BioWatch administrators told a House subcommittee in a statement in July 2008. "These real-world events have been a catalyst for collaboration."

Biologist David M. Engelthaler, who led responses to several BioWatch false positives while serving as Arizona's bioterrorism coordinator, is one of the many public health officials who see it differently.

"A Homeland Security or national security pipe dream," he said, "became our nightmare."

david.willman@latimes.com

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BioWatch technology couldn't detect lethal germs, tests found

Scientists say the U.S. biological defense system relied on kits that were far less able to help detect lethal germs than officials thought.

By David Willman

8:44 AM PDT, October 22, 2012

Washington

WASHINGTON — For two years, the nationwide BioWatch system, intended to protect Americans against a biological attack, operated with defective components that left it unable to detect lethal germs, according to scientists with direct knowledge of the matter.

The federal official who oversaw installation of the components was quietly shifted to a position with no responsibility for BioWatch, and the entire episode was kept out of public view.



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The U.S. Department of Homeland Security, which oversees BioWatch, opened an internal investigation, whose status remains confidential.

FULL COVERAGE: BioWatch system plagued by false alarms

In more than 30 cities, BioWatch samplers located atop buildings, in train stations and in other public places suck air through dry filters around the clock. Once a day, the filters are taken to public health laboratories to be analyzed for traces of smallpox, anthrax, plague and other pathogens.

Lab technicians extract genetic material from the filters and then use kits, called assays, to release fluorescent dyes into it. When a laser is shined through the mixture, the dyes are supposed to light up if one of the pathogens targeted by BioWatch is present.

The labs originally used a series of separate assays, each designed to detect a specific germ. In 2007, Homeland Security equipped most of the labs with new kits intended to screen for multiple pathogens at the same time.

The aim was to reduce personnel costs and enable faster detection of a biological attack, and thus a speedier response.

But the new components, called "multiplex" assays, triggered false alarms, a recurring problem with BioWatch since the system was put into operation nationwide in 2003.

After scientists at many of the labs voiced concerns, Homeland Security officials, in consultation with microbiologists from other federal agencies, ordered testing of the new assays.

The tests, conducted in secrecy at the Pacific Northwest National Laboratory in Washington state and the federal Centers for Disease Control and Prevention in Atlanta, found that the kits were unsuitable for BioWatch, scientists familiar with the matter said. They spoke on condition of anonymity, citing the sensitivity of the information.

The multiplex assays could not distinguish between the bacterium that causes tularemia, a potentially deadly condition also known as rabbit fever, and similar but benign organisms called "near neighbors" that are abundant in outdoor environments.

The original assays had exhibited the same problem. But the multiplex assays had an additional shortcoming, scientists said: They were found to be far less sensitive to the presence of actual pathogens than Homeland Security officials had presumed.

In late 2009, Homeland Security officials removed the new assays and returned to using kits that searched for pathogens one at a time.

Peter Boogaard, a Homeland Security spokesman, declined to respond to written questions about the matter. Jeffrey Stiefel, the department official responsible for installing the ill-fated assays, said he was not authorized to comment.

Some of the scientists familiar with BioWatch said the multiplex assays were put into use without adequate testing to validate their effectiveness.

The assays were designed at the CDC and the Lawrence Livermore National Laboratory and were built to Homeland Security's specifications by a private company, the scientists said.

Richard F. Meyer, a microbiologist who helped develop the multiplex assays while at the CDC and later supervised their installation as a contractor for Homeland Security, defended the kits.

Meyer said the original assays "were past their life cycle and in constant need of repair." Data collected by Livermore scientists, he said, "supported the use of the [new] technology."

Meyer acknowledged that he lost his contracting role with Homeland Security because of dissatisfaction over how the multiplex assays performed once installed.

"When you don't agree with those in charge you get pushed aside," he said in an email.

A spokesman for Livermore, Steve Wampler, declined to discuss the lab's role in developing assays for BioWatch.

The failure of the multiplex assays is one in a slew of problems that have beset BioWatch since President George W. Bush unveiled the system during his State of the Union address in January 2003.

Bush said Bio Watch would "protect our people and our homeland" against a germ attack by terrorists. In subsequent years, presidential appointees in Homeland Security have repeatedly assured Congress that Bio Watch was functioning effectively.

The Los Angeles Times reported in July that BioWatch has been unable to distinguish between dangerous and benign organisms, and that as of 2008, federal agencies had documented 56 false alarms.

In one of those incidents, during the 2008 Democratic National Convention in Denver, BioWatch units signaled the presence of the tularemia bacterium, triggering tense deliberations among local, state and federal officials over what steps should be taken to protect the public.

After follow-up tests found no traces of the germ at the convention site, officials decided not to take emergency measures, and that evening Barack Obama accepted his party's nomination for president on an outdoor stage, as scheduled, before a crowd of more than 80,000 people.

Not once have public health officials had enough confidence in a BioWatch alarm to evacuate an area, dispense antibiotics or take any other emergency action.

After considering the potential disruption from false alarms, federal aviation officials shelved plans to install air-sampling units inside the nation's major airports.

In response to The Times' reporting, congressional Republicans and a senior Democrat have written to Homeland Security Secretary Janet Napolitano seeking documents and explanations. Although Napolitano has not commented publicly, the department's chief medical officer, Dr. Alexander Garza, has staunchly defended BioWatch.

In a statement, Garza said in July that the system had never generated a false alarm. "The detection of commonly occurring environmental agents," he wrote, "is not a 'false positive.'" Asked to elaborate while appearing before a congressional panel Sept. 13, Garza said each detection by BioWatch was "a true positive."

The notion that such events — which Homeland Security calls BioWatch Actionable Results, or BARs — are not false alarms was earlier considered and rejected by a committee of experts appointed by the National Academy of Sciences.

In its report in October 2010, the committee said that "all BARs to date have been 'BAR false positives,' meaning they have signaled the potential occurrence of a terrorist attack when none has occurred."

FULL COVERAGE: BioWatch system plagued by false alarms

The committee warned that "repeated false alarms may eventually create a sense of skepticism or complacency that could delay or hinder an appropriate response to a true bioterrorism event."

One of the committee members, Northern Arizona University geneticist Paul Keim, said in an interview that the detection of a benign organism could not be considered a "true positive."

"That's why we call them near neighbors," Keim said. "If they cause disease, we call them a pathogen."

Garza, in his recent congressional testimony, said that the existence of the near neighbors had come as a surprise to Homeland Security and that the department was now seeking "more specific assays."

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Troubled BioWatch program at a crossroads

After years of concern over false alarms and other problems with the bioterrorism detection system, a House panel wants Homeland Security to explain why an additional \$3.1 billion should be spent on it.

December 21, 2012 | By David Willman, Los Angeles Times

WASHINGTON — Year after year, health officials meeting at invitation-only government conferences leveled with one another about Biowatch, the nation's system for detecting deadly pathogens that might be unleashed into the air by terrorists.

They shared stories of repeated false alarms — mistaken warnings of germ attacks from Los Angeles to New York City. Some questioned whether Biowatch worked at all.

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They did not publicize their misgivings. Indeed, the sponsor of the conferences, the U.S. Homeland Security Department, insists that BioWatch's operations, in more than 30 cities, be kept mostly secret.

Now, congressional investigators want Homeland Security Secretary Janet Napolitano to open the books on the 9-year-old program and explain why \$3.1 billion in additional spending is warranted.

The move by the House Energy and Commerce Committee — spurred by reports in the Los Angeles Times about BioWatch's deficiencies — puts the program at a crossroads.

On one side is mounting evidence that the technology does not work. On the other are companies eager to tap federal contracts, politicians fearful of voting against any program created to fight terrorism, and a top Homeland Security official who says the program is functioning properly.

Government records show that BioWatch signaled attacks more than 100 times when none had occurred. Nor is the system sensitive enough to reliably detect low yet infectious concentrations of such pathogens

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as anthrax, smallpox or plague, according to specialists familiar with test results and computer modeling. Another defect is BioWatch's inability to distinguish between particular pathogens that are genetically similar, but benign.

Lab and field tests found similar problems in the latest technology intended for BioWatch, "Generation 3." The congressional investigators are seeking internal documents illuminating BioWatch's performance, plus the private comments of Napolitano's top science and technology advisor, Dr. Tara O'Toole, who recommended killing Generation 3.

O'Toole's skepticism is shared by Dr. Donald A. Henderson, a renowned epidemiologist who led the global eradication of smallpox. Henderson, a federal anti-terrorism advisor when BioWatch was launched in 2003, says he has yet to see a "scientific justification" for it.

"It has never stood the test of rationality," Henderson said. "This whole concept is just preposterous."

Political ties

But as Napolitano weighs whether to deploy Generation 3 — at the cost of \$3.1 billion over its first five years — the program will not be easy to scale back.

The company in line to install Generation 3, Northrop Grumman Corp., is a major donor to federal campaigns with a broad presence in Washington.

From 2004 to 2012, the company's political action committee gave more than \$6 million to congressional candidates, campaign finance records show. Northrop Grumman, a top defense contractor, ranked No. 10 this year among all PAC donors to congressional campaigns.

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Northrop Grumman also hired the former head of BioWatch, Dr. Jeffrey W. Runge, as an advisor to assist its pursuit of the Generation 3 contract.

On Sept. 27, Runge told invitees to the Harvard Faculty Club that a survey he designed for what he called "homeland security related professionals" had found support for deploying the new technology, regardless of potential shortcomings.

Rather than wait for more research to refine Generation 3, Runge told the gathering, "the respondents seem to be saying ... Deploy the detectors, even if they can't pick up every intentional pathogen or genetic variation, and deal with the problems later."

Runge, who provided his prepared remarks to The Times, said Northrop Grumman solicited his advice a few months after he left the government in 2008 and paid him an hourly rate. The consulting arrangement ended in summer 2009, he said.

Runge said the company paid him to explain how the Homeland Security Department "is thinking, how Congress is thinking, about the future of biodetection." Among those he briefed, Runge said, was Northrop Grumman's project manager for Generation 3.

In 2010 and 2011, Northrop Grumman donated a total of \$100,000 to the Heritage Foundation, a conservative research group, which, beginning in July, circulated three commentaries supporting federal funding for BioWatch and Generation 3. The donations were disclosed in the group's annual reports.

Steven P. Bucci, a Heritage Foundation senior fellow, wrote on July 11, "BioWatch is far from an unnecessary expenditure. Congress should thus continue to fund the program."

The third Heritage essay, issued Dec. 12 and also written by Bucci, said that although BioWatch was "only marginally effective," Napolitano and President Obama should stay the course. "Cutting funding to this project," he wrote, "leaves us vulnerable in a way that will cripple our future security." Bucci said his writings were his own.

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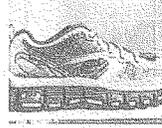
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latimes.com

BioWatch faces congressional hearing this week

A House panel will question officials under oath about the troubled system designed to detect airborne releases of anthrax or other biological weapons.

By David Willman, Los Angeles Times

6:53 PM PDT, June 16, 2013

WASHINGTON — A decade ago, then-Homeland Security Secretary Tom Ridge oversaw the start of BioWatch, the nationwide system designed to detect airborne releases of anthrax or other biological weapons.

In his 2003 State of the Union address, President George W. Bush had announced that BioWatch would "protect our people and our homeland."

Ridge's expectations were not so high.

"Everyone knew it was a primitive, labor-intensive, fairly unsophisticated attempt," Ridge recalled in a recent interview.



On Tuesday, a congressional panel is scheduled to question officials publicly about the program under oath. The House Energy and Commerce Committee began examining BioWatch last year in response to reports in the Los Angeles Times about the system's deficiencies.

In more than 30 U.S. cities, BioWatch units on rooftops and other outdoor locations suck air through dry filters, which are removed every 24 hours and tested at public health laboratories. BioWatch samplers have also been deployed at major spectator events, including the Super Bowl and national political conventions.

The system has been beset by false alarms — nearly 150 to date — some of which triggered tense deliberations over whether to order evacuations, distribute emergency medicines or shut down public venues. In each case, authorities decided to disregard BioWatch.

Confidential government tests and computer modeling have pointed out an even more serious failing: BioWatch could not be relied on to detect an actual germ attack, according to people familiar with its operations.

The federal government has spent more than \$1 billion on BioWatch, and the Obama administration has taken preliminary steps to spend billions more on an automated "Generation 3," in which air samples would be continuously analyzed by a "lab in a box" within each unit.

Deployment of Generation 3, however, has stalled. In March, members of the House and Senate appropriations committees — citing "serious concerns" about Generation 3 — said they were declining the Obama administration's request for nearly \$40 million for further testing and evaluation of the technology.

The committees reiterated their request that — before a final contract is awarded for the automated system — Homeland Security Secretary Janet Napolitano "certify ... that the science used to develop the technology is proven."

Napolitano's subordinates have repeatedly played down or denied flaws in the existing system.

Last year, the department's chief medical officer, Dr. Alexander Garza, a presidential appointee, asserted that BioWatch had never generated a "false positive."

Most of BioWatch's false alarms were triggered by organisms that are genetically similar to lethal pathogens but pose no threat to humans, according to people knowledgeable about the system.

Garza maintained these were not false positives because BioWatch found something in the environment, albeit not the deadly microbes it was intended to detect.

Experts appointed by the National Academy of Sciences have rejected this viewpoint — concluding in a 2010 report that all misidentifications of a pathogen by BioWatch were false positives that "signaled the potential occurrence of a terrorist attack when none has occurred."

The House investigative panel said in a statement last week that BioWatch "has been plagued by false alarms and other failures." According to information newly verified by federal officials, BioWatch has generated at least 149 false alarms.

Garza resigned his post this year to accept a private-sector job. Congressional investigators have questioned others at the Homeland Security Department and the U.S. Centers for Disease Control and Prevention, which administers the nation's stockpile of medicines to treat those exposed to a germ attack.

The investigators have sought to learn why Homeland Security Department officials did not do more to avert false detections of the bacterium tularemia after BioWatch's first false alarms for it in late 2003. Tularemia, also known as rabbit fever, can infect and in rare instances kill humans at relatively low concentrations.

In addition to pressing officials about BioWatch's troubles, investigators have traced how the system functions on a daily basis.

In the event of an intentional release of a pathogen, 36 hours or more could pass before lab testing of BioWatch filters alerted officials to the attack. By then, victims might be crowding emergency rooms, undermining the notion that BioWatch would allow authorities to quickly safeguard a stricken area or dispense medications in time to prevent sickness or death.

BioWatch was installed in 2003 amid widespread fear of biological terrorism — fear stoked, Ridge said, by the fall 2001 anthrax letter attacks, which killed five people.

The FBI ultimately traced those attacks not to a foreign terrorist but to a U.S. government scientist, Bruce E. Ivins, based at the Army's biowarfare research center at Ft. Detrick, Md. Ivins committed suicide in July 2008 after learning that prosecutors were preparing to file charges against him.

Given BioWatch's performance, Ridge said his former department should be wary of sinking more money into it. BioWatch, he said, evokes the Homeland Security Department's \$1-billion attempt — now abandoned — to use experimental technology as an invisible fence along the U.S.-Mexico border.

"What [Homeland Security] cannot afford to have if it's going to sustain any credibility with the public is the same kind of thing they did along the border," Ridge said.

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July 19, 2012

Dr. Thomas Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Frieden:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system. On July 8, 2012, the *Los Angeles Times* reported that the BioWatch air samplers have been plagued by false alarms and other failures. In particular, Federal agencies documented 56 BioWatch false alarms, and State and local health officials have expressed their lack of confidence in BioWatch. Further, according to this same article, officials at the Centers for Disease Control and Prevention told White House aides at a meeting on November 21, 2011, that they would not rush medications to the site of an attack detected by BioWatch unless a BioWatch warning was confirmed by follow-up sampling and analysis.

On July 12, 2012, Dr. Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS), posted a blog on the DHS website entitled "The Truth About Biowatch: The Importance of Early Detection of a Potential Biological Attack." In his posting, Dr. Garza wrote: "Recent media reports have incorrectly claimed that BioWatch is prone to 'false positives' or 'false alarms' that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result."

We note that Dr. Garza's representation that BioWatch has never had a false positive result is at odds not only with the incidents reported by the *Los Angeles Times* but also with the observation in an October 2010 report on the BioWatch program by the National Academy of Sciences. The NAS report stated:

Letter to Dr. Thomas Frieden
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From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been "BAR false positives," meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.

To assist the Committee in finding out how the BioWatch program is actually performing, and whether it is meeting public protection goals without unduly disrupting the public health system and local emergency responders, please provide the following by August 2, 2012:

1. All documents since January 1, 2011, relating to the CDC's views about the BioWatch program.
2. List of CDC attendees at the November 21, 2011, meeting with White House aides referenced in the *Los Angeles Times* article, and all documents relating to this meeting.
3. All documents containing data (including inconclusive data) showing whether the BioWatch program or any test used by the BioWatch program can accurately detect traces of dangerous pathogens.
4. CDC's view of the DHS claim that there has never been a false positive result, including the basis for concluding that the incidents reported in the *Los Angeles Times* and the BAR false positives referenced in the NAS report as not being false positives.
5. Information on any program improvements that have been made based on lessons learned from past BioWatch incidents.

An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Attachment

Letter to Dr. Thomas Frieden
Page 3

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Document 12



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 16, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Upton:

Thank you for your letter regarding the Department of Homeland Security's (DHS) BioWatch program.

Since the beginning of the BioWatch program, the Centers for Disease Control and Prevention (CDC) has provided assistance as requested by DHS. Specifically, CDC helped establish and staff BioWatch laboratories, develop and validate laboratory methods for detection of targeted biological threat agents, and coordinate the public health response to the possible detection of a biological threat agent. DHS BioWatch laboratories work closely with Laboratory Response Network (LRN) laboratories, which are coordinated by CDC with state and local public health authorities.

As discussed in separate documents being provided to the Committee on Energy and Commerce, the BioWatch program uses a strategy of serial testing and review to assure that a positive laboratory test alone does not trigger an unnecessary major public health response. After determination of a BioWatch Actionable Result (BAR), the jurisdictional authorities collect and review other information for evidence and discuss with federal BioWatch program officials to understand whether the BAR actually represents the detection of release of a biological threat agent or a related organism that may be naturally occurring in the environment or other possible cause. Although the BioWatch program has generated BARs that have been reviewed under this process, none of these has been determined to require a major public health response to date.

In the view of CDC, it is important that BioWatch maintain a robust strategy of testing and review to assure BARs do not lead directly to a conclusion that a threat exists or a high-consequence action is indicated without appropriate confirmation of the existence of a biological threat agent for which the response would be appropriate. CDC and DHS have worked to improve the tests and interpretation of tests results to reduce the number of BARs that do not reflect a true public health threat, and CDC is working with DHS on additional changes that should further improve laboratory testing and related analysis.

Thank you for the opportunity to provide information on the BioWatch program and CDC's work with DHS. Responses to the specific questions posed in your letter are enclosed.

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I appreciate your interest in this important program, and look forward to continuing to work with you to improve public health. If you have any questions or require additional information, please have your staff contact Shana Beavin in the CDC Washington Office at (202) 245-0600 or SBeavin@cdc.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Thomas R. Frieden".

Thomas R. Frieden, M.D., M.P.H.
Director, CDC

Enclosure

Summary of Responses to Information Requests on BioWatch

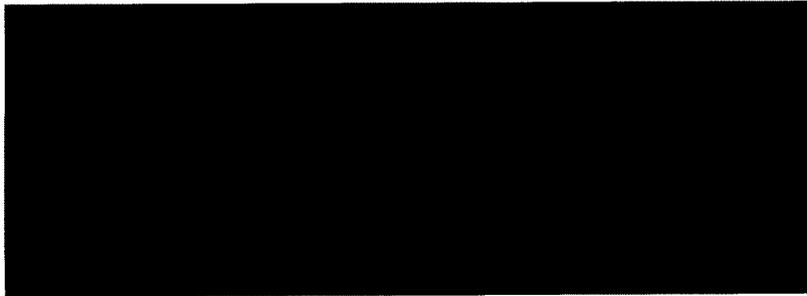
1. All documents since January 1, 2011, relating to the CDC's views about the BioWatch program.

CDC has not identified any documents relating to the Agency's views on the BioWatch program.

2. List of CDC attendees at the November 21, 2011, meeting with White House aides referenced in the *Los Angeles Times* article, and all documents relating to this meeting.

To clarify, the meeting referenced in the *Los Angeles Times* article took place on November 22, 2011. CDC is providing a list of the CDC attendees at the November 22, 2011, meeting.

3. All documents containing data (including inconclusive data) showing whether the BioWatch program or any test used by the BioWatch program can accurately detect traces of dangerous pathogens.



Because these documents contain sensitive information, we will work with your staff to ensure your access in an appropriate manner, while seeking limits on further disclosure.

Upon review, the Committee will notice the documents provided in response to this request are designated sensitive but unclassified (SBU). The justification for the SBU designation is as follows:

These documents contain sensitive information about specific devices, techniques, and targets of the LRN assays and should be handled accordingly. CDC requests these documents be safeguarded in a manner that protects them from disclosure, in order to prevent compromise of LRN effectiveness. Review of this material should be limited to those persons whose official duties require it.

4. CDC's view of DHS claim that there has never been a false positive result, including the basis for concluding that the incidents reported in the *Los Angeles Times* and the BAR false positives referenced in the NAS report as not being false positives.

It is important to clarify what is meant by false positive. At a basic level, a true positive test result is a result that indicates a condition is present when it is in fact present. A fire alarm that goes off in a building when there is a fire in the building is an example of a true positive. A false positive test result is a result that indicates a condition is present when it is NOT in fact present. A fire alarm that goes off in a building when there is NO fire is an example of a false positive. However, a fire alarm might go off due to the presence of smoke or steam, in the absence of a fire, generating what could be considered a false positive, but is both useful and possible to verify before taking further action.

When a test is performed to detect a dangerous but remediable condition, the goal is to detect as many instances of the condition as possible. Testers do not want to miss a remediable situation, e.g., a fire alarm failing to sound despite the presence of a fire. A second (or third) test or other review is used to verify the results. This strategy of serial testing and review is used in order to optimize the detection of true positives and minimize the positives that do not warrant high-consequence actions.

The BioWatch program uses a serial testing and review strategy to focus on detecting true positives and minimize the number of positives that might indicate a naturally occurring organism that does not merit a high-consequence action. The BioWatch testing strategy entails at least two separate laboratory tests and multiple reviews:

- The first laboratory test—the BioWatch screening test—is the most sensitive test and regularly produces preliminary positive results to be subjected to further testing.
- The second test—the BioWatch verification test which utilizes assays from the Laboratory Response Network—is more specific as it consists of a suite of assays against multiple segments of DNA. Samples that produce preliminary positive results in the first test undergo this second test, which yields far fewer positive results. Several strategies are used here to determine whether the positive result of the DNA probe is consistent with highly pathogenic organisms or other very similarly related, yet not as pathogenic subspecies of the same organism.
- The BioWatch laboratory director then reviews the results of a positive BioWatch verification test and, as deemed necessary, consults with CDC laboratory scientists and scientists from the BioWatch Program as part of the review. The review is performed to determine whether there is the possibility of a technical or procedural error producing the positive BioWatch verification test. If no technical or procedural error is found, the BioWatch laboratory director then determines that the positive BioWatch verification test constitutes what the BioWatch program calls a BioWatch Actionable Result or BAR. This means that higher level review outside of the laboratory is required.
- After determination of a BAR, the jurisdictional authorities collect and review other information for evidence to understand whether the BAR represents the detection of an organism that is naturally occurring in the environment, release of a biological threat agent, or other possible causes. This additional investigation may entail the review of laboratory, epidemiological, law enforcement, or intelligence information, and it may entail the collection of additional samples for laboratory analysis. The BioWatch program expects the jurisdictional authorities to review and discuss their findings on a national conference call

with federal BioWatch Program officials, and officials from DHS and other federal agencies that support the BioWatch Program before taking any high-consequence action.

Since its inception in 2003, the BioWatch program has experienced a number of BARs which have been attributed to environmental agents. These infrequent results are expected in testing for any rare condition. Although initial positive BARs do occur, it is important to note that BioWatch has implemented an overall response strategy to ensure that a single piece of data, such as a BAR, does not lead directly to a high-consequence action.

When DHS states that the BioWatch program has not produced false positive results, CDC's understanding is that they are looking at the overall outcome of the entire testing and review strategy (Steps 1-4 outlined above) rather than just the occurrence of a BAR in isolation from other pertinent information. And that a positive PCR test is indicating the detection of some substance of a targeted microorganism that may also occur naturally in the environment, but not be the act of bioterrorism.

Investigations of BARs have led to modifications of BioWatch testing that have substantially reduced the rate of occurrence of BARs in BioWatch testing over time. In 2012 to date, BioWatch has experienced only five BARs. Further improvements are underway in BioWatch assays that should further enable the BioWatch Program to distinguish between non-disease and disease causing strains of organisms that are naturally occurring in the environment.

5. Information on any program improvements that have been made based on lessons learned from past BioWatch incidents.

- Improvements to laboratory components of the BioWatch program were made as a result of consultations between CDC and DHS: In December 2009, BioWatch adopted a procedural change for *Y. pestis* in order to reduce the possibility of positive BAR for *Y. pestis*
- In March 2010, BioWatch implemented a comprehensive quality assurance program in order to provide standardized, on-going, external evaluation of laboratory performance. It focuses on six major areas of quality assurance: (1) document control; (2) data reporting; (3) procedures and equipment; (4) training, qualification and competency; (5) procurement; and (6) corrective action/root cause analysis.
- In August 2011, BioWatch reduced the real-time polymerase chain reaction cycle threshold (Ct) cut-off for both the BioWatch screening and LRN verification assays. The change was undertaken based on a systematic review of over 4,000 reactive screening results that required verification testing. Review of data after this change was implemented, comparing results from August 2010–July 2011 to those from August 2011–May 2012, revealed a 30 percent reduction in the number of reactive results observed for *F. tularensis*. This move to a lower Ct value is consistent with best practices from other biological environmental detection systems including the Department of Defense.
- The BioWatch program is preparing to field and CDC is developing more specific nucleic acid signatures for *F. tularensis*, *Y. pestis*, and *Variola* based on new knowledge about cross-reactivities of the current signatures with closely-related but not highly pathogenic organisms. Once the new signatures have been validated, they will be deployed into the

BioWatch program. This should further reduce the frequency of BARs, especially for *F. tularensis*.

- The BioWatch program recently began using an assay from the U.S. Department of Defense Critical Reagents Program for its initial screening test rather than LRN assays. This change eliminated duplication of signatures in the screening and verification assays and increased the specificity of the serial testing. This strategy was adopted in February 2012 and is now operational.

Over the course of the BioWatch program, CDC and DHS have collaborated to identify areas for enhancements to laboratory components of the BioWatch program. Together, both agencies work to implement necessary change. CDC will continue to work with DHS to make improvements as opportunities for advancement are identified.

Document 13

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3841

July 19, 2012

The Honorable Janet Napolitano
Secretary
Department of Homeland Security
Washington, D.C. 20528

Dear Secretary Napolitano:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system. On July 8, 2012, the *Los Angeles Times* reported that the BioWatch air samplers have been plagued by false alarms and other failures. In particular, Federal agencies documented 56 BioWatch false alarms, and State and local health officials have expressed their lack of confidence in BioWatch.

On July 12, 2012, Dr. Alexander Garza, Assistant Secretary for Health Affairs and Chief Medical Officer at the Department of Homeland Security (DHS), posted a blog on the DHS website entitled "The Truth About Biowatch: The Importance of Early Detection of a Potential Biological Attack." In his posting, Dr. Garza wrote: "Recent media reports have incorrectly claimed that BioWatch is prone to 'false positives' or 'false alarms' that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result."

We note that Dr. Garza's representation that BioWatch has never had a false positive result is at odds not only with the incidents reported by the *Los Angeles Times* but also with the observation in an October 2010 report on the BioWatch program by the National Academy of Sciences (NAS). The NAS report stated:

Letter to the Honorable Janet Napolitano
Page 2

From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been "BAR false positives," meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.

To assist the Committee in finding out how the BioWatch program is actually performing, and whether it is meeting public protection goals without unduly disrupting the public health system and local emergency responders, please provide the following by August 2, 2012:

1. All documents (including emails, meeting minutes, slides) since January 1, 2008, in the possession of Dr. Tara O'Toole, Dr. Alexander Garza, Dr. Michael Walter, Dr. Jeff Stiefel, and/or Dr. Segran Pollai relating to BioWatch or any generation of the BioWatch program.
2. All documents containing data (including inconclusive data) showing whether the BioWatch program or any test used by the BioWatch program can accurately detect traces of dangerous pathogens.
3. Evidence for the DHS claim that there has never been a false positive result, including the basis for concluding that the incidents reported in the *Los Angeles Times* and the BAR false positives referenced in the NAS report as not being false positives.
4. Information on any program improvements that have been made based on lessons learned from past BioWatch incidents.

An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Letter to the Honorable Janet Napolitano
Page 3

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 14

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (207) 225-2921
Minority (207) 225-3611

November 13, 2012

Dr. Thomas Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Frieden:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system.

On July 19, 2012, we wrote to you requesting information and documents to determine how the BioWatch program is performing and whether it is meeting public protection goals. We expressed particular interest in a news report indicating that officials at the Centers for Disease Control and Prevention (CDC) told White House aides at a meeting on November 21, 2011, that they would not rush medications to the site of an attack detected by BioWatch unless a BioWatch warning was confirmed by follow-up sampling and analysis. To date, CDC has provided insufficient responses to our July 19, 2012, inquiry. Moreover, in the intervening time additional details have come to light regarding program failures.

The Los Angeles Times reported on October 23, 2012, that the BioWatch system operated with defective components that left it unable to detect deadly pathogens for a two-year period, according to scientists with direct knowledge on the matter. The article raises further questions about the BioWatch program, in addition to the ones raised in our July 19, 2012, letter.

To assist the Committee in its examination of these additional issues, please provide the following by November 26, 2012:

1. All documents relating to the tests conducted by CDC that found multiplex assays unsuitable for BioWatch.
2. All documents dated since January 1, 2009, in the possession of Dr. Toby Merlin and/or Dr. Stephen Morse relating to BioWatch.

Letter to Dr. Thomas Frieden
Page 2

In addition to the above requested information, we seek your cooperation in responding to the July 19, 2012, request letter. The response from CDC to date has been inadequate, highlighting, at minimum, a lack of coordination and communication among agencies, and making clear that CDC or Department of Health and Human Services (HHS) is withholding responsive documents.

In the more than three months since our initial request, CDC has produced only two pages of test results. CDC staff advised Committee staff that documents have been submitted to the Department of Health and Human Services for clearance. However, HHS told Committee staff there are no documents from CDC in clearance, and that CDC advised them there are no responsive documents. CDC persisted in telling Committee staff that there are documents in clearance even after being advised that HHS denied that was the case. CDC has also claimed for weeks that a letter response is also in the clearance process at HHS.

On October 11, 2012, CDC provided a phone briefing for Committee staff with Dr. Toby Merlin. Dr. Merlin spent considerable time briefing Committee staff in cooperation with our efforts. In the course of that briefing, Dr. Merlin provided information demonstrating that CDC is in possession of responsive documents that have not been provided to the Committee. For example, Dr. Merlin acknowledged problems with the BioWatch assays cross-reacting with benign organisms in the environment, so-called near neighbors to the pathogen of concern, especially in the context of the Francisella tularensis test results. In response to a question from Committee staff, Dr. Merlin said he would call such a test result detecting a near neighbor a "false positive." This statement was responsive to request number 4 from the July 19, 2012, letter, one of several questions to which CDC has not provided an adequate written response. We urge CDC to resolve its internal difficulties with the Department and cooperate with the Committee's investigation as CDC has done on other occasions.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 15



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 25, 2013

The Honorable Fred Upton
Chairman, Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Upton:

Thank you for your letter and for the opportunity to provide further clarification and documents regarding the Department of Homeland Security's (DHS) BioWatch program and development of BioWatch multiplex assays.

As you are aware, the Centers for Disease Control and Prevention (CDC) provided assistance to the BioWatch program as requested by DHS. Specifically, CDC helped establish and staff BioWatch laboratories, develop and validate laboratory methods for detection of targeted biological threat agents, and coordinate the public health response to the possible detection of a biological threat agent. DHS BioWatch laboratories work closely with Laboratory Response Network (LRN) laboratories, which are coordinated by CDC with state and local public health authorities.

In your recent letter, you mention an October 22, 2012, *Los Angeles Times* article that raised concerns about the development and deployment of BioWatch multiplex assays. Unfortunately, that article gave an incorrect impression of CDC's involvement in a complex process. In 2006, CDC was asked by DHS to recommend an alternative laboratory technology for detection of bioterror agents. CDC recommended DHS consider use of multiplex assays, and provided technical expertise and detailed a scientist to work with DHS in the development of the multiplex assays technology for the BioWatch program. In 2007, after DHS and the Lawrence Livermore Laboratory (LLNL) completed work on development of these assays, DHS determined to move forward with initial deployment of the multiplex assays into the field. CDC did not, however, formally review or approve the performance of the assays before DHS began to deploy them in November 2007. In 2008, when performance data was shared with the CDC, CDC informed DHS of concerns about the assays that eventually led to their discontinuation by DHS. DHS subsequently established a BioWatch Technical Advisory Committee (BTAC) that included experts from several agencies, including CDC, to evaluate the multiplex assays. The BTAC ultimately determined that the previously deployed singleplex Real-Time PCR assays were more appropriate.

Per your letter's request, we are currently in the process of providing documents to the Committee, and we will continue to keep you and your staff updated on the status of this process.

Thank you again for your letter and for your interest in this important program. We look forward to continuing to work with you to improve public health. If you have any questions or require additional information, please have your staff contact Shana Beavin in the CDC Washington Office at (202) 245-0600 or SBeavin@cdc.gov.

Sincerely,

Thomas R. Frieden, M.D., M.P.H.
Director, CDC

Document 16

FRED LIPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (709) 225-2677
Minority (709) 225-2661

November 13, 2012

The Honorable Janet Napolitano
Secretary
Department of Homeland Security
Washington, D.C. 20528

Dear Secretary Napolitano:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system.

On July 19, 2012, we wrote to you requesting information and documents to determine how the BioWatch program is performing and whether it is meeting public protection goals without unduly disrupting the public health system and local emergency responders. Our initial inquiry came, in part, in response to news accounts of false alarms and other system failures. To date, the Department of Homeland Security (DHS or "Department") has provided insufficient responses to our July 19, 2012, inquiry. Moreover, in the intervening time additional details have come to light regarding program failures.

The Los Angeles Times reported on October 23, 2012, that the BioWatch system operated with defective components that left it unable to detect deadly pathogens for a two-year period, according to scientists with direct knowledge on the matter.

To assist the Committee in its examination of these additional issues, please provide the following by November 26, 2012:

1. Please confirm whether the BioWatch system operated with defective components. If so, please provide the date(s) DHS learned that the components were defective. If not, please provide the basis for DHS concluding that the components were not defective, and supporting documentation.

Letter to the Honorable Janet Napolitano
Page 2

2. A written explanation for why the Federal official who oversaw installation of the components was removed from his position of responsibility in the Biowatch program, and the date he was removed.
3. An explanation of the basis for the DHS decision to deploy the multiplex assays, and the supporting documentation and data for this basis, particularly test results validating their effectiveness prior to deployment.
4. An explanation for the DHS withdrawal of the multiplex assays, and the documentation and data supporting the basis for the withdrawal.
5. A list of the State and local partners of the BioWatch program, and the dates each of these partners were notified by DHS about the results of tests conducted at the Pacific Northwest National Laboratory and the Centers for Disease Control and Prevention that found that the multiplex assays were unsuitable for BioWatch.
6. A statement detailing the sensitivity of the multiplex assays for detecting actual pathogens, and supporting documentation and data for the statement.

In addition to the above requested information, we seek your cooperation in obtaining a response to the July 19, 2012, request letter. The response from DHS to date has been inadequate, raising serious questions about the Department's willingness to cooperate with efforts to ensure the success of the BioWatch program and transparency about its potential failures. Although DHS raised concerns with our inquiry and the Committee has attempted to accommodate, the Department continues to withhold key documents more than three months after our initial request.

When DHS expressed concern about the potential scope of the document request, Committee staff proposed initial production of a small batch of documents from five DHS officials named in the request letter. DHS agreed, but has so far produced documents from only three of the five DHS officials, along with a single document from a fourth.

DHS justified the non-production of documents from the remaining two officials, Undersecretary Tara O'Toole and Dr. Segrain Pillai, because the Science and Technology Directorate was involved with the future of the Biowatch program and not the past performance of Biowatch, which DHS considered to be the focus of the Committee's investigation. DHS instead permitted officials from the directorates of Health Affairs and Science and Technology (but not Dr. O'Toole or Dr. Pillai) to brief Committee staff last month.

After that briefing, DHS agreed to provide the documents from the remaining two officials as previously agreed to with Committee staff. More than a week later, and only in response to an inquiry from Committee staff, DHS staff notified the Committee that the Department would not provide the documents because of ongoing litigation between legislative and executive branches regarding congressional requests for internal, deliberative documents. This latest rationale for refusing to turn over the requested documents is inconsistent

Letter to the Honorable Janet Napolitano
Page 3

with DHS's previous document productions in this matter and is an insufficient reason for non-compliance with our requests.

We urge DHS to complete its agreement with Committee staff and provide the batch of documents from the remaining DHS officials, Dr. Tara O'Toole and Dr. Segran Pillai, by no later than November 26, 2012.

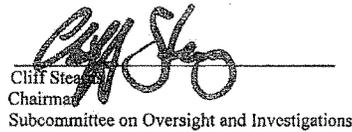
An attachment to this letter provides additional information about how to respond to the Committee's request.

If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 17

Office of Legislative Affairs
U.S. Department of Homeland Security
Washington, DC 20528



January 25, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Upton:

Thank you for your November 13, 2012 letter regarding the BioWatch program. I appreciate the opportunity to respond to your questions and provide a more comprehensive understanding of the BioWatch Program and its technology.

The Department of Homeland Security (DHS) is committed to utilizing the best technology available to allow the Nation to respond as quickly as possible to a biological threat and deliver life-saving medical countermeasures. BioWatch provides environmental biodetection, by utilizing a system of collectors whose filters are manually retrieved for subsequent analysis by laboratory technicians, and maintains an open dialogue with its federal, state, and local partners.

In 2006, as a part of the effort to increase the system's ability to accomplish its mission effectively and efficiently, DHS asked the Centers for Disease Control and Prevention (CDC) to recommend an alternative laboratory technology for detection of biothreat agents that would enable the BioWatch program to provide timely detection of these agents at reduced operating costs. CDC recommended that the BioWatch program evaluate use of multiplex assays¹, and in January 2007, CDC detailed a scientist to work with DHS on this technology.

Later in 2007, based on work conducted at DHS and the Lawrence Livermore National Laboratory (LLNL), DHS moved forward with initial deployment of the multiplex assays into the field, and DHS began a limited transition from single-plex assays. The timetable of this limited transition is given on the enclosed document.

In 2008, CDC raised concerns about potential limitations in the performance of the multiplex assay when performance data was shared with them, and DHS's Office of Health Affairs (OHA) requested that the Science and Technology Directorate (S&T) conduct an evaluation of the multiplex assays that were developed by LLNL and deployed in the BioWatch

¹ Multiplex assays can detect several different organisms in a single sample, and multiplex assays are generally more efficient, as they require less time and reagents.

The Honorable Fred Upton
Page 2

Program. S&T established a BioWatch Technical Advisory Committee (BTAC) that encompassed technical experts from half a dozen agencies and sub-agencies, with the goal of determining the robustness of the multiplex assays for use in the BioWatch program to meet the intended use and application. BTAC members evaluated reports and data generated by LLNL and the Pacific Northwest National Laboratory (PNNL) and determined that the previously deployed single-plex real-time polymerase chain reaction (PCR) assays were more appropriate.

As a result of these findings, the BTAC recommended to OHA on July 16, 2009 that BioWatch revert back to single-plex real-time PCR assays for sample analysis. BioWatch laboratories transitioned back to the single-plex real-time PCR assays by August 2009. State and local partners of the BioWatch program were informed of the PNNL study on January 19, 2010, in New York City. A list of state and local BioWatch jurisdictions is enclosed with this letter, as is a chart with the dates of the assay transition back to single-plex real-time PCR assays.

Your letter also references a media report that the BioWatch system operated with defective components for a two-year period. The BioWatch Generation 1/2 unit, also known as a portable sample unit (PSU), is an aerosol collector whose filters are manually retrieved for subsequent analysis in a laboratory. At no time did DHS determine that the PSUs were operating with defective components, nor did DHS receive any reports that the PSUs were malfunctioning due to defective components. While we do not know the reason for this assertion in the media report, it may be that the discussion of "defective components" was a reference to the concerns regarding the BioPlex assays.

With regard to the Department's production of documents responsive to your July 19, 2012 letter, we have produced approximately 3,000 pages of documents and are currently preparing more documents for you.

Thank you again for your letter. I hope this response addresses your concerns. DHS welcomes your interest in this important matter and looks forward to continuing to work with you. Should you have additional questions, please do not hesitate to contact me at (202) 447-5890

Respectfully,



Nelson Peacock
Assistant Secretary for Legislative Affairs

Enclosures

cc: The Honorable Cliff Stearns, c/o Clerk of the House
The Honorable Henry Waxman, Ranking Member, Committee on Energy and Commerce
The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight
and Investigation

Document 18

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
May 2011: 2021-725-2037
May 2011: 2021-725-3541

January 31, 2013

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20221

Dear Secretary Sebelius:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce continues its investigation of the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system. This letter hereby reauthorizes the request sent to the Centers for Disease Control and Prevention (CDC) on November 13, 2012.

It is our understanding that the CDC document production in response to the November 13, 2012, document request letter is still under review at the Department of Health and Human Services (HHS). There has been no production of any documents from HHS, although the Department of Homeland Security (DHS) has made substantial document production to the Committee in response to our BioWatch-related document request made on November 13, 2012. Prompt production of these documents from HHS is needed to help the Committee proceed with this inquiry with the benefit of the CDC's expertise and knowledge in this area.

We note that a December 22, 2012, article in the *Los Angeles Times* continued to raise concerns about BioWatch, especially the question of how best to protect public health. For example, the *Los Angeles Times* reported that Dr. Arthur L. Kellerman, a physician and public health researcher at Rand Corporation, who studied BioWatch as a member of a National Academy of Sciences committee, said it "has generated nothing but false alarms." Dr. Kellerman and other specialists, according to the *Los Angeles Times*, said the money spent on BioWatch could have paid for training and equipment to help medical professionals more quickly diagnose a patient exposed to an attack. These experts are concerned that the many false alarms invite complacency.

Letter to The Honorable Kathleen Sebelius
Page 2

Because of the CDC's role in BioWatch and the important public health protection issues raised, we urge you to expedite this document production so we can work with you and your Department more effectively on improving protection against the threat of bioterrorism.

To assist the Committee in its examination of the issues raised in the November 13, 2012, letter, please provide the following by February 14, 2013:

1. All documents relating to the tests conducted by the CDC that found multiplex assays unsuitable for BioWatch.
2. All documents dated since January 1, 2009, in the possession of Dr. Toby Merlin and/or Dr. Stephen Morse relating to BioWatch.

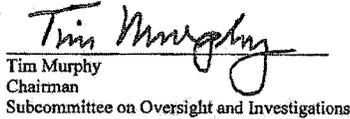
If the Department cannot provide complete document production by the requested deadline, we request that the Department provide evidence of cooperation with this request before February 14, 2013. Such evidence of cooperation must include a significant partial production, detailed information on how the production is being managed (number of FTEs handling, number of hours devoted to processing the request, number of pages being processed, internal emails substantiating the date CDC provided the documents to HHS), and a timetable of production.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,



Fred Upton
Chairman



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Thomas Frieden, M.D., Director, CDC

The Honorable Jim Esquea, Assistant Secretary for Legislation, HHS

The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment

Document 19

Slobodin, Alan

From: Mann, Melissa <melissa.mann@HQ.DHS.GOV>
Sent: Monday, June 10, 2013 4:22 PM
To: Slobodin, Alan; Meyer, Jonathan; Chieco, Gena
Cc: Anderson, Carl; Havens, Brittany; Cohen, Brian; Gopal, Kiren
Subject: RE: BioWatch production #13

Alan, since October 2003 there have been 149 BARS.

-----Original Message-----

From: Slobodin, Alan [<mailto:Alan.Slobodin@mail.house.gov>]
Sent: Monday, June 10, 2013 3:03 PM
To: Meyer, Jonathan; Chieco, Gena; Mann, Melissa
Cc: Anderson, Carl; Havens, Brittany; Cohen, Brian; Gopal, Kiren
Subject: FW: BioWatch production #13

This one may have been lost in the shuffle with folks out on vacation, etc., at the time of the request. Does DHS have an answer? Thanks.

-----Original Message-----

From: Slobodin, Alan
Sent: Tuesday, May 28, 2013 2:03 PM
To: 'Mann, Melissa'
Cc: Meyer, Jonathan; Chieco, Gena; Sessa, Eric; Gross-Davis, Leslie; Gopal, Kiren
Subject: RE: BioWatch production #13

How many BARS have occurred in the BioWatch program? Thanks.

-----Original Message-----

From: Mann, Melissa [<mailto:melissa.mann@HQ.DHS.GOV>]
Sent: Thursday, May 23, 2013 5:35 PM
To: Slobodin, Alan; Gopal, Kiren
Cc: Meyer, Jonathan; Chieco, Gena; Sessa, Eric; Gross-Davis, Leslie
Subject: BioWatch production #13

Alan, Kiren - Another production coming your way, est. delivery time noon tomorrow. If you have a conflict let us know.
Thanks,

Document 20

Slobodin, Alan

From: Mann, Melissa <melissa.mann@HQ.DHS.GOV>
Sent: Friday, June 14, 2013 11:13 AM
To: Gopal, Kiren
Cc: Cohen, Brian; Havens, Brittany; Anderson, Carl; Slobodin, Alan; Meyer, Jonathan; Chieco, Gena
Subject: jurisdictions and follow up
Attachments: BioWatch Jurisdictions.pdf

Kiren, per your request:

1. List of jurisdictions attached
2. Breakdown of BARS by year:
 - 2003: 8
 - 2004: 19
 - 2005: 4
 - 2006: 9
 - 2007: 31
 - 2008: 16
 - 2009: 20
 - 2010: 23
 - 2011: 14
 - 2012: 5

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Document 21

[REDACTED]

From: Chaitram, Jasmine (CDC/OID/NCEZID)
Sent: Tuesday, October 09, 2012 12:04 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: RE: Jasmine, Please remind me of the total number of BARS since BioWatch inception?

Categories: Red Category

We now have 149 BARS

Jasmine
LRN Program Office

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 09, 2012 10:18 AM
To: Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: Jasmine, Please remind me of the total number of BARS since BioWatch inception?

I'm apparently going to have to talk to a Congressional staffer on Thursday, and they anticipate this question.
Thanks,
Toby

Document 22

Slobodin, Alan

From: [REDACTED]
Sent: Wednesday, May 29, 2013 1:12 PM
To: Slobodin, Alan
Cc: [REDACTED] Gopal, Kiren; [REDACTED]
Subject: RE: BioWatch

Hi Alan-

Sorry for the delay in responding. Dr. Merlin was out of the office. He is available on June 18th for the hearing. Do you have any additional information on the hearing that you can share with us?

Here is the information you requested below.

Total BARS to date=149
Total for 2012 = 5
Total for 2013 to date = 0

Thanks,

[REDACTED]

From: [REDACTED]
Sent: Tuesday, May 28, 2013 4:08 PM
To: 'Slobodin, Alan'
Cc: [REDACTED] Gopal, Kiren; [REDACTED]
Subject: RE: BioWatch

Hi Alan

I will go back and check on the information requested. Dr. Merlin is out of the office today so we will check his calendar let you know about the 6/18 date.

Thanks,

[REDACTED]

From: Slobodin, Alan [<mailto:Alan.Slobodin@mail.house.gov>]
Sent: Tuesday, May 28, 2013 2:04 PM
To: [REDACTED]
Cc: [REDACTED] Gopal, Kiren; [REDACTED]
Subject: RE: BioWatch

Shana, according to CDC, how many BARs have occurred in the BioWatch program? Thanks.

From: [REDACTED]
Sent: Friday, May 17, 2013 4:53 PM
To: Slobodin, Alan
Cc: [REDACTED] Gopal, Kiren; [REDACTED]
Subject: RE: BioWatch

Hi Alan-

Thanks for your email and we will be in touch regarding next steps.

Thank you and have a nice weekend.

[REDACTED]

From: Slobodin, Alan [mailto:Alan.Slobodin@mail.house.gov]
Sent: Friday, May 17, 2013 1:00 PM
To: [REDACTED]
Cc: [REDACTED] Gopal, Kiren
Subject: BioWatch

I've been given the green light to proceed with a hearing on BioWatch that would be held June 12th. I wanted to give you a heads-up that we will be inviting CDC to testify at this hearing, and wanted to ensure an appropriate CDC witness is available to testify. Thanks.

Document 23

From: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Thursday, October 13, 2011 10:07 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
 Please share with Beth, that there were three process to support standards for biodetection out of DHS S&T.

1. Public Safety Actionable Assay which was intended to support the evaluation of Field Screening Assays manufactured of commercial companies for First Responder Use. The conops associated with this effort is directly attributed to safety related actions such as evacuation of buildings, decon of potentially exposed individuals, expediting the transfer of sample to the LRN for confirmation etc. In addition to the above regardless of whether a sample is positive or negative, the sample is still forwarded to a LRN lab for secondary testing to eliminated False Positives and False Negatives
2. Federal Standards for Assay Performance and Equivalency. This was specifically design to support and fulfill the National Biomonitoring Program and under a MOU signed among Asst Sec. from DoJ, DoD, HHS, DHS and USPS which all had a biomonitoring program at that time. The task was delegated to DHS S&T to implement a process for establishing Assay performance Equivalence among the programs so the federal partners recognize the credibility to support the initiation public health response in a timely manner. This is the effort Garza is referring to. We actually briefed CDC leadership about a year ago during Lisa Rotz time to Ali, Beth, Dan and others and they already signed off on it just like all the other agencies except of OHA and USPS at the current time. The issues with USPS is being dealt by NSS because they just don't have the money to continue and operate the BDS and they are the process of reevaluating the program (please hold this information close. This is not for sharing at the current time). With regards to OHA, we have forwarded all the versions multiple time over the past several years and they keep ignoring and not truly engaging in the effort although we have tried many time. They have come up with multiple excuses over the years and questions which we had address all of them. So, I don't know what their true concerns are, but for a high profile program like BioWatch, it will be in their best interest to put their assays and system through a robust process to ensure they function and operate at an optimal level to support the Nation with an early warning of a biological attack. Several months ago Mike Farrell from the BRRAT lab evaluated the Assay Chemistry being used by the NG Gen 3 system at the request of OHA BioWatch program. His finding were similar to our findings when we did the evaluation of Gen 2.5 the Bioplex assays. That is the assay chemistry is fundamentally flawed and have to be addressed immediately and had shared this with OHA. As per Mike, they ignored is and upon Mike revisiting this issue, they shared with him that they will fix it after procurement which is highly troubling (please check with Mike for specifics). I don't know if OHA BioWatch is worried that if they were to put the assays through the FSAPE process they might failed and is trying to bypass it. They have insisted to us that the PSAA process is a better process and as such want to put their systems through that process which was intended for Public Safety Actions. My thoughts on this is that they can go through the process and if they get a positive signal, they can retrieve the sample from the detectors and take to the closest LRN Lab for confirmation, however if they were to miss a detection, there is no mechanism to capture it (referring to false negative result) simply because the negative samples will not be retrieved and taken to a LRN Lab for secondary testing.
3. Public Health Actionable Assays. This is specifically to support the assay development, evaluation, validation and certification of the assays deployed and employed through the CDC LRN. This has nothing to do with OHA or BioWatch. This is strictly related to the LRN assays to support National BioPreparedness and Defense and Public Health Surveillance mission. These assays are intended to be highly robust for use in a LRN laboratory to evaluate environmental samples that comes to the lab, support epi investigation associated with a bioterrorism event as well as clinical sample to support medical and clinical intervention. We worked with many folks from CDC all the way from LRN TRC director, LRN Manager, Environmental Microbiology Director, SME Lab Directors, Branch Chiefs and Division Directors for the input and contribution to the PHAA plan simply because we wanted to ensure that the assays deployed and employed through the CDC LRN are highly robust to support the mission.

Hope this helps and I am on travel to the West Coast and will return back to the office next week. If you would like to chat, please let me know and I can give you a call at you convenience. Take care.

Pillai

 Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Thu Oct 13 08:53:21 2011
Subject: RE: Signatures on current PHAA document

Pillai,

I'm going to get the specifics from Beth again, because I want to be sure I get them right, and I will send them along later. I think they primarily have to do with the impression that the Biowatch program and Gen-3 will have to meet PHAA standards and be approved by PHAAC as a condition of deployment. But, let me see exactly what Beth says.
Toby

From: Pillai, Segaran [mailto:Segaran.Pillai@dhs.gov]
Sent: Thursday, October 13, 2011 8:31 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
Can you please share with me the concerns raised by Alex to Beth pertaining to the PHAA? Thanks and appreciate your help and assistance on this. Take care.
Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Wed Oct 12 11:42:41 2011
Subject: Signatures on current PHAA document

Pillai,

I met with Beth Bell and other members of our Center leadership yesterday, and we discussed the requested signatures on the PHAA document. Beth tells me that she recently met with Alex Garza from DHS-OHA where he explicitly raised his concerns about PHAA. We seem to be at a juncture where DHS-S&T and DHS-OHA need to resolve their internal disagreements over PHAA and present us with a PHAA document for CDC signature that has cleared stakeholders at DHS. Personally I believe there is a critical need for standards and the differences between DHS-OHA and DHS S&T are resolvable.

I am willing to discuss and help in any way you like.

Thanks,

Toby

Document 24

From: [REDACTED]
To: [Walter, Michael](#)
Subject: Re: FYI some good news, I think.
Date: Thursday, December 08, 2011 7:21:51 AM

Thanks Mike.

Would you like a meeting with FPS HQ to get a more consistent approach to providing biodetection in their facilities nationally? I know some of their senior leadership.

[REDACTED]
Sent from BB

From: Walter, Michael
To: Garza, Alexander <Alexander.Garza@dhs.gov>; [REDACTED]
Cc: [REDACTED]
Sent: Thu Dec 08 07:14:44 2011
Subject: FYI some good news, I think.

Dr. Garza/Bob... things you should be aware of since we do not have a staff meeting

1. We met with the USSS and EPA and have an agreement that EPA will provide Phase 1 and 2 sample support. EPA understands that they will change filters at NSSEs only if we request them to. They will also do the sampling plans for our and any systems that the USSS will put out...good meeting.
2. Had a conference call with the [REDACTED]. They are installing a commercial Bio-trigger (iBAC from ICXT) and wanted my advice on how to coordinate with the city and BioWatch regarding sample analysis and response. I recommended a meeting between Public Health and NYPD and at my suggestion they are now leaning towards deployment of a [REDACTED]. They would also like to discuss BioWatch [REDACTED]. I will meet with FPS in the next couple of weeks or early January, but will discuss the meeting with [REDACTED] today while I am up there. Meeting was facilitated by S&T.
3. Got word that JPEO has removed funding from all future biodetection programs with the exception of the tactical detection system. This includes shutting down their standoff program. This makes BioWatch the only game in town.

FYI in case it comes up.

Mike

Michael V. Walter, Ph.D.
 BioWatch Program Manager
 Office Health Affairs
 Dept. Homeland Security
 [REDACTED]

Document 26

Pillai, Segaran

From: Willner, Kristin (CTR)
Sent: Tuesday, January 03, 2012 4:16 PM
To: Pillai, Segaran
Subject: BioWatch read ahead for USST 3Jan12
Attachments: BioWatch read ahead for USST 3Jan12.docx

Electronic version of the read ahead material.

Background:

1) BioWatch Gen 3

Testing conducted on Northrup Grumman (NG) system has failed to meet:

- Assay specificity
- Assay reproducibility
- System sensitivity of [REDACTED] air
- Mean time of instrument availability (had problem 4 ½ day)
- System failed in subway (Failure of PC to yield results. PCR inhibition – potentially due to metallic dust)

Testing conducted on HS-MFSI system

- Assay reagents had problem of yielding potentially false positive results due to Vic signals in Mix 2 and Mix 3
- Assay issues are fixable
- OHA discontinued any further testing

2) Gen ½ - Lack of understanding

- System capture efficacy
- Agent degradation rate
- Sample processing efficacy
- Presence of PCR inhibitors and its impact on PCR inhibition for detection
- The true cost to operate Gen ½

3) OHA's RFP – for Phase II competition

- Requirements are impossible for any company to meet
- Designed to support only a single performer/vender – NG
- Not a fair and open competition for vendors/performers to participate and show the value of their system and engineering
- Clear display of OHA's biases toward a single system to move forward – NG

Path forward:

- 1) Cease any further testing associated with Gen 3 – since both systems have failed Phase I DT&E
- 2) Retract the RFP for Phase II Gen 3 competition
- 3) S&T takes the lead to investigate the current performance of Gen1/2 and what it costs to operate them
 - Perform a system level testing to understand its efficacy and LOD after capture
 - Evaluate each sub component to understand where quick improvements can be made to the system for better efficacy if possible
 - Perform a cost/benefit trade off study to understand the value of such a system/program
 - What does it truly cost to operate Gen ½
- 4) S&T takes the lead to further evaluate HS-MFSI system with the fixes for its assay
 - Sensitivity
 - Specificity

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- System sensitivity to meet [REDACTED]
 - Mean time for failures
 - Performance of system in subway
- 5) S&T conducts a study to understand the benefits of indoor vs outdoor monitoring
- Look at BTRA – selection of targets
 - Identify high threat and critical venues
 - Determine system's potential value and requirements for indoor monitoring vs outdoor monitoring
- 6) S&T evaluates potential use of Triggers/Confirmers
- Understand assay sensitivity
 - Understand assay specificity
 - Understand system sensitivity
 - Mean time for failure
 - Performance in subways
- 7) S&T evaluates Viable Bioparticle Capture system for potential outdoor use
- Evaluate the viability of an agent to ensure that our Biomonitoring Detectors were not spooked by threat agent nucleic acids
 - Maintain viability of non-spore forming organisms to support rapid antimicrobial susceptibility testing to initiate appropriate medical intervention
 - Support orthogonal based testing for additional confidence and confirmation (i.e. DFA, Antigen Based Detection, etc.)
 - Ascertain better spatial coverage in support of incident/event characterization for rapid and effective mitigation
 - When distributed geographically, this technology will assist in determining if the event was a point source or a line source release thus supporting attribution through law enforcement related investigation
 - Provide the ability to support detection and characterization of an intentional release of an agent not monitored through the Biomonitoring effort but detected through the Public Health Surveillance System– wider agent coverage
 - Support environmental monitoring for persistence of viable organisms after an event
 - Support Remediation and Recovery related efforts by continuously monitoring for viable organisms to determine decontamination efficacy, reaerosolization/persistence rates and/or agent decay rates
- 8) S&T redesigns the BioMonitoring Architecture effort:
- Robust
 - Cost effective
 - Clear benefit
 - Provide appropriate coverage and advanced warning to save lives
 - Embraced by the Public Health community
 - Ensure all data collection and understanding of system performance are taken into consideration
 - Broader agent coverage (other agents including enhanced, advanced, emerging, toxins, etc.)

- If possible, other classes of agents such as chem, rad, explosives and bio detection through a single system
- 9) S&T reevaluates a system approach for Bio Surveillance/Detection
- Evaluation of system approach/layered approach
 - Consider clinical surveillance
 - Public Health Surveillance
 - Bio Monitoring effort
 - Other efforts
- 10) S&T identify high priority investments for the next 5-10 years to pursue for implementation of a robust Bio Surveillance and Detection Program

Document 27

Pillai, Segaran

From: Drabkowski, Douglas
Sent: Monday, April 23, 2012 12:37 PM
To: Pillai, Segaran
Subject: BioWatch

Pillai -

I'm reviewing the updated TEMP from OHA.

The August 23, 2011 TEMP had a parameter for System-level sensitivity (Average air concentration of agents over the collection period) =
Threshold: [REDACTED] (bacteria/particles)
Objective: [REDACTED] (bacteria/particles).

However the updated January 20, 2012 TEMP has a parameter for System-level sensitivity they call: "Total Integrated Concentration" still described as the average air concentration of agents over the collection period but lists the Threshold/Objective KPPs as follows:

Threshold:
Indoor: [REDACTED] x minutes for bacteria)
Outdoor: [REDACTED] x minutes for bacteria)
Objective:
[REDACTED] x minutes for bacteria)

What kind of game are they playing with these system-level sensitivity numbers?



Document 28

S&T Chem-Bio Division Review and Comments
 BioWatch Documents – June 14, 2012

DOCUMENT: Acquisition Program Baseline (APB) for BioWatch Gen-3 Autonomous Detection System (OHA BioWatch APB Version 1.1, Dated April 16, 2012)

Comments:

- p.8 "Anticipate deploying next generation technology to replace an aging Gen-3 system."
Comment: Funding to develop and/or deploy such a technology not identified.
- p.8 "Gen-3 acquisition will be executed in two-phased approach to engage multiple vendors, provide maximum competitive opportunities for industry, and provide flexibility in selection of high performance/cost-effective solution. Phase II will have multiple awards for Performance testing with a down-selection to one vendor for the 4-jurisdiction OT&E." Comment: This does not indicate a sole source process option, only a process to engage multiple vendors in Phase II.
- p.9 "Phase I effort will provide sufficient information to determine viability of the technology for further investment." Comments: The information provided to DHS S&T for review provide serious concerns about the inability of the Northrop Grumman and HSSI technologies to fully meet Phase I requirements. It's important to note that the Northrop Grumman technology is currently going through further development to improve system sensitivity as it had 100-fold lower system sensitivity than what was desired in the operational requirement document. This is problematic as the requirement for Phase I testing was to evaluate only "mature" technologies. The Phase I source selection process included entry criteria to ensure vendors could provide "comprehensive, logical and detailed designs for mature autonomous detection systems." The Northrop Grumman (NG) system also failed to meet 1) assay specificity, 2) assay reproducibility, 3) system sensitivity, 4) mean time of instrument availability (had problems every 4.5 days), and the system failed indoors due to PCR inhibition of metallic dust.

Gen-3 Requirements (NG): Initial Analysis

OHA PPT Slide. Partial List of Requirements not met by NG testing

Requirement	Requirement	Status
4.1	BioWatch Agents	Met*
4.3	System Performance	
4.3.1	Autonomous Operation	Met*
4.3.2	Detection Cycle	Met
4.3.3	Time to Detect	Met*
4.3.4	System Sensitivity	Not Met
4.3.5	Probability of Detection	Not Met
4.3.6	Probability of False Positive	Not Met
4.3.7	Public Health Actionable Assay	Not Met
4.3.8	Viability	Not Tested
4.3.9	Reporting	Met*
4.3.10	Archiving	Met / Partially Tested
4.3.11	Self-Assessment	Met
4.3.12	Failure Analysis & Fault Isolation	Not Met

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This document contains information that is unclassified, but is exempt from automatic downgrading and declassification under the provisions of Executive Order 13526, 65 FR 68972 (November 9, 2000) because it is information that is specifically excluded from the provisions of Executive Order 13526, 65 FR 68972 (November 9, 2000).

- p.13 Program Cost:¹
 - a. Acquisition (T) \$903M (O) \$856M
 - b. O&M (T) \$6,529M (O) \$5,831M
 - c. LC Cost \$7,432M \$6,688M

¹Note: Baseline Threshold costs at 65% confidence level. Baseline Objective costs at 50% confidence level.

DOCUMENT: 20120509 Gen-3 APV V1.1 based on 20120321 timeline v2.pdf

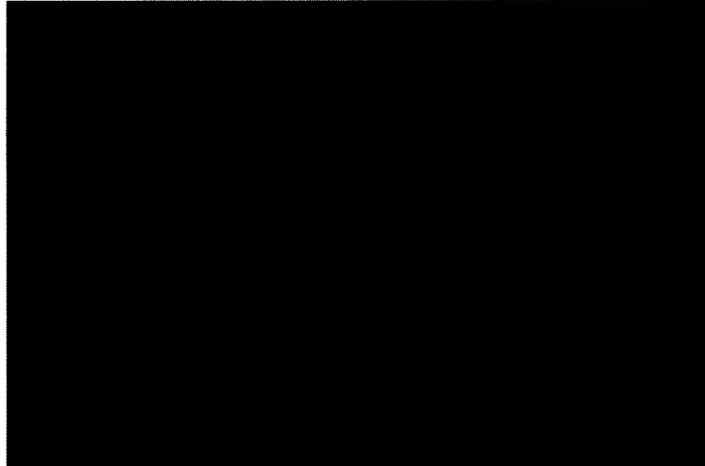
p.11 Section C.1: "Performance Parameters":

Comments: It appears that the system-level sensitivity measures are listed incorrectly for both threshold and objective. They are listed as organisms/m³ x minutes when they should be listed as Total integrated organisms with just the number of organisms [REDACTED]

DOCUMENT: BioWatch Gen-3 Systems Engineering Life Cycle Tailoring Plan (Version 1.0)

Jan 20, 2012 Comments:

- p.1 "The Gen-1/2 system detects 5 Agents of Biological Concern and provides outdoor coverage for approx. [REDACTED] in each of the 30 jurisdictions -- [REDACTED], and for 5 indoor facilities". **Comment:** On what basis is this coverage determined? What is the system sensitivity of the current Gen 2 system?
- p.4 "After completing Phase I the program also conducted a detailed requirements analysis through Sandia National Lab. The study assessed the utility of the autonomous detection systems with varying degrees of sensitivity in terms of detection timeliness, population coverage, and lives saved during a bioterror attack. This study was completed in January 2012. Based on the results, DHS decided to revise the ORD threshold requirement for System Sensitivity to reflect a more realistic articulation of the minimum acceptable level of performance." **Comment:** This raises concerns as the sensitivity requirements are critically important to ensure meeting appropriate technology Probability of Detection (Pd) metrics/requirements. In other words, if system sensitivity is increased to [REDACTED] over a 6 hour time window, the Pd will be in the range of [REDACTED] with 40 detectors deployed. In addition, a cost-benefit analysis should be performed to support a possible change to the ORD.
- p.6 "The total life cycle cost is estimated at \$4,347M at the 50% confidence level". **Comment:** Why is this value different than what is listed above in APB document?
- p.12 "Offerers for Phase II are not required to participate in Phase I; however, they must demonstrate that their proposed technology is ready for low-rate initial production." "The ARB approved the Phase II acquisition strategy for full and open competition for a "total system solution". **Comment:** A multiple vendor evaluation and approach is most appropriate for such a large and visible acquisition program, and more importantly was approved by ARB. This will allow for a comprehensive understanding of the best system available to support the BioWatch mission.
- P.26 "Assay Evaluation: "Conducted at LANL to verify candidate Gen-3 detectors' assay performance in terms of sensitivity, specificity and repeatability. The objective was to ensure the assay meets Gen-3 operational requirements and reduce the risk of the detector generating erroneous signals. **Comments:** Both technologies tested had significant deficiencies and both did not successfully complete Phase I testing. The Northrop Grumman (NG) assays by agent were shown to be [REDACTED] less sensitive than the current threshold requirement (per OHA) In addition, the Assay Evaluation Report generated



Comments:

The Northrop Grumman (NG) failures were so significant that OHA proposed major engineering modifications to the NG technology that included changing out the Collector, replacing the Analytical Subsystem Reader, and incorporating a sample preparation module that required several months to one year to complete. OHA awarded three (3) contracts for engineering change proposals. Such changes necessitate that the NG system be re-tested through Phase I T&E to understand if it meets much lower system-level sensitivity requirements! Both NG and HSSI/MFSI systems both didn't successfully pass Phase I testing. However, one system, NG was modified by OHA with Federal funding, and not the other. This poses **questions** regarding disparate decisions for testing, evaluation, and modifications of the NG system.

OHA Planned Modifications to Northrop Grumman System:

	ECP	Description	Estimated Improvement to Sensitivity
1	Enhanced Collector Concentrator	Replace SASS with continuous sample flow wetted wall cyclone (WWC) collector and inline Virtual Impactor (VI) particle separator	<ul style="list-style-type: none"> • 8-10X Improvement (at [REDACTED]) • Includes improvements in sampling efficiency and retention efficiency • Based on DHS S&T and NG testing
2	Enhanced Analytical Subsystem Reader	Replace flow cytometry based LX-200 reader with imaging based MegPix reader	<ul style="list-style-type: none"> • Unknown
3	Improved Fluidics Valve Material	Replace soft fluidics valve material with robust material that provides significantly better wear performance	<ul style="list-style-type: none"> • Unknown • Potentially enable the inclusion of sample preparation module

3

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- D.2. Phase I Decision Point – Northrop Grumman (N.G.) “Based upon the results of Probability of Detection, the NG-ADS assays met the Gen-3 Phase I DP#1 pass/fail criteria.
-
- D.2. Phase I Decision Point – Hamilton-Sundstrand (H.S.) “HSSI Assay Evaluation technically did not meet DP #1 due to performance problems early in the testing. Comment: The metric of success was that the vendor must detect at least one of the BioWatch Threat Agents at or below [REDACTED] per reaction with a Probability of Detection of 95%). The HSSI System passed this metric. Yet, the Contracting Officer determined that the assay evaluation results failed to meet the requirements of the Contract.

On December 17, 2010, OHA met with Hamilton Sundstrand to discuss the decision to no longer fund them within the BioWatch Gen 3 Phase I contract. HSSI questioned OHA’s decision on technical grounds. On December 30, 2010 OHA requested S&T/CBD to conduct an independent technical review of the testing data results relative to their decision.

Based on CBD’s review of the limited data set (for only one biological agent of concern) provided by OHA for analysis, CBD noted the following deficiencies in the testing and evaluation process:

- “The bench top test system employed for assay evaluation (the High Throughput Analytical Component or HTAC) was not the technology or configuration used in the fielded system. The HTAC system uses a different thermo cycler and micro fluidics than that used in the Hamilton Sundstrand (HSSI) analytical subsystem. To the best of our knowledge, no testing was performed on the HSSI analytical subsystem to determine if the assay evaluation data and conclusions from testing of the bench-top system are comparable to detection performance of the subsystem or system.”
- “The algorithm associated with the test system does not provide accurate interpretation of results based on the data provided, which includes many instances for potential false positive detections. Based on the analysis of the limited test data provided by OHA, it appears that the system configuration (the HTAC reader) tested by OHA has inconsistencies in the algorithm and chemistry used to determine a positive detection.”
- S&T/CBD expressed its concerns to OHA in writing that: “the Hamilton Sundstrand (HSSI) assay evaluation was performed on a bench-top system that is significantly different from the analytical subsystem and system (developed by S&T) and therefore cannot make conclusive statements on the operational HSSI assay and system performance. Without testing the actual HSSI analytical subsystem, the assay evaluation data provides little value to derive any substantive conclusions as to how the system will perform as required by the BioWatch program.”

In addition, the above Phase I Assay Evaluation using a subset of a PSAA panel revealed that the NG Assay had the potential to yield false positive and negative results which is a clear indication that the system failed Phase I testing.

DOCUMENT: Memorandum For the Record, Date: April 6, 2012. From: Dr. Michael Walter, Program Manager, BioWatch Program Office.

Comments:

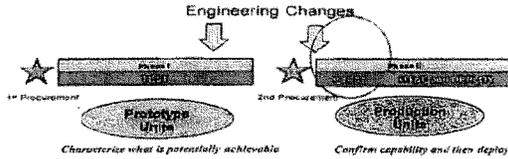
- o p.2 "Sandia National Laboratory Systems Analysis Study. "The BioWatch SPO commissioned SNL to lead a consortium of National Labs in the preparation of a performance trade-off study, examining the relative benefits of the time-to-detect system sensitivity, and number of deployed detectors related to lives saved. The resulting suggests that the System Sensitivity requirements contained in the Gen-3 ORD v.1.1 and v.2.0 were too stringent, prompting the SPO to update the System Sensitivity. As such, the BioWatch Program Office reduced the System Sensitivity threshold requirement from [redacted] (organisms/m3) to [redacted] (organisms/m3) x minutes for indoor environments and [redacted] (organisms/m3) x minutes for outdoor environments.

Comments: The Requirements used by OHA to update the Gen-3 ORD v 2.2 (dated January 2012) are very confusing and misleading. No information is provided as to the rationale for changing operational system sensitivity to [redacted]. Also, different system sensitivities are indicated for both INDOOR and OUTDOOR systems. Will different systems with different sensitivities be developed for indoor and outdoor to meet these metrics? Why have these requirements changed from a 6 hours collection period to a 3 hours collection period and what is the benefit? The Threshold for indoors is [redacted] x minutes for bacteria and viruses. The Threshold for outdoors is [redacted] x minutes for bacteria and viruses. The document states that these are equivalent to system sensitivities of [redacted]. These sensitivities are relatively low. For outdoor attacks, if the collector collects [redacted] org min/m³, then the [redacted]. If the collector requires [redacted] over 3 hours [redacted] org min/m³, the [redacted]. (Per Sandia National Lab study) CBD advises against changing system sensitivity requirements based solely upon the candidate systems tested. The system sensitivity must be set at a level that ensures a high probability of detection (Pd). S&T recommends [redacted].

Need for Changing the Schedule

- Confirmation that improvement in production units has occurred requires more detailed testing before deployment.

OHA PPT Slide of NG testing



Comments on next page

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Comments:

OHA plans to test the NG system with modifications at the start of Phase II. It is our recommendation that the ORD for sensitivity not be changed at the current time. Given the fact that OHA has already invested significant resources to support significant changes to the existing NG system about a year ago, it is our recommendation that the system be tested against the original ORD sensitivity level of [REDACTED] to understand the performance based upon the engineering changes prior to making ORD changes. It should also be noted that significant engineering changes by OHA to the Northrop Grumman system do NOT mean that the system sensitivity of the technology will become any lower.

DOCUMENT: Gen-3 Autonomous Detection System Operational Requirements Document v2.2 (Dated January 5, 2012)

Comments:

The most important changes to this document are found on page 3-2. The ADS system sensitivity metrics have been modified from the previous Operational Requirements Document. The August 2011 ORD requirement for system sensitivity was meeting a threshold of [REDACTED] and the objective of [REDACTED]. This has now been changed for threshold of [REDACTED] for outdoors/indoors. The concern is that the system sensitivities are being modified to match the metrics of the Northrop Grumman system, rather than ensuring that there is high confidence in the Probability of Detection (Pd) of the technology.

DOCUMENT: Gen-3 Autonomous Detection System Test and Evaluation Master Plan v 2.1

Comments:**Page D-3: Assay Evaluation**

"Assay Evaluation is designed to measure Gen-3 Detector assay performance in terms of sensitivity, specificity and repeatability. The test design will be based upon SPADA. The assay evaluation will use liquid samples of purified DNA processed through a high throughput bench-top version of the system's analytical subsystem to include an automated algorithm that detects and identifies the appropriate strains. The Assay evaluation will be conducted at LANL and CDC. Modifications to the assay evaluation event may be made if the assay has met all or some of the data requirements described in the Phase II RFP prior to the test event. A portion or the entire assay evaluation may not be required. Also, if the assay has met all or some of the data requirements described in the Phase II RFP, but has since received engineering changes or design modifications, then appropriate regression testing will be required. Assay evaluation regression testing will verify the performance of modified assay components to ensure no detriment to previously working functions."

Comments: This language raises questions or concerns as what is truly meant by "modifications to the assay evaluation event will be made if the assay has met all or some of the data requirements described in the Phase II RFP. A portion or the entire assay evaluation may not be required. No technology or system assays should get a pass from undergoing full evaluation of assays. What metrics will be used to evaluate and determine if an assay has met all or some data requirements as described in the Phase II RFP? 2. "The high-throughput bench-top version of each system's analytical subsystem will be used for system testing." Significant concerns were raised in Phase I

testing regarding the use, operation and performance of high-throughput bench top systems. As there were false positive and negative issues with the NG system it's highly recommended that if changes are made to the Assays within the Gen-3 system they must be re-tested to generate the appropriate data for subsequent evaluation to determine overall performance.

Page D-4: **Aerosol Collection Subsystem Test**
"Modifications to the aerosol collection subsystem test event may be made if the aerosol collection subsystem has met all or some of the data requirements described in Phase II RFP prior to the test event".

Comments/Questions: What is the decision making process? This is a concern, as in the Assay Evaluation above, that decision process will be used to evaluate if data requirements have been met? It is highly recommended that if changes are made to the Aerosol collection system it must be re-tested to generate the appropriate data for evaluation to determine performance.

Gen-3 Autonomous Detection System, Operational Requirements Document v 2.0, August 12, 2011, signed by Bob Ranhofer and Mike Walters (copy attached)

Comment: This document was not included in the list of IRB documents for review. The metrics were changed from the original [redacted] (in ORD v1.1) to include the objective of [redacted]. This ORD Version was not provided in the documents as sent. However, it's important to note that OHA decided to modify the System sensitivity requirements to the [redacted] last year.

3.1.4 System Sensitivity

The Gen-3 ADS shall have a system-level sensitivity, average air concentration of agents over the collection period, equal to or less than [T]:

- (a) [redacted] per cubic meter for bacteria (vegetative cells or spores)
- (b) [redacted] per cubic meter for viruses

The Gen-3 ADS shall have a system-level sensitivity, average air concentration of agents over the collection period, equal to or less than [O]:

- (a) [redacted] per cubic meter for bacteria (vegetative cells or spores)
- (b) [redacted] per cubic meter for viruses (DNA or RNA)
- (c) [redacted] per cubic meter for toxins

Document 29

Pillai, Segaran

From: Hall, Wendy
Sent: Thursday, July 12, 2012 8:25 PM
To: Drabkowski, Douglas; Pillai, Segaran
Subject: RE: GEN-3 IRT OUTBRIEF

Ah yes. But Jerry and I might not give up on that as we recommended some related items to A/S Heyman and would need to ask S&T for technical support to further our Policy thinking about Gen3 requirements that meet various biodefense policy objectives. And we have to have a more solid idea of our policy goals to be able to effectively evaluate the documents that OHA will be working to produce.

From: Drabkowski, Douglas
Sent: Thursday, July 12, 2012 1:29 PM
To: Pillai, Segaran; Hall, Wendy
Subject: FW: GEN-3 IRT OUTBRIEF

FYI – Apparently, IRT and IRB meetings postponed through the calendar year to address some of the S&T Acquisition Recommendations, but apparently not all.

Additional S&T recommendations NOT mentioned include:

- 1) System-level characterization of the current BioWatch Gen-2 performance.
- 2) Cost-benefit Analysis of the deployed Gen-2 vs the proposed Gen-3 system.
- 3) Evaluate if the N.G. assays have been updated to ensure greater assay sensitivity, specificity and reproducibility.
- 4) Independent Validation and Verification of the assumptions found in the Sandia National Laboratory models/studies.

Doug Drabkowski
Acting Deputy Director & Transition Branch Chief
Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20523



From: Durham, Debra
Sent: Thursday, July 12, 2012 1:21 PM
To: Drabkowski, Douglas; Murata, Christine; Benda, Paul

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Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
Office: 202-254-5808
Email: douglas.drabkowski@hq.dhs.gov

Document 30

Young, Loretta

From: O'Toole, Tara
Sent: Tuesday, June 19, 2012 3:03 PM
To: de Vallance, Brian
Subject: RE: Bio mtg

Dear Brian -
 Thanks for the update. I don't know what the time pressures are; OHA would know better. I would like very much to be at the IRB, but am traveling 4/27 and 28 and am on vacation the week of July 4.

I think a pre-mtg session would be very good idea. This is a highly visible, controversial acquisition, one of the largest (in \$ terms) in DHS, and people are watching for it - as WA Post article indicates. Also in the background is a 2010 National Academy of Sciences report requested by Cong Price (and extensively quoted by GAO).

The GAO report now circulating in DHS for accuracy check (release date in August) is highly critical of the acquisition process. There is another report on the state of the biowatch technology by HSSAI which the Secretary requested (have not seen it). S&T's written comments to the IRB express a lot of skepticism about whether the technology works and whether we are getting our money's worth. The House Approps bill does not include money for BW operational testing until the Secretary "certifies" that it is prudent to do so and provides an alternate plan (essentially an analysis of alternatives, which S&T also wants to see done).

Alex Garza, on the other hand, told me this morning that he does not regard the BioWatch Acquisition to be "high risk" and he has aggressively sought permission to proceed. So there will be a lot of different opinions about whether and how we should go forward. Not sure if a bigger or smaller mtg would be useful, but I think it would be useful to have a somewhat formal presentation of the "facts" and concerns from OHA, S&T (not T&E, I would present) and USM or their rep.

Alice Hill is also involved in this.

Let me know if I can help.
 Tara

Tara O'Toole MD, MPH

Under Secretary for Science & Technology Department of Homeland Security

tara.otoole@dhs.gov

-----Original Message-----
From: de Vallance, Brian
Sent: Tuesday, June 19, 2012 2:32 PM
To: O'Toole, Tara
Cc: [REDACTED]
Subject: Bio mtg

Dr. O'Toole,

MGMT does recommend that we move the big Bio mtg, which we usu accommodate it approved by the U/S, which it was here. Erin will let you know when we move it to. 2 Qs for you:

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1. I assume we consider this time sensitive for reasons that we discussed, so we need to resched it asap, correct? If so, we will do it as soon as MGMT can.

2. Do you recommend a separate (short) prep session for the larger mtg?

3. If so, who should attend the prep session?

Thx.

Brian

Document 31

Young, Loretta

From: O'Connor, Erin
Sent: Monday, June 25, 2012 7:35 PM
To: O'Toole, Tara
Cc: [REDACTED]
Subject: RE: BioWatch IRB

FYI

S2 met w/Huban and Alex and Amy Shlossman.

No larger meeting being scheduled at this time.

From: O'Toole, Tara
Sent: Tuesday, June 19, 2012 2:49 PM
To: O'Connor, Erin
Subject: RE: BioWatch IRB

I have had it on my calendar as a S2 mtg for about a month, but the mtg may have been called by USM.

It's up to the Deputy, but I think a prep session would be excellent idea.

This is highly complex acquisition – both because the technology is complex and hard to understand, and because of the unusual history of the program. It is a multi billion dollar deal.

Moreover, this is highly visible and controversial acquisition with story in yesterday's WA Post and no money for acquisition in OHA's House budget.

I think S&T and OHA have conflicting views of the program. Not sure what USM thinks.

I would really like to be at the IRB but am traveling 2 days next week and off the week of July 4.

Call if I can help.

Tara O'Toole MD, MPH

Under Secretary for Science & Technology
 Department of Homeland Security
 [REDACTED]

tara.otoole@dhs.gov

From: O'Connor, Erin
Sent: Tuesday, June 19, 2012 2:00 PM
To: O'Toole, Tara
Cc: Gifford, Ashley; Young, Loretta
Subject: BioWatch IRB

Dr. O'Toole:

Brian just said you were asking about a prep for BioWatch DC.

We didn't have a prep session on. Do you want a prep? If so, I'll ask S2.

Separately, IRB folks in MGMT JUST asked me to cancel and MOVE the BioWatch IRB.

Erin O'Connor
Office of the Deputy Secretary
Department of Homeland Security
Email: erin.oconnor@hq.dhs.gov



Document 32

Pillai, Segaran

From: Drabkowski, Douglas
Sent: Monday, August 06, 2012 11:38 AM
To: Pillai, Segaran
Subject: FW: BioWatch Gen-2 Data

Dr. Pillai - Please see below my follow-up emails to Mike Walters of OHA regarding our request for information specific to the current Gen-2 system. As of this date we have not received a response from OHA. Thanks. Doug

Doug Drabkowski
Acting Deputy Director & Transition Branch Chief
Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
[REDACTED]
Email: douglas.drabkowski@hq.dhs.gov

From: Drabkowski, Douglas
Sent: Friday, January 20, 2012 12:11 PM
To: Walter, Michael; Hooks, Robert
Cc: Gerstein, Daniel; Pillai, Segaran; Ranhofer, Robert; Johns, Malcolm; 'jerome.holtan@taurigroup.com'
Subject: RE: BioWatch Gen-2 Data

Thanks Mike!

In general we are trying to understand the current Gen-2 system sensitivity in order to better inform robust biomonitoring systems of the future.

As such, it would be most helpful to receive information on the following:

1. Available data that informs the current (Gen-2) system sensitivity.
2. Whether or not Dugway chamber testing was performed to understand current (Gen-2) system sensitivity for the five (or six) BioWatch agents.
3. What the current sample processing efficiency is for the five (or six) BioWatch agents.

Thanks in advance for your responses to these items. Regards -

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DHS HCEC BW 001112

From: Drabkowski, Douglas
Sent: Friday, January 13, 2012 4:40 PM
To: 'Hooks, Robert'; Walter, Michael
Cc: Gerstein, Daniel; Pillai, Segaran
Subject: BioWatch Gen-2 Data

Bob and Mike –

It was great having a meeting yesterday to discuss the merits of Fp and Pd in the context of BioWatch detecting biological releases that impact significant numbers of people.

During the meeting, you provided an affirmative response to Paul Benda's question regarding availability of test data for the performance of the current Bio Watch Gen-2 system (PSUs and lab extraction procedures). It would be appreciated if you can forward such data back to my attention within the next week.

Thanks much for your assistance in this matter.

Sincere regards -

Doug Drabkowski
Acting Deputy Director
Chemical and Biological Defense Division
Science and Technology Directorate
U.S. Department of Homeland Security
Washington, D.C. 20528
[REDACTED]
Email: douglas.drabkowski@dhs.gov

Document 33



SEP 07 2012

ACQUISITION DECISION MEMORANDUM

MEMORANDUM FOR: Dr. Alexander Garza
Assistant Secretary for Health Affairs

FROM: Rafael Borras 
Under Secretary for Management

SUBJECT: Bio-Watch Generation-3 Acquisition

A Department of Homeland Security (DHS) Acquisition Review Board (ARB) review of the Office of Health Affairs (OHA) Bio-Watch Generation-3 (Gen-3) Program, chaired by the Under Secretary for Management, was held on August 16, 2012. This ARB was a program review to determine the program's feasibility to approve the revised 2-Stage Acquisition Strategy and release the Gen-3 Phase II Stage 1 Request for Proposal (RFP) for performance testing.

The Bio-Watch Gen-3 Program has been working since August 2011 to develop a viable alternate 2-Stage Acquisition Strategy to mitigate programmatic and technical risk for Phase II in preparation for an Acquisition Decision Event (ADE) 2B milestone. The program has responded to all of the action items assigned in the June 2010, December 2010, and June 2011 Acquisition Decision Memorandums (ADMs). The program presented an alternative approach to reduce programmatic and technical risk based on the previous Phase I Gen-3 test results and the original acquisition strategy. The Bio-Watch Program has submitted ADE 2B acquisition documentation based on the multi-vendor acquisition strategy for DHS review. These efforts demonstrate significant progress in the Bio-Watch program's maturity and compliance of Management Directive (MD) 102-01. The program's lack of maturity and MD 102-1 compliance were cited as significant risk within the February 7, 2012. However, it was noted by the ARB that the program must update the Acquisition Program Baseline (APB) and associated documentation to reflect the change in the acquisition strategy.

During the Bio-Watch Program's Gen-3 Phase II acquisition planning, the Government Accountability Office (GAO) performed a program audit, and DHS commissioned an independent study by the Homeland Security Studies and Analysis Institute (HSSAI) to determine how to decrease the program risk. Both of these efforts concluded in July 2012. The draft recommendations of GAO and the HSSAI Study recommended that the Bio-Watch Program conduct additional Analysis of Alternatives (AoA) before the Gen-3 acquisition proceeds. HSSAI further recommended the program update the Concept of Operations (CONOPS) to ensure Gen-3 requirements adequately address "the full operational landscape." It further recommended that the program update other acquisition documentation to reflect the AoA and CONOPS.

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Based on these two separate activities, the program proposed a parallel path of conducting Gen-3 performance testing of ten units from each competitively selected vendor, while conducting the AoA and developing a CONOPS. The ARB had a productive discussion with the program about the benefits and risks of adopting this approach. The Acquisition Decision Authority gave contingent approval for the Bio-Watch Program to prepare two solicitations: 1) conduct an AoA and 2) conduct Gen-3 Stage 1 performance testing, based on the current Operational Requirements Document (ORD). Approval to release the RFPs is based on completion and ARB review and approval of the following tasks:

- Acquisition Plan: Must reflect the updated strategy and be approved by the Head of Contracting Activity and Chief Procurement Officer before the Gen-3 performance testing solicitation can be released.
- Integrated Master Schedule: Within two weeks of the ARB (August 30, 2012), the Bio-Watch Program is required to provide a Gen-3 Integrated Master Schedule reflecting the revised acquisition strategy and including stakeholder inputs and activities (i.e., all government, including Science and Technology Directorate and Office of Health Affairs (OHA) activities).

Before Gen-3 Stage 1 performance testing contract award(s) the Bio-Watch Program must return to an ARB. To support that ARB, the following actions must be completed and provided for review and approval no later than 45 days prior to the planned contract award date:

- AoA and CONOPS: The AoA must include a Cost-Benefit Analysis of the deployed Bio-Watch Gen-2 performance versus the proposed Gen-3 performance. The AoA must consider the current operational system, as an alternative approach, including a Threat Clarification Analysis to establish a basis for the recommended alternatives. The Bio-Watch Program must also complete a CONOPS that explains how bio-detection technology will be used in each type of environment required under this program and the role of state and local jurisdictions.
- Other Acquisition Document: The Bio-Watch Program must revise all other acquisition and systems engineering support documents (e.g. Acquisition Program Baseline (APB), Life Cycle Cost Estimate (LCCE), Operational Requirements Document (ORD), Test and Evaluation Master Plan (TEMP), and the Systems Engineering Life Cycle Project Tailoring Plan (SELCTP) as appropriate based on the AoA, CONOPS, and the revised 2-Stage Acquisition Strategy.

It is the responsibility of both the OHA and the Bio-Watch Program Office to ensure results of this ADM are promulgated to the affected organizations. The Office of Program Accountability and Risk Management (PARM) will provide support and assistance as needed. Please send action items, status, and supporting documentation to PARM@hq.dhs.gov. Should you have any questions, please contact Brian Chu at [REDACTED] or Brian.Chu@hq.dhs.gov.

cc:
Deputy Secretary
Under Secretary for Management
Deputy Under Secretary for Management
Chief of Staff, Under Secretary for Management
Assistant Secretary for Policy
Deputy General Counsel
Chief Administrative Officer
Chief Human Capital Officer
Chief Security Officer
Chief Financial Officer
Chief Procurement Officer
Chief Information Officer
Executive Director, Office of Program Accountability and Risk Management
S&T, Director, Operational Test & Evaluation
S&T, Systems Engineering Directorate
Chief Financial Officer, OHA
Chief Information Officer, OHA
Component Acquisition Executive, OHA
Program Manager, OHA Bio-Watch GEN-3 Program

Document 34

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Sunday, May 22, 2011 4:01 PM
To: Bell, Beth (CDC/OID/NCEZID); [REDACTED]
Subject: OPR on LRN - draft outline of presentation

Beth [REDACTED]

Here (below and attached) is the outline of my QPR presentation on LRN. I would like to be able to go over this with you on Monday. I am most concerned about what I should say about the challenges.

Thanks,

Toby

“Assuring the United States Can Detect and Respond to Infectious Diseases – The Role of the Laboratory Response Network (LRN).”

Background:

- The Laboratory Response Network (LRN) is a system of laboratories providing rapid, highly reliable testing and expertise for biological and chemical agents regarded as threats to the public health.
 - Hallmarks of LRN are:
 - Ready availability
 - State of the art science
 - Rapid testing
 - High precision and accuracy of the testing
 - Highly standardized assays and highly trained personnel
 - Ready availability of expertise to assist with interpretation of results.
- There are 170 LRN laboratories providing testing for biological agents, including (and I am going to confine my discussion today to this biologic testing):
 - Within the US: local, State, and federal civilian and Department of Defense (DoD) laboratories
 - Outside the US: Mexico and Canada, as well as DoD facilities
- LRN is organized and funded largely by the CDC, but is managed in collaboration with APHL and the participating laboratories.
 - CDC Preparedness funds come to NCEZID to develop, maintain, and support the program and laboratory assays
 - CDC Preparedness funds go to the States and some cities through the Public Health Emergency Preparedness (PHEP) funds to support the State and local participating laboratories.
 - DHS funds come to NCEZID to support assay development.

Recent Successes:

- LRN in States and some cities (and DoD) were rapidly able to perform testing for 2009 H1N1 on RT-PCR instruments deployed in LRN.
 - 2009 H1N1 pandemic demonstrated value in having distributed network of state of the art diagnostic laboratories
 - Probably over 90% testing for 2009 H1N1 influenza was performed in LRN laboratories in the States and some cities.
 - LRN has dramatically improved public health laboratory infrastructure nationwide

- Improving collaboration with FDA
 - Working with FDA on regulatory pathway for LRN assays
 - FDA has agreed to need to change in methods (absolute quantity of DNA rather than colony forming units) as limits of detection standard for RT-PCR assays
- Mexico LRN is up and running
 - Major obstacle has been shipping and receiving of materials – import and export permits, customs issues
- LRN has forged new, improved relationships between State and local public health laboratories and the clinical diagnostic community
 - According to APHL

Challenges:

- Funding
 - LRN vulnerable to decreases in Preparedness funding, especially because of collaborative nature of LRN.
 - PHEP funds to States now decreased for 2011
 - PHEP funds likely to decrease further in 2012
 - PHEP funds to States do not go directly to laboratories and there is no funding specifically for LRN.
 - Preparedness funds to NCEZID proposed to decrease in 2012
- Biowatch
 - DHS-run program to sample outdoor and indoor air in multiple cities
 - LRN and CDC must be able to understand and verify Biowatch results in order to be able to assist in decisions about appropriate public health action
 - Requires substantial CDC resources to perform this function
 - Is planning to implement new Biowatch testing technology (Gen 3) with more sampling, in more locations.
 - CDC has concerns about technology; failure to target/meet standards for public health actionable assay
 - CDC has concerns about impact of demands of increased testing on LRN
 - Biowatch program is unpopular is questioned in some quarters, including parts of DHS.
- Adding international laboratories
 - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations).



Presentation to CDC Director
 NCEZID Quarterly Performance Review
 May 225, 2011

"Assuring the United States Can Detect and Respond to Infectious Diseases - The Role of the Laboratory Response Network (LRN).

Background:

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 - Rapid testing
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 - Biowatch program is unpopular is questioned in some quarters, including parts of DHS.
- Adding international laboratories
 - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations).

[REDACTED]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 25, 2011 5:04 AM
To: Bell, Beth (CDC/OID/NCEZID); [REDACTED]
Subject: Almost best-and-final version of QPR presentation on LRN

Beth [REDACTED]

I was not able to send this out electronically yesterday afternoon and evening, because of a problem with Outlook. I gave Beth a hard copy, and the only substantive change since then is adding a discussion of "specimen surge" to the challenges.

Please let me know any suggestions or concerns you have.

Thanks,

Toby



QPR on LRN
052511 TM.docx

Presentation to CDC Director
NCEZID Quarterly Performance Review
May 25, 2011

"Assuring the United States Can Detect and Respond to Infectious Diseases – The Role of the Laboratory Response Network (LRN).

Background:

- The Laboratory Response Network (LRN) is a system that enables participating States, cities, federal agencies, and international partners to provide rapid, highly reliable laboratory testing for biological and chemical agents regarded as threats to the public health.
- I am going to speak today primarily about the biological side of LRN, which is 1) the largest operating component of LRN, 2) the foundation of LRN, and 3) supported by multiple Divisions in NCEZID.
- LRN facilities have the state-of-the-art equipment, personnel, training, reagents, procedures, information systems, quality assurance program, and the connection to subject matter experts that enables these facilities to produce and report laboratory results that are highly reliable and appropriate for public health actions.
- There are 165 total LRN laboratories: 115 State and local health department; 19 federal agency (FDA, NIH, CDC); 7 veterinary; 11 military (including South Korea); 13 international (Canada, UK, Australia, and [very soon] Mexico); and 3 higher level national facilities including CDC, USAMRIID, and Naval Medical Research Center.

- Standardized testing and reporting across all of these laboratories minimizes methodological variation and assures that a result from one laboratory is equivalent to a result from any other laboratory.

- CDC develops, produces, and distributes the tests and supplies the individual LRN laboratories with the test kits, policies and procedures, training, quality assurance, information systems (LRN-messenger), and supporting subject matter expertise.
- LRN is funded largely by the CDC from Preparedness funds. The intramural activities at CDC are funded by "Upgrading CDC Capacity funds" which NCEZID receives from PPHR. CDC also receives some funds from DHS for assay development. The State and local LRN laboratories are funded through the Public Health Emergency Preparedness grants from PPHR.
- The LRN equipment and personnel are so-called "dual use" resources and are used to support other State and local laboratory activities [REDACTED]
- APHL serves a critical role in facilitating the participation of State and local laboratories in LRN

Recent Successes:

- A substantial proportion of the testing for 2009 H1N1 influenza performed in States and cities (and DoD) was possible because of the LRN.
 - LRN laboratories served as the "warm base" for 2009 H1N1 test kits developed and distributed by CDC.
 - Equipment and personnel trained and experienced in real time PCR were readily available, and the LRN laboratories in the States and cities had worked on a predecessor influenza assay.
 - Proof of the public health value of "dual use" of standard testing platforms.
- In the past 2 years, CDC's collaboration with FDA on LRN has substantially improved.
 - CDC is working with FDA on mutually acceptable a mutually acceptable regulatory pathway for LRN assays.
 - FDA has agreed to need to change in methods (absolute quantity of DNA rather than colony forming units) for measuring sensitivity and specificity of PCR for detection of microorganism.

- Mexico LRN is almost up and running
 - Major obstacle has been shipping and receiving of materials – import and export permits, customs issues.
 - The remaining step is training now scheduled for late summer
- CDC is improving its PCR assays for biothreat agents.

 - We plan to change the cycling time threshold for the assays which will decrease the number of non-verifiable positive results for Ft.

Challenges:

- Decreased Preparedness funding is impacting LRN
 - Within CDC, we are critically examining how we spend dollars on assay development and deployment. Our first priority is improvement of assays for our existing menu of targets.
 - Compliance with FDA regulations will have a cost.
 - For the LRN laboratories in the States and cities, decreased PHEP funding will have an impact.
 - We are committed to maintaining the quality of LRN testing and reporting as the backbone of LRN.
 - We will be working with APHL and our State and local partners to look at strategies for operating LRN in this environment.
 - (I may not say this) The elephant in the room is the question about how many LRN laboratories do we need in the States and cities.
- The Biowatch continues to be a major challenge to LRN.

 - CDC currently supplies kits for the PCR testing of these environmental samples. CDC serving as the source for the assays may change in the near future, but this change will not address the fundamental challenge.
 - The fundamental challenge that testing large numbers of low probability environmental specimens for these agents inevitably generates occasional positive PCR result. CDC and LRN must be able to

understand and be able to verify Biowatch results in order to be able to assist in decisions about appropriate public health action.

- The Biowatch program is now developing new technology (which they call Gen 3), and CDC has concerns about this new technology, which we are actively discussing with DHS. Concerns about:
 - Sensitivity and specificities of the assays.
 - Claims that the new technology generates “confirmed” results.
 - Potential workload impact on LRN from increased number of devices that are continuously sampling and reporting.
- Biowatch program is unpopular is questioned in some quarters, including parts of DHS.
- Adding international laboratories
 - Supplying reagents and equipment on a routine basis to other countries is challenging (customs, export and import licenses, IATA regulations).
- Planning and exercising for specimen surge
 - Some types of events could produce a dramatic increased demand for LRN testing, particularly of environmental specimens
 - How to manage this surge requires scenario planning and exercising that needs to occur.
 - Space and logistics for surge testing is a basic problem that we need to address.

Presentation to CDC Director
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Document 35

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Thursday, May 26, 2011 8:12 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: FW: I'm going to have another private conversation tomorrow with Mike Walter and [REDACTED]



Information:
 BioWatch Gen-3



RE: INFO: ...Multiplex informati...



INFO: Multiplex
 information f...

Hi Toby, in addition to what I sent you last night, here are some additional e-mails providing information on panels 3 and 4. If you want to look at the spreadsheets, I will send the passwords in a follow on e-mail.

Thanks, Mike.

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Thursday, May 26, 2011 12:15 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: I'm going to have another private conversation tomorrow with Mike Walter and Ulana Bodnar

Hi Dr. Merlin, here are some specifics:

We have not seen the results of the SPADA assay validation studies that are finished and the report from DHS is pending.

DHS S&T and the CDC would be much happier if these assays underwent the intense PHAA standards that we are currently pursuing in that they would be the best that they could be from a confidence standpoint for supporting public health decisions.

The CDC was specifically told on more than one occasion that the two vendors competing for the Gen 3 procurement were developing their own assays PCR detection assays because for legal reasons they could not be provided with government-developed assays. We have since found out that this is not true and DHS claims also to not have known.

There were a few different iterations of the assay panels of the APDS system that was field tested in NYC. That system experienced problems and was ultimately pulled with the 3rd panel version of the assays. The fourth version was under development at that time and that is the panel that is now incorporated into the Gen 3 system. Following the demise of the APDS, side by side testing of the APDS and LRN Ba assays showed the APDS assay/chemistry to be 100 fold less sensitive than the LRN assay/chemistry. Same assay, different platforms and chemistries.

Of the 19 Gen 3 panel assays, 13 are current LRN assays and 2 others are the additional VRL3 and VRL 4 signatures that the BioWatch program uses. Inger Damon knows that these assays cross react with various other pox viruses and also knows that these assays experience specificity challenges in the

context of the Luminex multiplexed chemistry. Inger received funding from DHS through an IAA to evaluate the Gen 3 assays, when they were revealed to her and she realized they were the current LRN/BioWatch signatures she did not want to waste time evaluating them because she already knew that they cross react with other pox viruses which is why she is currently working hard to replace VRL1 and VRL2. She is so concerned that they are using these assays in the Gen 3 that she talked to CDC leadership about pulling out of the IAA.

Two of our three [REDACTED] assays and all of the [REDACTED] assays are in the Gen 3 system. Jeannine Petersen has demonstrated that all the [REDACTED] assays cross react with novicida-like environmental organisms. We see a huge amount of environmental cross reactivity in these assays all over the U.S., but in particular for places like Houston. There is an additional [REDACTED] assay in the Gen 3 system from LLNL. I do not know anything about this assay or its performance characteristics. I also do not know what algorithms will be applied to the Gen 3 assays to determine a positive detection.

Recent experience has caused us to strongly suspect that environmental cross reactivity is happening with the [REDACTED] assays, although we have not been able to definitively demonstrate this. It is important to note that NYC is currently not testing BioWatch extracts for [REDACTED] as they have no confidence in the LRN [REDACTED] assays because of the "false positives" which operationally they have no tolerance for. There is no reason to think they would have increased confidence in these assays in a different platform/chemistry.

Nine of these LRN/BioWatch signatures have the probes reversed (bind to the other DNA strand) from their original design. No specific data has been put forth to justify this change and it is not clear that this change does not alter assay performance characteristics.

I think DHS will and possibly rightly, point to changes they have made in the assays, algorithms, engineering, etc. and the successful robust systems testing and even the successful Chicago field test as justification for continuing down this road.

Bottom line for me is that despite whatever changes they have done, or assay and systems validation that they perform, the Gen 3 system with these assays is going to be dead on arrival at the Public Health Labs, especially and importantly at NYC. This will be simply because of a lack of confidence due to previous experience with environmental cross reactivity and the problematic APDS deployment. Confidence in the system is going to be paramount with the current "actionable" nature of the signal that is intended. I just don't see how this is going to be possible.

At the end of the day, if the Gen 3 system goes forward as is and fails it will be a lot of wasted money (billions) and I worry that the CDC (us) might be seen as partially responsible because we knew what was going on.

It could fail simply be being rejected by the Public Health Labs, particularly by an important jurisdiction like NYC. It is interesting that they requested (according to Pillai) that DHS S&T brief NYC stakeholders on why the APDS system failed in parallel with Scott Hughes asking some very pointed questions in Chicago about the parallels between the APDS system and Gen 3.

Please don't hesitate to call me if you want to discuss anything in detail.

Thanks, Mike
[REDACTED]

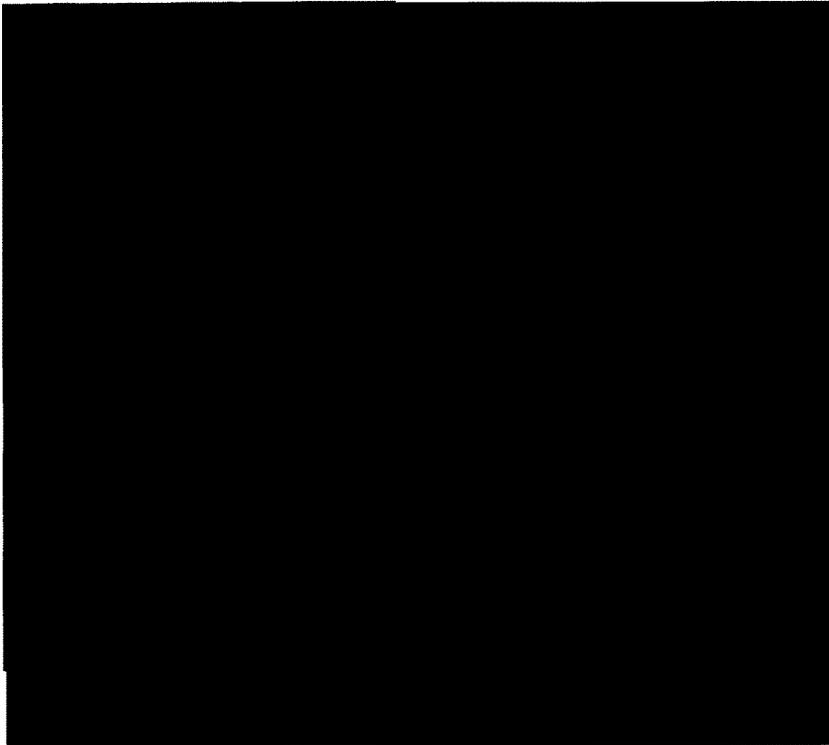
Document 36



From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Friday, June 24, 2011 9:16 AM
To: Farrell, Michael (CDC/OID/NCEZID); Kellogg, Richard (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: FW: 06-23-2011 Incident Notice - BioWatch Notification - F. tularensis, Houston, TX - CLOSED

I understand the disposition of this, but it illustrates to me the squishy definition of a BAR. What is the action here? Who has made the final determination of the action to take? What is that determination? It's obviously not urgent, but I would like to discuss. There seem to be different definitions of a BAR, according to the jurisdiction (e.g. NYC versus Houston).

Toby



Document 37

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 2:04 PM
To: Kellogg, Richard (CDC/OID/NCEZID)
Cc: (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID); Farrell, Michael (CDC/OID/NCEZID)
Subject: RE: LRN Comment on Proposed email to Ranhofer about Biowatch Gen3 signature concern

Richard,
 Thanks very much for your summary. This is very helpful. We had an initial discussion with Joe Foster while you were out. What is driving this forward now is the question of continued participation in the Gen3 development, pending resolution of this issue.
 Thanks,
 Toby

From: Kellogg, Richard (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 1:54 PM
To: Merlin, Toby (CDC/OID/NCEZID); Holmes, Harvey T. (CDC/OID/NCEZID); Farrell, Michael (CDC/OID/NCEZID)
Cc: (CDC/OID/NCEZID)
Subject: RE: LRN Comment on Proposed email to Ranhofer about Biowatch Gen3 signature concern

Toby—Although I do not know Dr. Ranhofer, this matter ostensibly relates to the Gen 3 autonomous bio-monitoring system and anticipated deployment by DHS OHA for BioWatch. At issue is the breach in informational security that I alluded to in the most recent PHAA briefing to DPEI and NCEZID and which from a due diligence perspective would warrant implementation of tighter informational security policies associated with sensitive CDC and LRN information.

Although Inger and Mike may have more detailed information, it appears that sensitive information that may have been shared with LLNL (and which should have at least been controlled by Non Disclosure Agreements to protect intellectual property and sensitive national security information related to detection of biological threat agents) was “tossed over the fence” (i.e. unauthorized transfer with no strings attached) to a commercial platform developer (Northrop Grumman). How this transpired is a conundrum to me since all previous work we have done with LLNL for these type of projects (e.g. BioNet Study) was protected by highly structured and signed NDAs as standard practice.

Beyond the aforementioned legal/informational security issue is the concern that the sequence information that NG now has is likely not the best technical information to support the efficacy of validation (specificity and sensitivity) for some of the high consequence infectious threat agents which the Gen 3 system is supposed to detect in bio-monitoring of the largest populations centers in the US. I believe you can imagine the consequences of the potential false positive testing results that Inger mentions below.

We (LRN) have not pursued resolution more aggressively due to problems with ascertaining the facts on how this series of events transpired and given that some of the other information may have been under derivative classification from the original sources (hence potential legal prosecutions for violation). Also, given lesser situations in the past, there is the potential prospect of needing to involve the FBI.

I believe Inger has outlined what is needed for going forward. We need to understand exactly what transpired that resulted in the current situation and then take actions to institute better informational security/intellectual property protections as well as remediate the known likelihood for generating false positive results in the BioWatch Program (to which CDC is currently a principal partner).

Richard

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 12:52 PM
To: Holmes, Harvey T. (CDC/OID/NCEZID); Kellogg, Richard (CDC/OID/NCEZID); Farrell, Michael (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: RE: Proposed email to Ranhofer about Biowatch Gen3 signature concern

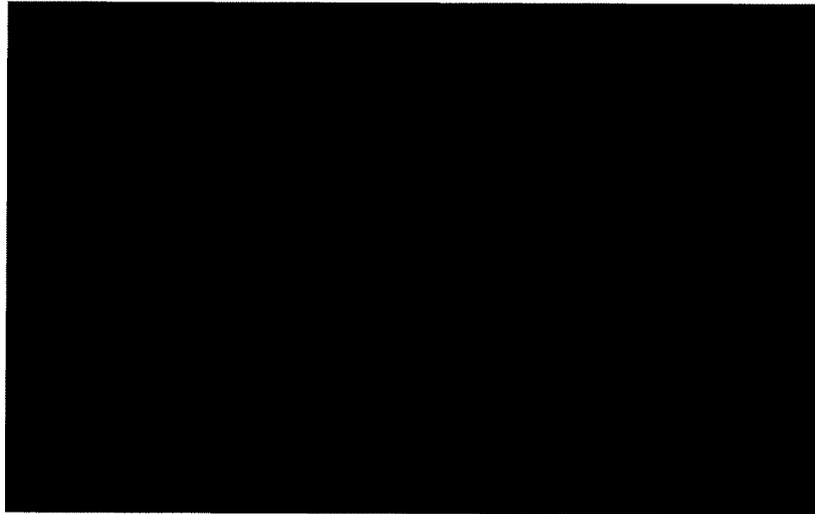
Harvey, Richard, and Mike – I forgot to copy you just now on this email. Please read and advise.
Thx,
Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, June 09, 2011 12:43 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Proposed email to Ranhofer about Biowatch Gen3 signature concern

[REDACTED]

Thanks for drafting this. I just got back to my office from the PHPR retreat. I don't know Dr. Ranhofer, but I would be happy to send this. Since the issue extends beyond variola, we might want it to come from either Joe Foster or me, though. I'm copying Harvey, Richard, and Mike for their awareness and comments.

Thanks,
Toby



Document 38

[REDACTED]

From: Holmes, Harvey T. (CDC/OID/NCEZID)
Sent: Wednesday, August 10, 2011 1:53 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Chaitram, Jasmine (CDC/OID/NCEZID); [REDACTED]
Subject: FW: Multiplex

For awareness... as the saga continues.

Harvey

From: Holmes, Harvey T. (CDC/OID/NCEZID)
Sent: Wednesday, August 10, 2011 1:51 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Multiplex

[REDACTED]

I believe that's the point...our conversations with DHS leadership on September 11, 2008 during our VTC revealed the fact that CDC leadership did NOT accept or approve Multiplex Panel 1/ Panel 2 equivalency, see summary of VTC below.

And in fact, during that VTC teleconference.... CDC politely 'agreed to disagree' with DHS' position that the data was equivalent.

As a reminder, the VTC was scheduled because of comments made by CDC leadership during BioWatch National Meeting in Philadelphia....emphasizing that multiplex performance data had not been reviewed or seen by CDC and that CDC disagreed with DHS's statement that we had approved it.

Harvey

From: Holmes, Harvey T. (CDC/CCID/NCPDCID)
Sent: Friday, September 12, 2008 9:51 AM
To: Holmes, Harvey T. (CDC/CCID/NCPDCID)
Subject: Highlights of BW Multiplex VTC...Additional Thoughts

Additional thoughts:

- Senior-level DHS personnel became aware/discovered that DBPR leadership did NOT accept or approval Multiplex Panel 1/Panel 2 Equivalency.
- It was then revealed that Dr Meyer had accepted them.
- It was clearly stated that Dr Meyer was not authorized to accept/approve such decisions but that authority resides within the BRRAT Lab
- The reason BW Program is in its current situation....is bcs CDC/DBPR/SME have not been involved in the decision process for selecting Panel 2, Panel 3 or the acceptance of APDS.
- DHS leadership have made key multiplex panel-selection decisions based on misinformation/mis-placed authority w/o the approval or authorization of DBPR's leadership
- DHS has chosen not to directly engage with DBPR's leadership related to Panel 2 and 3 selection.

From: Holmes, Harvey T. (CDC/CCID/NCPDCID)
Sent: Thursday, September 11, 2008 1:56 PM

To: [Redacted]
Cc: [Redacted]
Subject: Highlights of BW Multiplex VTC...

- Lisa,
- Panel 3 will continue to be used with any signal/signature requiring WET REAGENT verification
 - WET REAGENT verification is a 'short-fix' while Panel 3 undergoes a 'fast-track' validation process.
 - Expansion of Multiplex is on hold, until Panel 3 validation is completed
 - I agreed to serve as CDC/POC to assist Dr Pillai (and LLNL) in defining the performance data needed to meet CDC's approval....an experimental design is expected in a week.
 - Dr Bowen and I focused on the lack of performance data for Panel 3 and that we were not comfortable, from a data-driven decision process, to endorse the deployment of Panel 3.
 - This opinion was not shared by the majority, if not any, DHS participants.
 - Indeed, when asked whether anyone would discontinue the use of Panel 3. .CDC was the only voice saying 'yes'
 - ...
 - A solution/proposal to move forward with the current BioWatch Multiplex situation will be sent directly to you for consideration and approval by CDC leadership.
 - Again, my overall sense was that CDC's perspective was not shared by most of participants.

Segaran,
I'll give you a call tomorrow to move forward with an experimental design....

Bob,
Lisa will be out of the office most of next week, if you could include Sherrie Bruce, Mike Bowen, and me on the solution/proposal

Respectfully,
Harvey

From: [Redacted]
Sent: Wednesday, August 10, 2011 12:14 PM
To: [Redacted]
Cc: [Redacted]; Holmes, Harvey T. (CDC/OID/NCEZID); [Redacted]
Subject: RE: Multiplex

Dr. Bowen, Thank you again for your response. I just need to clarify one point. Do you have anything in the files that documents (an email or a decision memo) that Dr. Meyer approved on behalf of the CDC, assay panel 1 and panel 2 as equivalent for **Multiplex/Bioplex in 2007**? I ask that because my files indicate that Dr. Meyer was relieved as the BRATT Director in **Oct of 2006**. That would indicate that he **did NOT** have the authority to make that approval. Please provide confirmation if at all possible that Dr. Meyer did leave the BRATT Director's job in Oct 2006. I have the Email/Memo authored by Dr. Rotz that lays out exactly what Dr. Meyer's role and authority was as a detailee from the CDC to DHS, but it was written in **Oct of 2007**. I am looking for definitive prove that the CDC did make the approval of panel 1 and panel 2 as equivalent with a date so that it can be shown that when Dr. Meyer made that decision he did or did not have the authority to make such a decision. It all depends on when he (Meyer) left the CDC as the BRATT Director and if any documentation exists that the CDC ever approved panel1 and 2 as equivalent. .

Thank you so much for your continued cooperation and patience ,

From: [Redacted]
Sent: Thursday, August 04, 2011 1:14 PM
To: [Redacted]
Cc: [Redacted]
Subject: RE: Multiplex

[REDACTED]

Panel 1 was never deployed. Panel 2 was the first panel used in the field. The BRRAT Lab has electronic records with all the panel 1 test data. I no longer have access to these records. As I recall, panel 1 was tested extensively at CDC but there were some deficiencies in the validation of poxvirus and Burkholderia signatures.

The attached file contains a presentation made by DHS/LLNL during a CDC/DHS teleconference held on Sept. 1, 2008. Page 4 contains an assay development timeline.

During the teleconference, it was revealed that the 2007 decision by CDC to accept panel 1 and panel 2 as equivalent was made by Dr. Meyer.



From: [REDACTED]
Sent: Thursday, July 28, 2011 2:45 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Multiplex

Dr. [REDACTED]
Dr. [REDACTED]
Dr. [REDACTED]

Good Afternoon All!

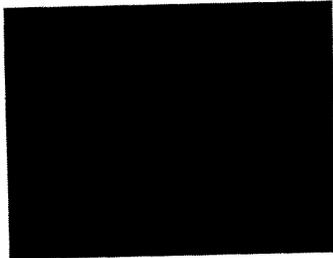
Just to refresh everyone's memory, I, [REDACTED] (DHS- Office of the Chief Security Officer) and [REDACTED] (Deputy Chief, Internal Security and Investigations Division) are completing the investigation into the development, deployment and eventual stand down of Multiplex/Bioplex and APDS Gen 2.5 .

For a long time now the investigation has continued under the belief that the initial panel (Panel 1) for the Multiplex/Bioplex was initially co-developed at the CDC by the CDC (Rich Meyer and LLNL) and was validated and approved. The problems began when all the changes were made to panel 1 thus becoming panel 2 and eventually panel 3. I am learning now that even panel 1 had problems and was not validated by the CDC for deployment/use.

I would greatly appreciate if any of you can remember the processes involved here and provide any information as it relates to Panel 1 being approved or not. Of course, documentation that would substantiate that panel 1 was approved or not for use and/ or any documentation/communications between the CDC, LLNL and DHS as it relates to the Multiplex/Bioplex assay panels being validate/approved by the CDC would be a huge help. If the panels were not

validated and/ or approved by the CDC any documentation or communications between the CDC and DHS advising that status would be a huge benefit in the investigation.

Thank you all very much for your patience, understanding and continued cooperation in this endeavor,



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Document 39

[REDACTED]

From: Kellogg, Richard (CDC/OID/NCEZID)
Sent: Friday, September 09, 2011 12:23 PM
To: Sosin, Dan (CDC/OPHPR/OD); [REDACTED]; Merlin, Toby (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: RE: Feedback on Tara O'Toole Discussion

Dan—you raise a number of issues that likely require more detailed discussion but my initial feedback is:

Item #1—When FDA reviewed the stringency and process for PHAA assay development their conclusion (setting GMP instrument issue aside) was that it would lead to 510k clearance for IVD medical device use.

Item #2—Current dilemma with OHA BioWatch is that they currently want to use the PSAA standard to qualify their assays for pulling Public Health level action triggers. PSAA (SPADA via AOAC contracts) was meant to provide a test qualification standard for screening assays used by traditional first responders.

Item #3—The NIST issue has some prior (forgotten history) on how the policy path was decided by DHS. There is not actually a hard requirement to use the SPADA type process. There are actually exemptions, which include exigencies associated with preparedness and response, that DHS decided not to take. Joel Ackelsburg (NYC) and I made this clear to them back in the day. The “pay to play” model that they developed has been an acknowledged failure relative to sustainment with the assay developers for the first responder community. I especially know this from my last two years of work on (and report from) the interagency Hand Held Assay WG with Bert Coursey (at DHS from NIST) and Matt Davenport (at DHS and funding SPADA with AOAC contractor).

Richard

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Friday, September 09, 2011 11:40 AM
To: Kellogg, Richard (CDC/OID/NCEZID); [REDACTED]; Merlin, Toby (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: Tara O'Toole

I bumped into Tara while visiting DHS yesterday and we rode up the elevator together. I took the opportunity to put in a good word for Pillai and our work with him and Tara jumped right into the PHAA/BioWatch issue (I rode to her floor for a bit more time to talk!).

Tara asks good questions and wants to do the right things here, but also wants our support, particularly in communicating with Alex Garza and OHA if we think PHAA is the right standard.

1. I shared support for the PHAA model developed over multiple years of deliberation and she asked if it was “too rigorous”. I find it hard to believe that when it comes to taking actions involving human life we can be too rigorous, the cost balance does seem to be an issue. In addition to being sure ourselves that this is the right standard, we might want to consider getting support elsewhere. FDA commented on the process, I believe, but don't recall how that endorsement came out.
2. I shared that DPEI had some success at the BW meeting addressing concerns about the Gen3 process, but was not definitive on what that understanding was. It seemed that before the BW meeting that there was discussion about the Gen3 conops changed to not being public health actionable. It would help to clarify that point. Even though the need to meet with Alex on this particular point was addressed, it is clear that Tara feels her program would benefit our ongoing engagement with him to support their work.
3. The monkey wrench about NIST or other national standards organizations seems to still be an issue. Tara indicates that NIST is hugely expensive and nobody wants to pay for that. Without it, we will need to address

why we think PHAA is different (and does not require blessing of a national standards organization) and why this is the right standard for this high consequence application.

It might be good to follow up with Pillai to be clear what S&T wants/needs from us to keep this methodology in play.

Thanks,

Dan

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Mailstop D-44
Atlanta, GA 30333

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Document 40

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Friday, September 09, 2011 12:36 PM
To: Sosin, Dan (CDC/OPHPR/OD)
Subject: RE: Feedback on Tara O'Toole Discussion

Dan,
 I think this warrants another 1:1 meeting of just you and me. I will look at the calendar and schedule.
 Thanks,
 Toby

From: Kellogg, Richard (CDC/OID/NCEZID)
Sent: Friday, September 09, 2011 12:23 PM
To: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: RE: Feedback on Tara O'Toole Discussion

Dan—you raise a number of issues that likely require more detailed discussion but my initial feedback is:

Item #1—When FDA reviewed the stringency and process for PHAA assay development their conclusion (setting GMP instrument issue aside) was that it would lead to 510k clearance for IVD medical device use.
 Item #2—Current dilemma with OHA BioWatch is that they currently want to use the PSAA standard to qualify their assays for pulling Public Health level action triggers. PSAA (SPADA via AOAC contracts) was meant to provide a test qualification standard for screening assays used by traditional first responders.
 Item #3—The NIST issue has some prior (forgotten history) on how the policy path was decided by DHS. There is not actually a hard requirement to use the SPADA type process. There are actually exemptions, which include exigencies associated with preparedness and response, that DHS decided not to take. Joel Ackelsburg (NYC) and I made this clear to them back in the day. The “pay to play” model that they developed has been an acknowledged failure relative to sustainment with the assay developers for the first responder community. I especially know this from my last two years of work on (and report from) the interagency Hand Held Assay WG with Bert Coursey (at DHS from NIST) and Matt Davenport (at DHS and funding SPADA with AOAC contractor).
 Richard

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Friday, September 09, 2011 11:40 AM
To: Kellogg, Richard (CDC/OID/NCEZID); Merlin, Toby (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: Tara O'Toole

I bumped into Tara while visiting DHS yesterday and we rode up the elevator together. I took the opportunity to put in a good word for Pillai and our work with him and Tara jumped right into the PHAA/BioWatch issue (I rode to her floor for a bit more time to talk).

Tara asks good questions and wants to do the right things here, but also wants our support, particularly in communicating with Alex Garza and OHA if we think PHAA is the right standard.

1. I shared support for the PHAA model developed over multiple years of deliberation and she asked if it was “too rigorous”. I find it hard to believe that when it comes to taking actions involving human life we can be too rigorous, the cost balance does seem to be an issue. In addition to being sure ourselves that this is the right

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Atlanta, GA 30333

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Document 41

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, October 13, 2011 10:11 AM
To: 'Pillai, Segaran'
Subject: RE: Signatures on current PHAA document

Pillai,
 Thanks for the clarification. That is very helpful. I have not understood exactly why Biowatch is hung up over PHAA, except that occasionally they want to refer to Gen-3 results as public health actionable (and I have disagreed with them).

Thx,
 Toby

From: Pillai, Segaran [mailto:Segaran.Pillai@dhs.gov]
Sent: Thursday, October 13, 2011 10:07 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
 Please share with Beth, that there were three process to support standards for biodetection out of DHS S&T.

1. Public Safety Actionable Assay which was intended to support the evaluation of Field Screening Assays manufactured of commercial companies for First Responder Use. The conops associated with this effort is directly attributed to safety related actions such as evacuation of buildings, decon of potentially exposed individuals, expediting the transfer of sample to the LRN for confirmation etc. In addition to the above regardless of whether a sample is positive or negative, the sample is still forwarded to a LRN lab for secondary testing to eliminated False Positives and False Negatives

2. Federal Standards for Assay Performance and Equivalency. This was specifically design to support and fulfill the National Biomonitoring Program and under a MOU signed among Asst Sec. from DoJ, DoD, HHS, DHS and USPS which all had a biomonitoring program at that time. The task was delegated to DHS S&T to implement a process for establishing Assay performance Equivalence among the programs so the federal partners recognize the credibility to support the initiation public health response in a timely manner. This is the effort Garza is referring to. We actually briefed CDC leadership about a year ago during Lisa Rotz time to Ali, Beth, Dan and others and they already signed off on it just like all the other agencies except of OHA and USPS at the current time. The issues with USPS is being dealt by NSS because they just don't have the money to continue and operate the BDS and they are the process of reevaluating the program (please hold this information close. This is not for sharing at the current time). With regards to OHA, we have forwarded all the versions multiple time over the past several years and they keep ignoring and not truly engaging in the effort although we have tried many time. They have come up with multiple excuses over the years and questions which we had address all of them. So, I don't know what their true concerns are, but for a high profile program like BioWatch, it will be in their best interest to put their assays and system through a robust process to ensure they function and operate at an optimal level to support the Nation with an early warning of a biological attack. Several months ago Mike Farrell from the BRRAT lab evaluated the Assay Chemistry being used by the NG Gen 3 system at the request of OHA BioWatch program. His finding were similar to our findings when we did the evaluation of Gen 2.5 the Bioplex assays. That is the assay chemistry is fundamentally flawed and have to be addressed immediately and had shared this with OHA. As per Mike, they ignored is and upon Mike revisiting this issue, they shared with him that they will fix it after procurement which is highly troubling (please check with Mike for specifics). I don't know if OHA BioWatch is worried that if they were to put the assays through the FSAPE process they might failed and is trying to bypass it. They have insisted to us that the PSAA process is a better process and as such want to put their systems through that process which was intended for Public Safety Actions. My thoughts on this is that they can go through the process and if they get a positive signal, they can retrieve the sample from the detectors and take to the closest LRN Lab for confirmation, however if they were to miss a detection, there is no mechanism to capture it (referring to false negative result) simply because the negative samples will not be retrieved and taken to a LRN Lab for secondary testing.

3. Public Health Actionable Assays. This is specifically to support the assay development, evaluation, validation and certification of the assays deployed and employed through the CDC LRN. This has nothing to do with OHA or BioWatch.

This is strictly related to the LRN assays to support National BioPreparedness and Defense and Public Health Surveillance mission. These assays are intended to be highly robust for use in a LRN laboratory to evaluate environmental samples that comes to the lab, support epi investigation associated with a bioterrorism event as well as clinical sample to support medical and clinical intervention. We worked with many folks from CDC all the way from LRN TRC director, LRN Manager, Environmental Microbiology Director, SME Lab Directors, Branch Chiefs and Division Directors for the input and contribution to the PHAA plan simply because we wanted to ensure that the assays deployed and employed through the CDC LRN are highly robust to support the mission.

Hope this helps and I am on travel to the West Coast and will return back to the office next week. If you would like to chat, please let me know and I can give you a call at your convenience. Take care.

Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Thu Oct 13 08:53:21 2011
Subject: RE: Signatures on current PHAA document

Pillai,

I'm going to get the specifics from Beth again, because I want to be sure I get them right, and I will send them along later. I think they primarily have to do with the impression that the Biowatch program and Gen-3 will have to meet PHAA standards and be approved by PHAAC as a condition of deployment. But, let me see exactly what Beth says.
 Toby

From: Pillai, Segaran [mailto:Segaran.Pillai@dhs.gov]
Sent: Thursday, October 13, 2011 8:31 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Re: Signatures on current PHAA document

Hello Toby,
 Can you please share with me the concerns raised by Alex to Beth pertaining to the PHAA? Thanks and appreciate your help and assistance on this. Take care.

Pillai

Sent using BlackBerry

From: Merlin, Toby (CDC/OID/NCEZID) <tfm5@cdc.gov>
To: Pillai, Segaran <Segaran.Pillai@dhs.gov>
Sent: Wed Oct 12 11:42:41 2011
Subject: Signatures on current PHAA document

Pillai,

I met with Beth Bell and other members of our Center leadership yesterday, and we discussed the requested signatures on the PHAA document. Beth tells me that she recently met with Alex Garza from DHS-OHA where he explicitly raised his concerns about PHAA. We seem to be at a juncture where DHS-S&T and DHS-OHA need to resolve their internal disagreements over PHAA and present us with a PHAA document for CDC signature that has cleared stakeholders at DHS. Personally I believe there is a critical need for standards and the differences between DHS-OHA and DHS S&T are resolvable.

I am willing to discuss and help in any way you like.

Thanks,

Toby

Document 42

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Wednesday, October 19, 2011 7:48 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Toby, Agree. The amount of animosity between the 4th and 6th floor is pretty evident from time to time. More than happy to chat whenever your schedule permits or during our time in ATL.

Travel safe,
Jim

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, October 19, 2011 5:23 AM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim, We at CDC often seem to be caught in the middle of the DHS-OHA DHS S&T dispute. I actually think a lot of this could be resolved, at least in regard to the substantive issues, if the parties put their minds and hearts to it. We should certainly talk about this.

Best,
Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 9:23 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Hi Toby,

Just in and seeing your message...I'm still waiting on my DHS blackberry.

Alex and I chatted a bit about these issues. The OHA-S&T looks to not be getting better.

Feel free to ring me up if you'd like, I'll be up for a bit.

Thanks for the potential dates Toby..I'll forward down to the folks in ATL doing the scheduling.

Jim

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 18, 2011 5:49 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim,

Here is the list of things that I would like us to discuss:

- 1) The interface between Biowatch and public health

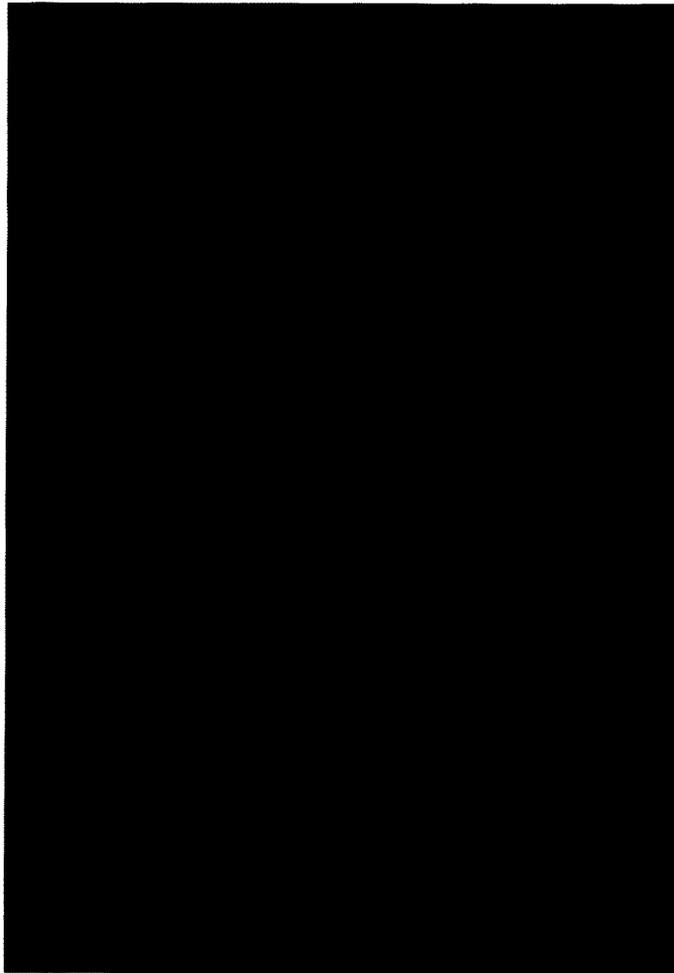
- 2) Our concerns about the Gen-3 program
- 3) The strained relationship between DHS-OHA and DHS-S&T on standards for testing for biothreat agents.

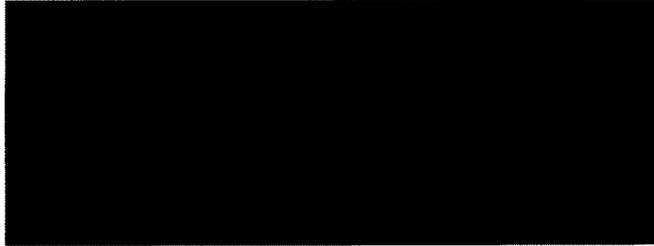
I'm going to send you a copy of my calendar for the dates when you'll be in Atlanta. Let me know what works best for you for us to meet. I am tentatively scheduled to travel to DC on November 2 for an anthrax meeting, but that may change.

I very much enjoy working with Mike Waiter and Ulana, and I know Sally Philips and she's great. I think you've got a very good job.

Best,

Toby





From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 5:15 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Should have said....No worries. I'd say enjoy but....

Big Fingers on an iPad

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 18, 2011 4:52 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim, This meeting here just keeps going on and on, and I can't break away. I am going to send you an email a little later that outlines some things we can talk about later.
Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 1:06 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: BioWatch and such

Toby,

Both of those times are in my prime sleep band but for you I'll make an exception...ha,ha

I'm good with either and should be able to accommodate...your call, literally and figuratively.

Looking forward to chatting and working with you as well my friend.

Thanks,
Jim



From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, October 18, 2011 12:51 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: BioWatch and such

Jim,

It's going to be great having you at DHS-OHA and to get to work with you again. As you have heard from Ulana, I am in regular touch with her and Mike about the Biowatch program and other related laboratory testing activities. I am traveling this week, but I would like to talk with you for maybe 30 minutes before you head over to Biowatch. This afternoon after 5 or tomorrow morning before 9 would make it easiest to work around my anthrax meetings here.

Best,

Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Tuesday, October 18, 2011 10:39 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: BioWatch and such

Hi Toby,

Hope all is well on your side of the Mason-Dixon Line and the new job is working out.

I've chatted with Ulana a bit and will be heading over to BioWatch on Friday to spend some time so I wanted to check in to see if there were any issues you'd like me to look in on while I am there. I realize that you and your folks are pretty hardwired there already but thought I would ask.

Planning on being down your way on 31OCT-2NOV and hope to get an audience with you and Steve to see how I can facilitate for you up this way.

Look forward to catching up in a slower paced (at least for me) environment than the EOC.

James Hayslett, PharmD, MPH
DHS/OHA Liaison Officer
DHHS/CDC/OPHPR/OD
Washington, DC

██████████

Document 43

[REDACTED]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, November 17, 2011 2:59 PM
To: Hayslett, James (CDC/OPHPR/OD)
Cc: [REDACTED] (CDC/OID/NCEZID)
Subject: Follow-up from Toby Merlin to NYC DOH

Jim,
This outlines some of the steps on improved guidance that we/CDC need to work on with Biowatch.
Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, November 17, 2011 2:51 PM
To: 'Colin Stimmler'; Welsfuse, Issac (CDC health.nyc.gov); Beth Maldin
Cc: [REDACTED]
Subject: RE: Draft DHS OT&E Guidance

Colin, Beth, and Issac,

Thanks for asking us to the exercise yesterday. It was very helpful for us both to see the dynamics of the situation you all are in with regards to a single BAR. Thanks also for the OT&E document.

Issac, I would like an electronic copy of your "Asks" one pager, if you could send it to me.

On my call today with Mike Walter and Ulana Bodnar, we did discuss several of the issues that were raised in our meeting at DOH yesterday. And, here's the follow-up:

- 1) Biowatch Program and CDC agree on the need to develop federal guidance for how jurisdictions should handle a single BAR. Mike Walter is going to take the lead with CIDRAP in setting up a focus group with Biowatch, CDC, NYC and a few other large cities to work on this.
- 2) Biowatch Program and CDC agree on the need to develop federal guidance or plans for management of environmental sampling after detection of an event. Mike Walter is going to take the lead on this.

I will send you follow up on the others items discussed later.

PS: We got a taxi pretty quickly on Broadway, got to the hotel and then to the airport with plenty of time to spare.

Thanks,

Toby

From: Colin Stimmler [mailto:cstimmler@health.nyc.gov]
Sent: Thursday, November 17, 2011 11:28 AM
To: Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Cc: Beth Maldin; Welsfuse, Issac (CDC health.nyc.gov)
Subject: Draft DHS OT&E Guidance

Hi Toby [REDACTED].
Thanks again for meeting with us yesterday. As requested attached is the draft DHS OT&E Guidance. Let me know if you need anything else.

Colin

Colin Stimmler

Document 44

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, November 17, 2011 2:57 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: FW: Letter we/DPEI are sending to DHS-OHA about our concerns on Gen-3 ORD

Jim,

I will send you emails to keep you in the loop on major activities. As I discussed with you when you were here, we have sent this letter below to Mike Walter and Bob Rahnhofer. I spoke with Mike today, and it seems that it was acceptable. Beth has let Ali know.

I understand that the ORD is currently derailed while the sensitivity issue is being addressed. It's interesting. I don't think anyone actually knows the sensitivity of the current PSU system for detecting bacteria or viruses in actual aerosols.

Best,

Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Tuesday, November 15, 2011 11:10 AM
To: Bell, Beth (CDC/OID/NCEZID)
Subject: Letter we/DPEI are sending to DHS-OHA about our concerns on Gen-3 ORD

Beth,

Below and attached is the letter that Mike Farrell (who serves as our technical representative to the Gen-3 ORD) and I drafted this past weekend, and which we are sending to the Gen-3 team at DHS-OHA. It identifies our major areas of concerns about the device and technology. One thing that it doesn't mention is that DHS-OHA is proceeding with operational testing and evaluation at 4 or 5 select cities, before they have gotten a device that actually works.

Thanks,

Toby

November 14, 2011

Mr. Robert Rahnhofer
Acquisition Director, Gen-3 Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dr. Michael Walter
Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dear Bob and Mike:

This letter is in response to your emails dated Friday, October 28 and Wednesday, November 9 requesting CDC concurrence on the updated Operational Requirements Document (ORD) version 2.1 dated September 12, 2011 for the Blowatch Gen-3 Autonomous Detection System.

From our discussion at the annual BioWatch conference in Tampa, FL, your emails, and the comment resolution matrix, we understand that you feel that our concerns about the Gen-3 system can and will be addressed without modifying ORD v2.1. With your assurances that our concerns will be addressed as the procurement process moves forward and before operational deployment, we are willing to provide our concurrence to ORD v2.1. We are requesting that you acknowledge the concerns that we feel need to be addressed for an acceptable operational system:

1. The system sensitivity specified in [REDACTED] is not sufficient to detect concentrations of organisms in aerosols that can cause disease in humans. From your email dated October 28, it appears that a change in sensitivity might be forthcoming.
2. The key performance parameter for the threshold only specifies *Francisella tularensis* and does specifically exclude the *F. tularensis* subspecies or near neighbors known to cause frequent BARS in the current BioWatch system.
3. There are concerns specific to the current NG-ADS system, which become material should that system proceed into the next phase of the procurement:
 - a. Thirteen of the pathogen detection assays being used in the current NG-ADS system are LRN assays of which several of them, in particular YPMT2, YPMT9, YPMT12, YPMT16, FT1, FT2, and FT3 are known by both our programs to cross react with non-target organisms endemic in some regions of the country. These supposed near-neighbor organism are collected on the BioWatch air filters and have frequently been the cause of false positive laboratory results. In our opinion, these assays are not suitable for the purposes stated for the Gen-3 system.
 - b. Nine of the pathogen detection assays being used in the current NG-ADS system, in particular BA2, MP2, MP3, YPMT2, YPMT9, YPMT16, VRL1, VRL2, and VRL4 seem to have detection probe designs that are not complementary to the captured biotinylated PCR product strand, but rather complementary to the PCR product strand that is not captured. Despite the fact that this flawed chemistry has demonstrated that it can detect pathogens from near neighbors, it is not clear exactly how this happens. Either the formation of a tripartite structure between the probe and both the biotinylated and non-biotinylated PCR product strands occurs, or an overabundance of the biotinylated forward primer that exists after the PCR reaction may be responsible. Regardless, this flawed chemistry/design is extremely worrisome especially in the context of a constantly changing and complex sample matrix such as an air collection sample.

We understand that the procurement process is complicated, and we hope this provides an adequate mechanism of both acknowledging our concerns that need to be addressed and providing concurrence to the ORD.

We would be happy to discuss further, if you like.

Sincerely,



ORD 2.1 contingent
concurrence ...

November 14, 2011

Mr. Robert Ranhofer
Acquisition Director, Gen-3 Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

Dr. Michael Walter
Program Manager
Biowatch
Office of Health Affairs
Department of Homeland Security

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the formation of a tripartite structure between the probe and both the biotinylated and non-biotinylated PCR product strands occurs, or an overabundance of the biotinylated forward primer that exists after the PCR reaction may be responsible. Regardless, this flawed chemistry/design is extremely worrisome especially in the context of a constantly changing and complex sample matrix such as an air collection sample.

We understand that the procurement process is complicated, and we hope this provides an adequate mechanism of both acknowledging our concerns that need to be addressed and providing concurrence to the ORD.

We would be happy to discuss further, if you like.

Sincerely,

Document 45

[REDACTED]

From: Beth Maldin <bmalidin@health.nyc.gov>
Sent: Thursday, November 17, 2011 3:35 PM
To: Merlin, Toby (CDC/OID/NCEZID); Colin Stimmeler; Weisfuse, Issac (CDC health.nyc.gov)
Cc: [REDACTED]
Subject: RE: Draft DHS OT&E Guidance
Attachments: BioWatch Asks of CDC 20111115.docx

Thanks again for coming and glad to hear your trip home was uneventful! We look forward to hearing more about 1 and 2 below as well as anticipated timelines. We will also be interested in sharing what we have developed so far to provide a starting point and get your feedback.

Thanks again!
 Beth

From: Merlin, Toby (CDC/OID/NCEZID) [mailto:tfm5@cdc.gov]
Sent: Thursday, November 17, 2011 2:51 PM
To: Colin Stimmeler; Isaac Weisfuse; Beth Maldin
Cc: [REDACTED]
Subject: RE: Draft DHS OT&E Guidance

Colin, Beth, and Issac,

Thanks for asking us to the exercise yesterday. It was very helpful for us both to see the dynamics of the situation you all are in with regards to a single BAR. Thanks also for the OT&E document.

Issac, I would like an electronic copy of your "Asks" one pager, if you could send it to me.

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Thanks,

Toby

From: Colin Stimmeler [mailto:cstimmle@health.nyc.gov]
Sent: Thursday, November 17, 2011 11:28 AM
To: Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Cc: Beth Maldin; Weisfuse, Issac (CDC health.nyc.gov)
Subject: Draft DHS OT&E Guidance

Hi Toby & Steve,

Thanks again for meeting with us yesterday. As requested attached is the draft DHS OT&E Guidance. Let me know if you need anything else.

Colin

Colin Sfirmier
Director - BioWatch Planning & Special Projects
Office of Emergency Preparedness and Response
NYC Dept of Health & Mental Hygiene
2 Gotham, Queens (6-94)



Asks for the Federal Government: Before, During and After a BioWatch Actionable Result (BAR)

1. Federal public health planning and response
 - a. There is no detailed consensus on what a federal response to a BAR would look like (roles, responsibilities)
 - b. Not clear who at the Federal level has responsibility for developing and coordinating potential response to a BAR
 - c. Federal indemnification for the City of New York in the event of a false reactive identification of an organism relating to a BAR.
2. Federal guidelines: remediation methods and re-occupancy criteria
 - a. Remediation: No standard methods for remediation so every jurisdiction may approach this differently
 - b. Re-occupancy: Lack of realistic standards for remediation and re-occupancy (Following large-scale contamination the objective to remediate and re-occupy contaminated buildings within weeks to months, not years). For example, estimates range from 50 – 300+ years to complete NYC cleanup after wide area anthrax release using the 2001 remediate and re-occupancy standards (federal standards: zero acceptable risk)
 - c. Characterizing the scope and scale of the incident: Characterizing the scale and scope of incident- including testing of subway train ventilation filters to rule-in likelihood of subway exposures
 - d. Equipment: Evaluate use of handheld or portable field instruments for use in characterization and in remediation post-BAR (rather than sending samples to a lab), critical because Public Health Lab will not be able to analyze the number of samples that we imagine will be collected for full site characterization and remediation after a bio contaminating event in an indoor facility
 - e. Decontamination: Human decontamination & Guidance on disposal or washing of clothing
 - f. Surrounding area: Recommendations for buildings in the area of an outdoor and indoor facility BAR (e.g., evacuate, close windows, turn off HVAC, etc.) and setting perimeter.
3. Modeling Tools
 - a. Expand current BioWatch Indoor Reach Back Center (BIRC) modeling from current indoor locations to adjacent facilities, subways, and outdoor areas to understand impact of outdoor venting
 - b. Need further modeling on the risk in subways and re-suspension after continued operation.
4. Laboratory support
 - a. Surge capacity for laboratory materials- reagents and environmental sampling materials
 - b. Coordination of sending out samples for surge testing within LRN
 - c. Guidance on post-BAR surge testing (e.g., direct verification without screening; efficacy of increasing the tempo of PSU collections and testing)
 - d. Continued engagement with DHS on Gen 3 program.
5. Surge capacity
 - a. Epidemiology staff surge capacity
 - b. Medical Surge capacity
 - c. Environmental Sampling surge capacity – sampling personnel to assist with incident characterization and mitigation including return to service of critical infrastructure and verification of remediation.
6. Timing and Amount of assets for Mass Prophylaxis
 - a. Timing, status, and availability of Anthrax vaccine and other therapeutics, including anthrax immune globulin or antitoxins, and materials needed for mass casualty response.

Document 46

[REDACTED]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Sunday, May 06, 2012 11:11 AM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: Follow-up on NYC Biowatch concerns

Beth,

I got a chance to speak briefly with Jay Varma about the NYC Biowatch concerns. I think the bottom line is that NYC public health feels that public health is struggling to be heard in a program that is dominated by DHS and law enforcement but which has huge implications for public health departments. This seems to be most acute in NYC, where the police and fire department dominate the policy making.

As you know we have been aware of these concerns and have been taking steps to improve the situation. I thought it would be useful for me to enumerate them explicitly, so that you are aware of what we are doing the next time this comes up:

- 1) I have been taking a much more active role in engagement with Biowatch than previous Division leadership.
- 2) I have appointed new Division liaisons to the Biowatch program, which should provide us a much more effective voice.
- 3) I am personally attending the Biowatch national meetings where major policy decisions are discussed.
- 4) We are reviewing and commenting on the new Biowatch indoor and outdoor guidance documents.

The limitation of this, of course, is that DHS/Biowatch is still in the lead on these policies, and it will take some time to influence the direction. Steve Papagiolas and I will be seeing members of the NYC Biowatch Advisory Committee at the Biowatch indoor guidance meeting this week, and I will review with Colin Stimmler from NYCDOMMH the steps we are taking.

Toby

Document 47

[REDACTED]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 16, 2012 12:08 PM
To: Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [REDACTED], Holmes, Harvey T. (CDC/OID/NCEZID); [REDACTED]
Subject: RE: Question to follow-up Biowatch Indoor Working Group

Let's walk/talk through this with you, Geoff, Steve and Mike by phone or in person, so that I am sure that I understand.
Thx,
Toby

From: Chaitram, Jasmine (CDC/OID/NCEZID)
Sent: Wednesday, May 16, 2012 12:02 PM
To: Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Cc: [REDACTED], Holmes, Harvey T. (CDC/OID/NCEZID)
Subject: RE: Question to follow-up Biowatch Indoor Working Group

More information to answer question : Have the number of Ft screens positives and BARS decreased since the implementation of CRP reagents and the QA program?

From August 2010 to August 2011 there were approximately 635 out of 1828 (35%) screen reactives for Ft with a CT value ≥ 40 . Of the 23 BARS reported in the email below for the same time period, 8 had all 3 signatures with CT value ≥ 40 . Four of these were in Houston

From August 2011- May2012 there were potentially 91 screen reactives with CT value ≥ 40 , most of which were called negative. If these were all called reactive there would have been about 20% of reactives with CT over 40. This includes reactives on the CRP panel.

The number of reactives decreased from 1828 to 370. The number of BARS for Ft has decreased as well. I believe the change in CT value and the QA program contributed to this decrease.

Jasmine
LRN Program Office

From: Chaitram, Jasmine (CDC/OID/NCEZID)
Sent: Thursday, May 10, 2012 10:42 AM
To: Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Cc: [REDACTED]
Subject: RE: Question to follow-up Biowatch Indoor Working Group

I have to look at data more closely and of course there are a number of other factors that contribute to whether or not an FT BAR is declared. Here is initial assessment of number of FT BARS for comparable time periods. In August 2011 the program implemented the new CT cut off of 40 cycles.

August 2010-May 2011: 23
August 2011-May 2012: 4

Jasmine

LRN Program Office

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 09, 2012 12:32 PM
To: [REDACTED] Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: RE: Question to follow-up Biowatch Inddor Working Group

it would be good to know how much of the reduction has been due to reduction of Ct threshold versus use of CPR reagents versus the QA program.

Toby

From: [REDACTED]
Sent: Wednesday, May 09, 2012 11:49 AM
To: Merlin, Toby (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: Re: Question to follow-up Biowatch Inddor Working Group

Hello,

In the absence of actual numbers, I would say yes but due mainly to our decision to reduce the cutoff for Ct values from 45 to 40.

Jas may have actual numbers to support the reduction in reactives.

[REDACTED]
Sent from Geoff Jackson's Blackberry device

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 09, 2012 11:43 AM
To: Chaitram, Jasmine (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: Question to follow-up Biowatch Inddor Working Group

Have the number of Ft screens positives and BARS decreased since the implementation of CRP reagents and the QA program?

Thx,

Toby

Document 48

[REDACTED]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, May 23, 2012 9:53 AM
To: Bell, Beth (CDC/OID/NCEZID); [REDACTED]
Subject: Thoughts for 11:30 call about Beth's upcoming meeting with Tara O'Toole

This is going to sound a lot like a justification for a liaison in Tara O'Toole's office.

There is a lot that happens at DHS S&T that has profound impact on public health downstream, and we could better understand and mitigate these decisions if we had some sort of seat at the table. Here are some examples:

- 1) The material threat assessments (MTA) which DHS is required to perform by statute. These drive the downstream decisions about medical countermeasure acquisition, diagnostic test development, Biowatch testing, and preparedness plans. But the MTAs seems to be developed without input from people who really understand the agents, diseases, or practical implications of these decisions.
- 2) S+T R+D agenda. This also has profound impacts on public health, and we would benefit if our voice were heard.

Toby

Document 49

[REDACTED]

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 7:09 PM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Subject: RE: biowatch story
Categories: Red Category

Ali, glad to discuss further however you would like. I would say that the operational and technical problems may not be surmountable, ie I am not sure there is a technology good enough to work the way DHS has envisioned BW Gen 3 to function. Let us know if you'd like to meet or what. Toby Merlin has thought most comprehensively about this topic.

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Wednesday, June 20, 2012 12:02 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Subject: Re: biowatch story

Beth:

This is very helpful.

So tactically, this specific device appears to be premature for deployment for various reasons.

I will want to follow up with you to solicit your strategic assessment of the Biowatch program given your Center's and personal experience all these years? Are the technical and operational issues in BW Gen 3 requirements surmountable or a proxy for our way of saying BW is a bad idea? Could BW be a good idea with better technology and some changes in approach such as limited to maybe anthrax? We should assure we have a single Agency position as we interact with DHS.

Thanks again,

Ali

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 06:05 AM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); [REDACTED] Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Ali, Toby says that the Gen 3 program is being reviewed by Judge Mary Hill, who as you know is a trusted confidant of Janet Napolitano; they have known each other since law school. It was initially prompted by the GAO or OIG study. Toby says that some folks at DHS have been encouraging Mary Hill to talk to folks at CDC to get their take on Biowatch and Gen3, which may be the reason for the call from Tara O'Toole.

As for our opinions about Gen 3, we have a number of concerns as outlined in a general way by Toby below. We sent a detailed letter with our technical concerns mostly around #1 to DHS at the time they were

last reviewing their contract. Happy to send that if you'd like, or expand on the below. We have communicated these concerns to the biowatch program.

- 1) Currently CDC and others (DHS S&T) have identified serious problems with the specificity and sensitivity in the Gen3 system under development by Northrop Grumman. On a day to day operational basis, we are most immediately concerned about the risk for false positives which could be a regular occurrence.
- 2) The Gen3 system generates positive results which would require investigation and confirmation before action could be taken on these results. There is currently no concept of operations for how this investigation and confirmation would take place.
- 3) The Gen 3 system is being deployed to Biowatch sites before the device has been shown to work effectively.

Beth

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:37 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); [REDACTED] Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Beth:

As discussed earlier today, your professional judgment of the BioWatch program including the new Gen-3 expansion would be very helpful and appreciated for my upcoming conversation with Tara. Recognizing that DHS money is not going to be diverted to CDC, is there anything we see worthwhile in that program? Although the cost is an abomination and a positive reading will still require somebody to go get the canister and cut into the purported timeliness.

The underlying premise was originally considered sound from a national security perspective – no different from NORAD. A network of monitors in select cities to detect aerosol releases of high hazard agents to give public health a head start to prophylaxis.

Thanks,

Ali

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:01 PM
To: [REDACTED] Khan, Ali S. (CDC/OPHPR/OD); [REDACTED] Bell, Beth (CDC/OID/NCEZID)
Subject: RE: biowatch story

Catch the caption on the photo! Funny how bad information can come from upstanding news organizations. VaxGen was a high profile BARDA “failure” and there is no VaxGen anthrax vaccine in the SNS.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer

Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Mailstop D-44
Atlanta, GA 30333
[REDACTED]

From: [REDACTED]
Sent: Tuesday, June 19, 2012 3:51 PM
To: Khan, Ali S. (CDC/OPHPR/OD); Sosin, Dan (CDC/OPHPR/OD); [REDACTED] Bell, Beth
(CDC/OID/NCEZID)
Subject: biowatch story

Washington Post

http://www.washingtonpost.com/business/economy/anthrax-alert-system-at-risk-as-cost-estimate-hits-57-billion/2012/06/18/pjQAZQwTKV_story.html

[REDACTED]
RADM, USPHS

Director, Influenza Coordination Unit

Document 50

[REDACTED]

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Thursday, June 21, 2012 1:43 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Subject: RE: biowatch story

Thank you for the offer Beth, that would be very helpful. I'll ask Barbara to set something up.
And please also keep in confidence that Tara is asking about BW. There are some very severe politics in DHS right now.
Best,
Ali

From: Bell, Beth (CDC/OID/NCEZID)
Sent: Wednesday, June 20, 2012 7:09 PM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Subject: RE: biowatch story

Ali, glad to discuss further however you would like. I would say that the operational and technical problems may not be surmountable, ie I am not sure there is a technology good enough to work the way DHS has envisioned BW Gen 3 to function. Let us know if you'd like to meet or what. Toby Merlin has thought most comprehensively about this topic.

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Wednesday, June 20, 2012 12:02 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Subject: Re: biowatch story

Beth:

This is very helpful.
So tactically, this specific device appears to be premature for deployment for various reasons.

I will want to follow up with you to solicit your strategic assessment of the Biowatch program given your Center's and personal experience all these years? Are the technical and operational issues in BW Gen 3 requirements surmountable or a proxy for our way of saying BW is a bad idea? Could BW be a good idea with better technology and some changes in approach such as limited to maybe anthrax? We should assure we have a single Agency position as we interact with DHS.

Thanks again,

Ali

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Sent: Wednesday, June 20, 2012 06:05 AM
To: Khan, Ali S. (CDC/OPHPR/OD)
Cc: Sosin, Dan (CDC/OPHPR/OD); [REDACTED]; Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Ali, Toby says that the Gen 3 program is being reviewed by Judge Mary Hill, who as you know is a trusted confidant of Janet Napolitano; they have known each other since law school. It was initially prompted by the GAO or OIG study. Toby says that some folks at DHS have been encouraging Mary Hill to talk to folks at CDC to get their take on Biowatch and Gen3, which may be the reason for the call from Tara O'Toole.

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- 1) Currently CDC and others (DHS S&T) have identified serious problems with the specificity and sensitivity in the Gen3 system under development by Northrop Grumman. On a day to day operational basis, we are most immediately concerned about the risk for false positives which could be a regular occurrence.
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- 3) The Gen 3 system is being deployed to Biowatch sites before the device has been shown to work effectively.

Beth

From: Khan, Ali S. (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:37 PM
To: Bell, Beth (CDC/OID/NCEZID)
Cc: Sosin, Dan (CDC/OPHPR/OD); [REDACTED]; Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: biowatch story

Beth:

As discussed earlier today, your professional judgment of the BioWatch program including the new Gen-3 expansion would be very helpful and appreciated for my upcoming conversation with Tara. Recognizing that DHS money is not going to be diverted to CDC, is there anything we see worthwhile in that program? Although the cost is an abomination and a positive reading will still require somebody to go get the canister and cut into the purported timeliness.

The underlying premise was originally considered sound from a national security perspective – no different from NORAD. A network of monitors in select cities to detect aerosol releases of high hazard agents to give public health a head start to prophylaxis.

Thanks,

Ali

From: Sosin, Dan (CDC/OPHPR/OD)
Sent: Tuesday, June 19, 2012 5:01 PM
To: [REDACTED]; Khan, Ali S. (CDC/OPHPR/OD); [REDACTED]; Bell, Beth

(CDC/OID/NCEZID)

Subject: RE: biowatch story

Catch the caption on the photo! Funny how bad information can come from upstanding news organizations. VaxGen was a high profile BARDA "failure" and there is no VaxGen anthrax vaccine in the SNS.

Daniel M. Sosin, MD, MPH, FACP
Deputy Director and Chief Medical Officer
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Mailstop D-44
Atlanta, GA 30333
[REDACTED]

From: [REDACTED]

Sent: Tuesday, June 19, 2012 3:51 PM

To: Khan, Ali S. (CDC/OPHPR/OD); Sosin, Dan (CDC/OPHPR/OD); [REDACTED]; Bell, Beth (CDC/OID/NCEZID)

Subject: biowatch story

Washington Post

http://www.washingtonpost.com/business/economy/anthrax-alert-system-at-risk-as-cost-estimate-hits-57-billion/2012/06/18/gjQA2QwTKV_story.html

[REDACTED]
RADM, USPHS

Director, Influenza Coordination Unit

Document 51

[REDACTED]

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Friday, June 29, 2012 2:50 PM
To: Hayslett, James (CDC/OPHPR/OD)
Subject: RE: Life, Liberty and the Pursuit of Assays

Jim,

I really don't know. Mike has not identified anything to me. A few things come to mind, but nothing new:

- 1) I was vocal at the Indoor Guidance meeting.
- 2) We have been trying to get the Biowatch program to better define what a BAR is.
- 3) We did provide extensive requested comments on the requested Biowatch Outdoor Guidance.

Mike and I used to have monthly calls before Ulana left, and now we don't. Do you think I should reach out to Mike and just ask him how things are going?

Thanks,

Toby

From: Hayslett, James (CDC/OPHPR/OD)
Sent: Friday, June 29, 2012 1:45 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Life, Liberty and the Pursuit of Assays

Hi Toby,

Hope all is well down your way and it is cooler than here.

Alex and I were chatting earlier and he mentioned that Mike Walter came to him regarding some issues with CDC and PHAAs that were causing Mike some consternation.

Alex had asked that I touch base to get some background/insight that would be useful for him to understand the CDC position.

Apologies that this is a bit cryptic but Alex didn't have all the details when we talked.

Thanks in advance,
Jim

Document 52

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 1:53 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Garza's Statement

Stephen,
The 37/37 would reflect specificity, not sensitivity. He makes no claim regarding sensitivity.
Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 1:51 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Garza's Statement

Hi Toby,

The way I would interpret his statement is:
7 million tests without a false positive = 100% specificity. 37/37 positives were true positives (i.e., "naturally occurring pathogens were detected in environmental samples) = 100% sensitivity. Garza is claiming that all positives were pathogens that are known to occur naturally in the environment.

Thanks,
Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 1:07 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Garza's Statement

Stephen,
Thanks for forwarding this. I don't see that Garza claims 100% sensitivity and specificity for BioWatch here. I will work on the text you forwarded.
Thanks!

Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 9:37 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Garza's Statement

THURSDAY, JULY 26, 2012

The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack

*-Posted by Dr. Alexander Garza,
Assistant Secretary for Health Affairs and Chief Medical Officer for DHS*

We all know the importance of early detection in the treatment of diseases and medical emergencies. Routine screenings and monitoring as well as rapid response save thousands of lives every year. The same principles

apply when mitigating the effects of biological threats, which is why DHS works with state and local officials through the BioWatch program to monitor for traces of dangerous pathogens in public places where large groups of people gather to ensure that we respond quickly when a potential threat is identified.

There has been some confusion reported in the news lately about how the BioWatch program works and what it is intended to do. First announced in 2003, BioWatch is the nation's first early detection and warning capability for biological attacks. DHS partners with public health laboratories, which are members of the Centers for Disease Control and Prevention's (CDC) Laboratory Response Network, to conduct rapid analysis and provide information and expertise to governors and local emergency officials when a pathogen is detected in order to determine whether it indicates a potential biological attack.

Recent media reports have incorrectly claimed that BioWatch is prone to "false positives" or "false alarms" that create confusion among local officials and first responders. These claims are unsubstantiated. To date, more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result.

Out of these more than 7 million tests, BioWatch has reported 37 instances in which naturally-occurring biological pathogens were detected from environmental sources. Many of the pathogens the BioWatch system is designed to detect occur naturally in the environment, such as the bacteria that causes anthrax, which has been used as a weapon, but is also found in nature. For example, near the nation's Southwest border there have been a number of instances where a bacterium that is endemic in the environment has been identified. Thankfully, none of the instances were actual attacks. The detection of commonly occurring environmental agents is not a "false positive."

Much like a home smoke detector goes off for both burnt toast and a major fire, the smoke detector is meant to notify you of a potential fire before it's too late. BioWatch works very much the same way. If BioWatch detects a potential threat, state and local officials as well as first responders have the ability to investigate the incident to the fullest and determine if there is a credible threat to the public.

These tools alone cannot and do not declare that a biological attack has occurred. Experts must interpret the data and quickly make tough, logical decisions about the reality of the threat. BioWatch is designed to provide the nation with the greatest lead time possible to respond to the potential release of a biological agent. The faster we detect an event, the more lives we can save by responding and delivering medical countermeasures. Looking forward, the scientists who operate the system will continue their work to improve BioWatch to keep the nation safe from any potential biological threats.

Document 53

[REDACTED]

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:52 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Toby,

I agree with your comment whole heartedly. Unfortunately, the hype is different than reality.

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:44 AM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Stephen,

Candidly, I do not believe that a high consequence action can be initiated based only a BAR, even if the test methodology conforms to PHAA. There are many other potential sources of error than just cross reactivities.

Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:34 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Hi Toby,

With the current BioWatch system, filters are collected and analyzed in a laboratory. Thus, there is a delay between when the release occurred and when it was detected through laboratory analysis. Confirmation may occur in the same laboratory facility. In Gen3, they envision that the release would be detected by the autonomous collection/analysis unit and the results sent to a central site where some action would be initiated. I think there is more time for a thoughtful consideration of the data with the current system than what they envision (or hyped) with Gen3. I agree that there is little "bang for the buck" with Gen3 and it is likely to be a casualty of the Country's current fiscal situation.

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 10:19 AM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Stephen,

I am not sure there is much of a long term future for Gen3 in the current budgetary environment. That said, Biowatch has already deployed into select indoor environments, where it is problematic to send teams in for phase 1 sampling without evacuating the building.
Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 9:54 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

Hi Toby,

I think your changes are great and to the point. One thought though. I heard that BioWatch is considering deploying Gen3 in indoor environments (They may have decided not to but I don't know for sure). Their mantra has been "detect to treat" in order to reduce morbidity and mortality in the event of a release. Thus, it becomes even more important to have high confidence assay results if public buildings are to be evacuated in the event of a BAR, and prior to confirmation.

Thanks for your input,

Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 9:40 AM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: Stephen, Here it is. Sorry. I regularly forget to include the attachments.

<< File: TM revisions to SM summary of 07222012.docx >>

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 9:32 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Stephen, Here's my version of the November 22 meeting for your review.

Hi Toby,

There was no attachment.

Thanks,
Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, July 25, 2012 5:04 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Subject: Stephen, Here's my version of the November 22 meeting for your review.

Stephen,
This is my version. Of course, only you can say what you said and what you intended.
Toby

Document 54

[REDACTED]

From: Weber, Angela (CDC/OID/NCEZID)
Sent: Thursday, July 26, 2012 1:21 PM
To: Merlin, Toby (CDC/OID/NCEZID); Morse, Stephen A. (CDC/OID/NCEZID)
Cc: [REDACTED]; Weber, Angela (CDC/OID/NCEZID)
Subject: Congressional Letter & Mention of "Trace" Detection

Stephen and Toby,

I realize that much attention has been placed on the issues related to Ft. However, I would like to also bring up issues related to how DHS OHA has referred to BioWatch's ability to detect "traces of dangerous pathogen" (refer to question #3 on the Congressional request to CDC).

Since we are being asked about this, I think it's critical that we provide clarification as to why this is misleading. In the course of working on BioWatch, I have heard OHA repeatedly sell this capability as a way to tout how sensitive the assays are at detecting low concentrations of organisms. This is flawed as there is supporting data showing that the collection system is not capable of detecting trace concentrations of organisms (the collector itself is known to leak around the filter). This is an important point to make from the public health standpoint as the system (regardless of whether you are addressing the current system or Gen 3) is not capable of detecting the lower concentrations associated with infectious doses. This is true of all the agents and not only Ft as it relates to sampler collection efficiency, etc.

The other critical point to bring up related to this is based on basic industrial hygiene practice. DHS OHA should not be claiming that the Ft BARs were associated with trace detections because they have absolutely no way of knowing what was in the environment (airborne) at the time the organism was collected. Most likely, there was a very large aerosol present when it was detected as BioWatch requires large concentrations to be present. I believe Stephen has more information on the concentrations that are needed.

Best,
Angie

Document 55

Morse, Stephen A. (CDC/OID/NCEZID)

From: Weber, Angela (CDC/OID/NCEZID)
 Sent: Thursday, August 16, 2012 3:03 PM
 To: Morse, Stephen A. (CDC/OID/NCEZID); [REDACTED]
 Cc: Weber, Angela (CDC/OID/NCEZID); [REDACTED]
 Subject: RE: Trace amounts

Thanks Stephen.

I went through the process below of also estimating the time it would take to inhale a concentration equivalent to the ID50 for Ft as most of the collectors run on a 24-hour period versus a 12-hour period. This is only theoretical of course as it is a number simply based on what can be detected on the filter so lots of caveats are needed around this. Because of all the caveats, I'm glad to see that you recommended only focusing on the analytical portion! Please feel free to share this with Toby. I'm going to pass it along to Steve Papagiolas (copied here) as he works on the response aspects of BioWatch.

One thing I would note is that estimated breathing zone concentrations should not be based on the Ct values reported for a BAR. I could see someone may want to try doing this in a response, but it would be a misuse of data. The primary reason for this is that the BioWatch collectors are area samples that in most all cases are not in the breathing zone of the public. Plus, the Ct value is semi-quantitative at best – when taking into account all the other unknowns involved, the Ct value really is more of a qualitative estimate (e.g., Is something there or not? If so, is it a relatively high or low concentration). The idea that 35 is treated as a magical number for the Ft response is concerning and all involved should realize that number was simply picked as no Ct values for Ft were found lower than this and no one has gotten sick at the levels that had been reported. This would be important to bring up with DPEI, so in the case BioWatch ever detects a true BAR, the appropriate interpretation of the data can be made. Additionally, what shows up on the filter is only a fraction of what was in the air during the sampling period due to the poor collection efficiency of the collector as well as all the air that passes around the filter (it leaks, but because the appropriate studies have not been done, we don't know how much it leaks). So...a Ct value for any of the agents is a true guess and should not, under any circumstances, be used to estimate an exposure dose or to determine what area was involved in the release that had sufficient concentrations that would result in an infection.

Another caveat to add regarding the sampling volume (in calculations below) is that I went ahead and assumed a collection flow rate of 100 lpm. I noted, however, in the BioWatch programs "BioWatch Field Operations SOP" that they are only using secondary calibration devices (instead of primary), only calibrating once a quarter (should be done before and after every sample but I'm guessing this would be too labor intensive for them), and flow rates must be adjusted based on barometric pressure and temperature (another reason it must be done every day – as you can imagine, the temperature fluctuations over 3 months). None of this is mentioned in their SOP so my guess is that if trained personnel (e.g., industrial hygienists) went out and calibrated a portion of the PSUs out there (including those in Denver for example so you could see if they were adjusting for higher altitudes), I would think you would find quite a variation in the operational flow rate of the PSUs currently in use. This is another reason for treating the Ct values as only qualitative – who knows how much air is actually being collected from day to day. Another concern this brings up is lowering the cut-off Ct value for Ft to get around the analytical problems and false positives. In doing so, you are making the assay even less sensitive when already the LOD is very high at around 2.4×10^5 organisms (this is not a trace level as claimed by DHS).

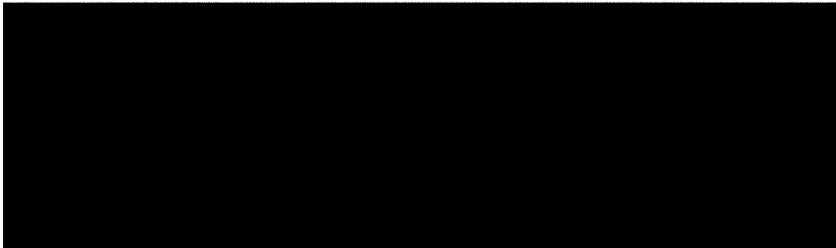


Thanks for sharing the below.
Angie

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Friday, August 03, 2012 5:05 PM
To: Weber, Angela (CDC/OID/NCEZID)
Subject: FW: Trace amounts

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Wednesday, August 01, 2012 1:46 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: RE: Trace amounts

Hi Toby,



Stephen

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Wednesday, August 01, 2012 1:22 PM
To: Morse, Stephen A. (CDC/OID/NCEZID)
Cc: [REDACTED] Holmes, Harvey T. (CDC/OID/NCEZID); Chaltram, Jasmine (CDC/OID/NCEZID)
Subject: FW: Trace amounts

Stephen,

Thanks for taking the lead in drafting this. The numbers of bacteria on a filter (approximately 2.4×10^5) are in the same range as numbers provided independently by Harvey, and this does make sense.

What seems to be important is not just the number on the filter, but the number of cells per unit volume of air sampled. I don't know enough about the BioWatch system to know the average amount of air sampled per filter. Do you? Can we calculate the number of bacteria per ml of air? We know the average volume of air that an adult inspires per minute. From all of this, someone would need to calculate how many minutes of exposure to the air with the bacteria would give a LD₅₀. If it would take a long exposure to get an LD₅₀, that would sound like a trace amount. If it would take a very short exposure to get an LD₅₀ that would not sound like a trace amount.

A lot of this is really respiratory toxicology kind of work. Maybe we just need to stop at the number of bacteria on the filter, and let others determine how that relates to air infectivity?

Toby

From: Morse, Stephen A. (CDC/OID/NCEZID)
Sent: Monday, July 30, 2012 8:56 AM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: [REDACTED]
Subject: Trace amounts

Hi Toby,

I took a crack at addressing the question concerning what is meant by "trace amounts." Feel free to comment.

Thanks,
Stephen

What is meant by trace amounts?

Trace amounts have been described as a BAR with a high C_T value (ca. 40). However, that does not give one a feel for how many organisms are actually present on the filter that when analyzed result in a high C_T value. In order to understand this, I have performed the following calculations:

1. Only $\frac{1}{4}$ of the filter is used for extraction (x4);
2. Nucleic acid extraction efficiency is, at best, ca. 1% using bead beating (x100) (it's probably closer to 0.1%);
3. Final elution volume is 150 μ l of nucleic acid extract of which 5 μ l is analyzed/reaction (x30);
4. RT PCR sensitivity is about 20 organisms/reaction.

Therefore, a positive result would require:

$20 \times 30 \times 100 \times 4 = 240,000$ organisms (or 2.4×10^5 cells) on a filter just to get a positive result at the cutoff. This is not a trace amount of a pathogen. For example, the ID_{50} for *F. tularensis* is 10–50 organisms. However, it indicates that false negative results remain problematic with low numbers of agents.

Document 56

[REDACTED]

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 6:03 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Subject: Fw: Question #3 about the LOD summaries

Categories: Red Category

Fyi...

From: Beck, Linda [mailto:linda.beck@hq.dhs.gov]
Sent: Monday, October 22, 2012 05:13 PM
To: Farrell, Michael (CDC/OID/NCEZID)
Subject: RE: Question #3 about the LOD summaries

Hi Mike,
Sorry for the delay. I wanted to check with a few folks.

We do not have data that show how the filters and extraction from the filters affects LOD. However:

- We did analysis earlier this calendar year where we made assumptions based on SME input regarding filter extraction efficiency and DNA extraction efficiency and plugged in the assay LODs based on the testing referenced above to calculate Gen-1 / Gen-2 sensitivity. The results are contained in a white paper and briefing that are classified SECRET
- The "Reference System Test" that we are trying to kick off at DPG is designed to measure filter extraction efficiency and DNA extraction efficiency, as well as the entire system's LOD. Unfortunately, this dataset will not be available until Feb 2013 at the earliest.

Looking forward to seeing you tomorrow.
Hope this helps!
Linda

From: Farrell, Michael (CDC/OID/NCEZID) [mailto:mqf2@cdc.gov]
Sent: Monday, October 22, 2012 1:49 PM
To: Beck, Linda; [REDACTED]
Subject: FW: Question #3 about the LOD summaries

Hi Linda and Kathleen, fyi below in regards to my query.

Mike

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 1:49 PM
To: Merlin, Toby (CDC/OID/NCEZID)
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID); [REDACTED]
Subject: FW: Question #3 about the LOD summaries

Hi Dr. Merlin – that is true we have not done those studies. I will reach out to the SPO and see what may have been done in this area, perhaps in concert with Gen 3 comparative testing, that might provide some info on the LOD of spiked filters with the current Gen 2 processes.

Mike.

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 11:34 AM
To: Farrell, Michael (CDC/OID/NCEZID); [REDACTED]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Re: Question #3 about the LOD summaries

Mike,

Thanks for the responses. The bottom line is that the summaries we have provided to the committee do NOT provide LOD for the LRN assays on BioWatch filters. Have we done those studies? Do we know how the filters and extraction from the filters affects LOD? Thx! Toby

From: Farrell, Michael (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 09:17 AM
To: Merlin, Toby (CDC/OID/NCEZID); [REDACTED]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: RE: Question #3 about the LOD summaries

Hi Dr. Merlin, some answers below in red in parentheses

Mike.

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 7:10 AM
To: Farrell, Michael (CDC/OID/NCEZID); [REDACTED]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Question #3 about the LOD summaries

These summaries are about 4 years old and look at 3 instruments and 3 extraction methods. I assume by now virtually all of the labs are using the 7500 dx fast. Are they all using a standard extraction method? (the extraction methods are standardized – a choice of two automatic (Roche), or one manual kit (Qiagen)) Does this make a difference in LOD? (Yes, it can – I would have to see the data) Do we have an extraction recommended for BioWatch filters? (the Biowatch process uses a distinct extraction method amenable to air filters that is not used in the LRN) Thanks! Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 06:32 AM
To: Farrell, Michael (CDC/OID/NCEZID); [REDACTED]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: RE: Explanation of discarding data from positive NTC's in analysis of LOD of FT primer/probe set

Second question: What is the reaction volume of the analysis? (25 ul) Is it the same for all instruments? (yes) Is it 10 microliters? (no)

Thx,

Toby

From: Merlin, Toby (CDC/OID/NCEZID)
Sent: Monday, October 22, 2012 6:27 AM
To: Farrell, Michael (CDC/OID/NCEZID); [REDACTED]
Cc: Holmes, Harvey T. (CDC/OID/NCEZID); Chaitram, Jasmine (CDC/OID/NCEZID)
Subject: Explanation of discarding data from positive NTC's in analysis of LOD of FT primer/probe set

Mike or Laura,

It looks like I'm going to have to brief Congressional staff this week on the summaries we provided of the LOD studies. In the Ft summary, we talk about laboratories experiencing problems with positive NTC and we discard those data. NTC is a non template control, right? (yes) What is that exactly? (It is a PCR reaction with all of the ingredients except water replaces actual sample volume. This controls for potential contamination of reagents that might lead to a false positive result) It has not target Ft, so why would a number of sites have problems with positives? (For FT3 assay, the former BioWatch screening assay, we and others through 3rd party testing have observed an underlying NTC reactivity of approximately 1 in every 500 reactions. The reason is unknown, however nearly all of these occur at ct values above 40 and was one of the drivers of our decision to change from 45 to 40)

Thanks,

Toby

[REDACTED]

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Sent: Monday, October 22, 2012 6:03 PM
To: Merlin, Toby (CDC/OID/NCEZID)
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Categories: Red Category

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Thanks,

Toby

Document 57

PETER T. KING, NEW YORK
CONGRESSMAN

BENNY D. THOMPSON, MISSISSIPPI
CONGRESSMAN



One Hundred Twelfth Congress
U.S. House of Representatives
Committee on Homeland Security
Washington, DC 20515

July 9, 2012

The Honorable Janet Napolitano
Secretary
U.S. Department of Homeland Security
301 7th Street SW- Mail Stop 0020
Washington, DC 20528

Dear Secretary Napolitano:

I am writing to express my continuing concern regarding the Department of Homeland Security's BioWatch program and to request a copy of an analysis conducted by the Department in January, which, according to a July 8, 2012 article in the *Los Angeles Times*, found significant failures in the BioWatch Generation-3 technology.¹

Since its inception, I have raised serious questions regarding the BioWatch program's cost, the efficacy of BioWatch technology, and whether the technology is responsive to current threat assessments. Over the last decade, approximately \$800 million has been invested in developing BioWatch technology. Democratic Members of this Committee have raised questions about the accuracy of the readings produced by the currently deployed generations of BioWatch technology and delays in the development of BioWatch Generation-3. In response, the Department has told Members that current BioWatch technologies will prevent needless deaths and that the development of the next-generation technology is on track. The *Los Angeles Times* story, however, calls these statements into question and notes that one State health official has called BioWatch "a colossal waste of money."²

The *Los Angeles Times* reports that federal agencies have documented 56 BioWatch false alarms in cities using the currently deployed technology. Due to the high number of false alarms, reports indicate that State and local health officials have relatively little confidence in the technology. Moreover, this lack of confidence seems to be shared at the Federal level. Officials at the Centers for Disease Control and Prevention have said that they would not begin distribution of medications without performing additional tests to confirm the BioWatch result, thereby undermining any therapeutic benefits anticipated as a result of an advanced warning system.

¹ David Willman, "The Biodefender that Cries Wolf," *Los Angeles Times*, at A1 (July 8, 2012).

² *Id.*

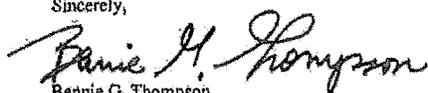
FOR OFFICIAL USE ONLY

DHS HCEC BW 005601

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2012 JUL 10 PM 12:15

Thank you for your attention to this matter. Should you have any questions or require additional information, please contact Cherri Branson, Chief Counsel of Oversight, Committee on Homeland Security, at (202) 226-2616.

Sincerely,

A handwritten signature in black ink that reads "Bennie G. Thompson". The signature is written in a cursive, flowing style.

Bennie G. Thompson
Ranking Member

The Committee on Energy and Commerce
Supplemental Memorandum



June 18, 2013

TO: Members, Subcommittee on Oversight and Investigations
FROM: Majority Staff
RE: Committee Investigation of the Department of Homeland Security BioWatch Program

Executive Summary

On June 18, 2013, the Subcommittee on Oversight and Investigations is holding a hearing titled, “Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism.”

The Committee’s investigation of the Department of Homeland Security’s (DHS) BioWatch program began almost one year ago, on July 19, 2012, with letters to DHS and the Centers for Disease Control and Prevention (CDC). BioWatch is a program that was launched by President George W. Bush in January 2003 and administered by DHS. The purpose of this program is to monitor and detect select biological agents in the air that could be used in a covert terrorist attack. Since 2003, approximately \$1 billion has been spent on this program.

The Committee opened this investigation after a National Academy of Sciences (NAS) report and media articles noted that the BioWatch system was generating “false positives” or indicating “the potential occurrence of a terrorist attack when none has occurred.”¹ A DHS official, however, stated that the reports of “false positives” were incorrect and unsubstantiated, and that “there has never been a false positive result.”²

During this investigation, the Committee has obtained documents from the DHS and the CDC, and the Committee staff has conducted interviews of three officials from DHS and two officials from CDC.

The documents provided to the Committee and the interviews of officials involved in the BioWatch program have revealed new details and raise additional questions about the management and effectiveness of the BioWatch program that should be examined at the Subcommittee’s June 18 hearing. The new details include:

¹ National Academy of Sciences, *Biowatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats*, National Academies Press, at 50 (2011).

² Posting of Alexander Garza, Assistant Secretary for Health Affairs, to DHS blog, “The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack,” <http://www.dhs.gov/blog/2012/07/12/truth-about-biowatch> (July 12, 2012).

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Subcommittee Hearing
Page 2

- The threat the BioWatch program was intended to address and protect — a doomsday scenario of a large-scale attack — has changed since the program was started in 2003. According to a DHS official involved in bioterrorism risk assessment, large-scale bioterrorism attacks are less likely, and small-scale bioterrorism attacks more likely.
- Information produced to the Committee does not show a DHS strategy responding to a bioterrorism attack that reflects the changes in threat assessment and reductions in public health departments that have occurred since the program was launched. According to a DHS contractor report, the lack of such an overarching strategy impedes proper assessment of BioWatch's role in biodefense.
- After more than a decade of operation, DHS still lacks crucial data demonstrating the effectiveness of the current technology, BioWatch Generation-2 (Gen-2). The lack of such data would seem to impede the ability to conduct cost-benefit analysis comparing BioWatch Gen-2 to the new technology, BioWatch Generation-3 (Gen-3). This is needed for an analysis of alternatives, a required step in the DHS acquisition process.
- Since 2004, DHS has been seeking to develop and deploy BioWatch technology that would include air sampling and analysis of samples in the same device. If successful, this technology would reduce BioWatch's detection time to 6 hours from the current 36 hours. Unfortunately, DHS has spent close to \$300 million on developing autonomous detection systems that failed to meet requirements as well as on expenditures on Gen 2.5, a system that was deployed for two years and withdrawn because it proved to be an ineffective technology that was improperly approved.
- Several statements by DHS about the performance of the BioWatch program are disputed by other government scientists or contradicted by information obtained in this investigation.

I. BioWatch Is Hampered By Lack of DHS Strategy Reflecting Current Threat and Response Capability

This section of the memorandum discusses the factors that have impacted the effective development of a BioWatch system.

A. The Changing Threat

In January 2003, at the direction of President George W. Bush, DHS launched the BioWatch program to provide, maintain, and support aerosol monitoring capability for selected biological agents in certain metropolitan areas to provide an early warning system within 12-36 hours against a covert, large-scale aerial attack. According to a DHS official, "BioWatch was

Majority Supplemental Memorandum for the June 18, 2013, Oversight and Investigations
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never intended to detect at low levels; it was designed to detect catastrophic attacks that would cause more than 10,000 casualties.”³

At the time BioWatch was started, it was a response to a bioterrorism threat viewed as originating primarily from a state-actor program based on a combination of factors. These factors included the longstanding threat from bio-warfare agents developed by state actors such as the former Soviet Union; the September 11, 2001, attacks by Al Qaeda; the anthrax letters mailed in 2001, (which, while a low level attack, was believed by some to have originated from a state actor)⁴; and the specific concern about Iraq’s biological weapon program. In fact, in 2004, the program manager for BioWatch noted that BioWatch deployment was part of “domestic preparedness during war with Iraq and Al Qaeda.”⁵

Since 2004, to improve the speed of response to the threat, DHS has sought to develop a “laboratory-in-a-box” system that would include air sampling and biological agent detection in the same device. BioWatch Generation 3 (Gen-3) is the result.⁶ The current system is a two-step process, requiring periodic collection of samples that are then brought to local public health laboratories for testing of the samples. The advantage of Gen-3 would be to reduce the time of detection from 36 hours to less than 6 hours by combining collection and testing in one device. In addition, DHS has envisioned deploying Gen-3 to additional cities with an increase to approximately 50 locations, with more population coverage in each city, and with more tests being performed daily.

In 2004, President Bush issued Homeland Security Presidential Directive (HSPD) 10, which tasked DHS with conducting bioterrorism risk assessments. Starting in 2006, the DHS Science and Technology Directorate has conducted a bioterrorism risk assessment (BTRA) every two years.

³ Comment from DHS official to July 7, 2012 article in the L.A. TIMES, *The biodefender that cries wolf*, attached to an email from Michael Walter, DHS BioWatch program manager to Kate Nichols of DHS, July 10, 2012, 12:24 pm.

⁴ Although the anthrax letters are cited as one of the reasons for launching BioWatch, U.S. officials noted that the anthrax attacks of October 2001 would probably have not been detected by BioWatch mainly because the outbreak was caused by a tiny amount of anthrax – one to two grams – and because the release was indoors, where the sensors do not monitor. Judith Miller, *Threats and Responses: Biological Defense; U.S. Deploying Monitor System for Germ Peril*, N.Y. TIMES, January 22, 2003 (online version). Nevertheless, during a Committee staff interview on June 5, 2013, Dr. Jeffrey Steifel, a DHS official and former BioWatch program manager, asserted that BioWatch was used to screen the President’s mail. Committee staff requested that DHS provide substantiation and clarification of this claim. DHS told staff that BioWatch was never used to screen the President’s mail, but was only used to screen DHS mail. It should be noted that the National Academies of Science Report stated that BioWatch is not designed or deployed to detect environmental exposures to infectious agents distributed by certain means (e.g., the 2001 anthrax letters). NAS at 40.

⁵ P. Estacio, Senior Medical Advisor and BioSecurity Program Executive, DHS, Bio-Watch Overview, September 27, 2004 cited in Congressional Research Service memorandum, “Information for a hearing on the Department of Homeland Security BioWatch program,” at 5 (June 7, 2013).

⁶ U.S. Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 (September 10, 2012) available at <http://www.gao.gov/assets/650/648026.pdf>.

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DHS officials have confirmed to the Committee that the threat has evolved since 2003. During a staff interview on June 6, 2013, Dr. Segaran Pillai, the DHS Chief Medical and Science Advisor in the Chemical and Biological Division, confirmed his involvement with conducting the BTRA and noted the changes in the bioterrorism threat since the launch of BioWatch. Dr. Pillai stated that over the last decade, the threat has evolved from one dominated by state-actor programs to one principally composed of non-state actors. The current trends in bioterrorism are troubling because of advances in biotechnology and the ongoing concern of dangerous biological agents being widely available in other countries that do not have select agent regulation. The implication of these changes, according to Dr. Pillai, is that a large-scale bioterrorism attack is less likely now than it was 10 years ago; instead, a small-scale attack is more likely.

Although a small-scale threat appears to be more likely than a large-scale attack, Majority staff has not found evidence that DHS bioterrorism strategy has been restructured to address this changing threat.⁷ DHS continues to pursue BioWatch Gen-3, a costly expansion of primarily outdoor monitoring for a large-scale attack.

The degree to which BioWatch should focus on outdoor monitoring is the subject of some debate. In fact, even some proponents of environmental monitoring question continued disproportionate emphasis on outdoor monitoring. A former BioWatch program manager, Dr. Jeffrey Stiefel, during the Committee staff interview stated his personal opinion is that Generation-3 should not be used outdoors and should be an indoor program. Moreover, according to an internal DHS email from 2011, the Joint Program Executive Office at the Department of Defense appears to be moving away from expansion of environmental monitoring by removing funding from all but one of its future biodetection programs in this area.⁸

Significantly, the August 27, 2012, report by the Homeland Security Studies and Analysis Institute (HSSAI), suggests a lack of strategy on which the value of BioWatch, and its focus on outdoor monitoring, can be properly assessed. As one of its three major observations, HSSAI stated “the lack of an overarching biodefense strategy impacts our ability to appropriately assess the contribution of environmental sampling (including use of aerosol point detectors) to

⁷ President Obama released a National Strategy for Biosurveillance in July 2012. The document is aspirational and directs that a strategic implementation plan be completed within 120 days. It does not explicitly mention BioWatch, although some of the guiding principles would be germane to BioWatch. Staff did not find a strategic implementation plan that was publicly released, and the Congressional Research Service could not confirm its existence. So far, staff has not seen evidence from this effort that reflected the kind of strategy that would determine the appropriate role for BioWatch in light of recent trends.

⁸ Email from Michael Walter (DHS Program Manager) to Alexander Garza and Robert Hooks, December 8, 2011 7:14 am: “Got word that JPEO has removed funding from all future biodetection programs with the exception of the tactical detection system. This includes shutting down their standoff program. This makes BioWatch the only game in town.” According to the September 21, 2012 Chemical Biological Defense Program Advance Planning Briefing for Industry, Q&A Panel, Friday, Sep 21, 2012, 0800-1100, unclassified, at 9. “Are there plans for the development of a standoff bio-detection program? If so, what are the changes and vision for coordination within disease surveillance? The DoD plans no new starts in this area for fiscal year 2013. However, standoff bio-detection continues to be a high priority within the Joint Services; and we will continue to pursue potential materiel solutions in this area.”

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the DHS biosurveillance mission in general.”⁹ HSSAI added in a footnote, “While BioWatch Gen-3 Program has clearly articulated the advantages of an autonomous detection system to environmental sampling, the translation of this capability to the broader DHS biosurveillance mission is currently not well understood due to the lack of an overarching national biodefense strategy.”¹⁰

Dr. Tara O’Toole, now serving as the DHS Undersecretary for Science and Technology, but at the time, was with the University of Pittsburgh Center for Biosecurity, testified in March 2007, on the importance of such a strategy. She stated, “I will urge that DHS initiate a strategic examination of the current state of ‘biosurveillance’ and develop a five-year strategy for biosurveillance in collaboration with other federal agencies and key stakeholders.” Through such a strategy, she believed “that the country could make different and more useful and cost-effective investments in biosurveillance than are currently planned.” Among the questions that she believed to deserve examination were:

Does it make sense to invest limited biodefense funds in more advanced BioWatch technology even as we cut funds for the public health personnel needed to analyze BioWatch data, as we are now doing? Many public health professionals at the March 15 White House meeting noted that assessment of BioWatch data requires use of limited public health resources that might be otherwise employed to greater effect.

. . . Would we improve detection more cost-effectively by focusing on raising clinicians’ awareness of bioweapons-related disease or by making investments in point-of-service diagnostic tests, which could not only detect bioweapons agents but also help identify victims once an attack occurs?

. . . How useful will BioWatch data be in determining the site of the bioweapons release and who was exposed? In previous TOPOFF exercises, dueling ‘plume models’ of both radiological and biological weapons releases caused great confusion.¹¹

Given the lack of overall bioterrorism strategy, important pieces of information and analysis are either missing or were not used to make good policy decisions. As noted in 2010, the Chair of the National Academies of Science Committee that reviewed BioWatch commented that estimates of the likelihood and the magnitude of a biological attack, or how the risk of a

⁹ Homeland Security Studies and Analysis Institute, *Revised BioWatch Gen-3 Program Acquisition Assessment: Executive Summary and Annotated Briefing*, Prepared for Department of Homeland Security Program Accountability and Risk Management Office, August 27, 2012, at x.

¹⁰ *Id.*

¹¹ House Committee on Appropriations, Subcommittee on Homeland Security, Testimony of Tara O’Toole, MD, MPH, March 29, 2007, available at http://www.upmchealthsecurity.org/website/resources/To%20USG/Testimony_Briefings/2007/20070329-btprepanddhscmo.html.

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release of an aerosolized pathogen compares with risks from other potential forms of terrorism or from natural diseases are crucial in judging the value of the BioWatch approach.¹² HSSAI also stated it is not clear how the risk of a release of an aerosolized pathogen compares with risks from other potential forms of terrorism or from natural disease.¹³ Thus, a cost-benefit analysis of BioWatch is constrained because there is no assessment of the validity of the important assumption that the risk posed by the threats addressed by BioWatch is significant enough to justify the program over other investments in this area.¹⁴

B. Availability of Public Health Responders to Bioterrorism Attacks

The value and effectiveness of BioWatch early detection is premised on the capability of state and local public health authorities to respond, for example, by directing the mass dispensing of medications or establishing mass treatment centers. As the HSSAI report noted, “. . . [A]s a detection system for disease threats, it [BioWatch] needs to be accompanied by the capability to respond with appropriate public health or medical measures that will minimize illness and death. Without response, the warning of an attack will not produce a benefit.”¹⁵

DHS continues to move forward on an expansion of BioWatch despite uncertainties about Gen-3 performance and the burdens it would place on states and localities that are already financially strained. The CDC, in particular, has referenced the potential of decreased capability of public health agencies to respond to bioterrorism events. An internal CDC document noted the agency’s concerns about Gen-3 because of a “potential workload impact on LRN [Laboratory Response Network] from increased number of devices that are continuously sampling and reporting.”¹⁶

The competing demands on state and local public health officials have been described by DHS scientists who have noted the increasing strategic role of public health surveillance. These scientists observed that “[a] bioterrorism event will likely be detected in many cases through Public Health Surveillance from Human illness instead of BioWatch!”¹⁷ These scientists also noted “[t]he need for POC [point-of care] diagnostics to enhance Public Health Surveillance and Detection is critical to support the National Biodetection, Preparedness, and Response/Mitigation mission.”¹⁸

Further, these DHS scientists cited a number of limitations in the BioWatch system in a slide presentation for the DHS Undersecretary for Science and Technology: we cannot put

¹² House Committee on Appropriations, Subcommittee on Homeland Security, Testimony of Bernard Goldstein, *Biosurveillance: Smart Investments for Early Warnings*, 111th Congress (February 25, 2010). These areas were outside the scope of the NAS report, but Dr. Goldstein’s comments highlight the broader considerations concerning BioWatch.

¹³ HSSAI Report, *supra* note 12 at 13.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Presentation to CDC Director, NCEZID Quarterly Performance Review, May 25, 2011. The document appears to be an outline of a presentation by Dr. Toby Merlin.

¹⁷ Segaran Pillai and Douglas Drabkowski, DHS slides on BioWatch, December 2011 (slide 29).

¹⁸ *Id.*

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biodetectors everywhere, biodetectors have limitations in terms of system sensitivity and are very costly to operate. The scientists also noted that, low infectious dose agents are likely to be picked up by human infection and least likely by BioWatch due to smaller release sizes and the system's lack of sensitivity, and even with the strictest sensitivity standard, the DHS scientists found that the probability of detection is about 50 percent at best.¹⁹ As a result, these scientists stated that it was likely that authorities would see humans becoming sick in many situations that were not detected by BioWatch because of low infective dose and lack of system sensitivity for outdoors.²⁰

C. The Lack of Strategy and Impacts on Policy and Technical Development

Some internal DHS documents indicate that DHS leadership is well aware of the problems posed by a lack of clear strategy and with DHS' ability to improve the system. Unfortunately, the available evidence shows that DHS' priority has been on resolving internal DHS differences on BioWatch Generation-3, without reexamining biodefense strategy. This is illustrated in an email exchange between two senior DHS officials, Dr. Tara O'Toole, the DHS Undersecretary, and Alice Hill, Senior Counselor to DHS Secretary Janet Napolitano. According to her February 13, 2012, email, Ms. Hill wrote:

. . . In trying to determine what should occur with Gen3, both OHA [Office of Health Affairs] and S&T [Science and Technology Directorate] need to identify their positions. My intention is to do everything I can to see if OHA and S&T can come to agreement as to appropriate next steps.

If there is no agreement, I believe that this issue will be referred to a third party.

In my opinion, it is better from a department perspective that OHA and S&T scope how this moves forward. Even if there are competing views on the wisdom/viability/accuracy etc. of Bio-watch Gen 3, it seems like we should be able to articulate the questions that need to be decided jointly. I think it would be an unfortunate development if we can't get to at least agreement on where we go. My intention is to see if we can get to a jointly articulated path forward by Wednesday. I would prefer that any discussion I have regarding the potential agreement be done with Alex [Garza, then DHS Assistant Secretary for Health Affairs] and you (or your or Alex's designees) so that we can make sure there are no misunderstandings.

I hope this addresses the concerns you raised.

¹⁹ Id. at slide 31.

²⁰ Id. at slide 10.

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In response, in a February 13, 2012, email, Dr. O'Toole referenced the need for DHS to deal with the broader strategic and policy issues in making BioWatch decisions:

To go beyond a very narrow question of 'what does the available data so far say about what to do with [Gen-3] system's readiness to go to operational testing' necessitates that we consider the larger issue of 'how should DHS move forward on environmental sensing/biosurveillance, given these test results and the available alternate options.' But you keep pushing back on this approach, saying that these are matters to be determined in the bioarchitecture group. This is a real impasse. The technical 'issues' – i.e. what is technically possible, in what time frames at what cost and to what benefit, are inextricably bound up with policy questions and there is really no way to separate them.

... I am trying to be useful and practical. The Secretary should take credit for refusing to go forward on a complex acquisition without clear evidence that the technology is ready to be used in realistic operational settings. Failure to do this in the past brought us ASP [Advanced Spectroscopic Portal monitor program cancelled by DHS in 2011] and SBInet [Secure Border Initiative Network, electronic border surveillance system cancelled by DHS in 2011]. This is a very complex technology and no one else has yet succeeded in building it. But that leaves the 'what's next' question unaddressed. Can you tell us more precisely what the Secretary expects to emerge from the 3rd party review?

The "what's next" question should include the broader strategic and policy question on the appropriate role for environmental monitoring or sampling. It appears that the DHS Office of Health Affairs (OHA) and the DHS Science and Technology Directorate (S&T) still have not resolved their differences. During his interview with Committee staff on May 30, 2013, DHS BioWatch program manager Dr. Michael Walter stated that OHA and S&T had not come to agreement on the questions to be decided jointly.

Overarching strategy and policy is needed to help determine requirements in a Generation 3 system. Such a concern has been reflected in internal DHS communications. In a July 12, 2012, email, Wendy Hall, a DHS special senior advisor on biological agents, wrote: "Ah yes. But Jerry and I might not give up on that as we recommended some related items to A/S Heyman [DHS Assistant Secretary for Policy] and would need to ask S&T for technical support to further our Policy thinking about Gen3 requirements that meet various biodefense policy objectives. And we have to have a more solid idea of our policy goals to be able to effectively evaluate the documents that OHA will be working to produce."²¹

The lack of a strategy raises concerns about whether biodefense spending is unbalanced, disproportionately directed toward an outdated approach against bioterrorism and not directed

²¹ Email from Wendy Hall to Douglas Drabkowski and Segaran Pillai, July 12, 2012, 8:25 pm.

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enough to ensure adequate capacity in state and local health departments to respond to an actual attack. An updated strategy is needed to decide the optimal approach for BioWatch.

D. Current Status of BioWatch Program

After already spending close to \$280 million on autonomous detection or Gen-3 technologies and on the failed systems of Gen 2.5, a key question to examine at the June 18th hearing is whether the DHS Secretary should be permitted to certify the science of new BioWatch technologies to be acquired before an overall biodefense strategy is determined.

The problems that DHS has experienced over several years with the deployment and the failure of operational testing of autonomous detection systems has finally caused the Congress to put Generation-3 on pause. However, the lack of a strategy impedes the ability to properly assess the cost and benefits of the BioWatch program, an assessment that would appear to be essential to an ultimate decision by the DHS Secretary to certify for Generation-3 acquisition. DHS' current approach, obtaining documentation and scientific support in response to the September 2012, GAO report and other reviews, is a positive step but it is unclear how it will account for the threshold matter of what the U.S. biodefense strategy is.

According to GAO, DHS has spent \$104 million on BioWatch Gen-3 acquisition.²² In addition, the S&T Directorate has invested in R&D activities to develop a next-generation pathogen detection system for use as a BioWatch Gen-3 system. According to the S&T Directorate, it spent approximately \$160 million between FY 2004 and FY 2008, to develop potential BioWatch Gen-3 systems.²³ In addition, DHS deployed an Autonomous Pathogen Detection System, BioWatch Generation-2.5 (Gen-2.5), but that pilot program was halted when the system began malfunctioning in the field. While the cost of Gen 2.5 is not known precisely, the DHS OHA FY 2009 Congressional Budget Justification (CBJ) stated that \$20.4 million would be to procure and field 150 automated pathogen detection system sensors and another \$3.6 million to operate and maintain APDS Block 1 sensors procured in 2008.²⁴

A reassessment of bioterrorism strategy could also help address long-standing concerns and controversies about the value or appropriate role of BioWatch. As noted in an internal CDC document, "Biowatch program is unpopular[,] is questioned in some quarters, including parts of DHS."²⁵ Dr. Donald A. Henderson, an epidemiologist who led the global eradication of

²² U.S. Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 (September 10, 2012) available at <http://www.gao.gov/assets/650/648026.pdf>.

²³ Congressional Research Service memorandum, *Information for a hearing on the Department of Homeland Security BioWatch program*, at 5 (June 7, 2013).

²⁴ OHA FY 2009 CBJ at OHA-32. Interestingly, the GAO testified at a House Committee on Homeland Security Subcommittee hearing on July 16, 2008 and stated that DHS told them the Gen 2.5 units would cost \$120,000 per unit to procure and \$65,000-72,000 annually per unit to operate and maintain. According to an internal DHS document, the cost estimates used for Gen 3 showed \$117,000 per unit and but a much higher \$174,000 per unit for operation and maintenance. See Pillai and Drabkowski, *BioWatch*, December 2011, slide 3.

²⁵ Presentation to CDC Director, NCEZID Quarterly Performance Review, May 25, 2011. The document appears to be an outline of a presentation by Toby Merlin.

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smallpox and was an anti-terrorism advisor when BioWatch was launched, has said that he had yet to see a “scientific justification” for it.²⁶ He added that: “It has never stood the test of rationality. This whole concept is just preposterous.”²⁷ Specifically, on strategy, Dr. Henderson stated: “We are now 11 years afterward [the post-9/11 attack], and we still do not have a coordinated plan.”²⁸ Moreover, the Bipartisan WMD Terrorism Research Center’s Bio-Response Report Card in October 2011, determined that the usefulness of BioWatch is unclear.²⁹ The report noted that “BioWatch Generations I & II have suffered from early growing pains and system limitations.”

II. Flawed Implementation and Mismanagement Have Undercut BioWatch Effectiveness

Part of the controversy involving BioWatch is the way the program was launched. It was rolled out within 80 days, with little scientific testing, and imposed on the state and local health departments without explicit increased funding for BioWatch, leading some to view the program as an unfunded mandate.

Proponents of BioWatch have acknowledged the rushed deployment and the scientific shortcomings, but have justified going forward anyway. Dr. Jeffrey Stiefel, the DHS BioWatch program manager from 2004-2008, wrote in a July 9, 2012, commenting on the Los Angeles Times article on BioWatch wrote:

In the end, the article is basically stating that basic science was never performed before fielding BW. What I mean by basic science is sampling the air to catalog endogenous organisms and ensure when BW was deployed, we would have had probe/primer sets that would not react to near neighbors.

1. This is a valid point. BW was fielded quickly on the direction [sic] of the President. 2. One has to take the immediate political and intelligence [sic] climate into account, before judgement is passed on the fielding of BW. We were about [sic] to go to war with a foe that stated unequivocally [sic] that they would use biological and chemical weapons against [sic] the US and its [sic] partners

Given the context of the time, the accelerated rollout of BioWatch is understandable. However, there were scientific issues that were known at the time BioWatch started or became known in the early years of BioWatch. The Committee’s investigation found that these issues were not dealt with promptly or adequately. This section of the memorandum examines some of

²⁶ David A. Willman, *Troubled BioWatch program at crossroads*, L.A. TIMES, December 21, 2012.

²⁷ *Id.*

²⁸ Josh Margolin, *Nightmare state of anti-bioterror plan*, N.Y. POST, September 18, 2012.

²⁹ Senator Bob Graham, Senator Jim Talent, Randy Larsen, and Lynne Kidder, *The Bipartisan WMD Terrorism Research Center’s Bio-Response Report Card: 21st Century Biological Threats*, October 2011 at 26.

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these issues that have troubled the BioWatch program, including faulty test results and implementation and quality control problems, including with the assays.

A. Faulty Test Results

One of the expected problems with a complex technology like BioWatch is that the testing used by this system must be able to distinguish bacterial organisms from a target agent in a bioterrorist attack from another bacteria that exists naturally in the environment. These kinds of bacteria that exist in the environment are referred to as “near neighbors.”

During a May 23, 2013, interview with Committee staff, Dr. Stephen A. Morse of the CDC told the staff that, before the BioWatch program was launched, he served in 2002, on a committee advising the Defense Threat Reduction Agency. This committee was examining the issue of near neighbors and biological threat agents in connection with a study called “Defense of Cities.” Around the time in late 2002, or early 2003, as BioWatch was being stood up, he said he was told by the Chairman of the committee that the committee was being shut down after only six months without any reason given. Such work as described by Dr. Morse would have been pertinent to the near neighbor problem now confronting BioWatch.

The “near neighbor” issue is not a new one. A precursor Department of Energy program to BioWatch called BASIS (Bio Aerosol Sentry and Information System) indicated issues with initial false-positive results. In February 2002, it was deployed at the Winter Olympics in Salt Lake City. On February 12, 2002, there four initial positive tests for anthrax at the airport.³⁰ Then Utah Governor Mike Leavitt was faced with a decision over whether to close the airport. After consulting with CDC and other officials, Governor Leavitt decided to wait for confirmatory tests, which tested negative.³¹

The most significant near neighbor positive-result problem in the BioWatch program has involved *francisella tularensis*, the bacteria that cause tularemia or rabbit fever. During his interview with Committee staff, DHS scientist Segaran Pillai said that when BioWatch was launched in 2003, the assay for *francisella tularensis* was designed to detect several species of that bacteria, including *francisella tularensis novicida*, a type of bacteria considered non-pathogenic³² that exists in the environment but is not one used in biological agents of concern. By October 2003, the BioWatch program got its first BioWatch Actionable Result (BAR) in Houston, Texas for *francisella tularensis*, but it turned out it was for the non-pathogenic *francisella tularensis novicida*. After this test result, DHS helped fund a study conducted by Los Alamos National Laboratories and scientists at Northern Arizona University.³³ According to Dr. Pillai, this study published in 2005, showed that *francisella tularensis novicida* was an entirely different species of *francisella tularensis* and should no longer have been a target for BioWatch detection.

³⁰ David Willman, *Troubled BioWatch program at crossroads*, L.A. TIMES, December 21, 2012.

³¹ *Id.*

³² Pillai and Drabkowski, BioWatch, December 2011, slide 19.

³³ Susan Barns, et. al., “Detection of Diverse New *Francisella*-Like Bacteria in Environmental Samples, Applied and Environmental Microbiology, September 2005, 5494.

Even though the 2005 study that DHS commissioned showed that *francisella tularensis novicida* should not be a BioWatch target, the assay was not redesigned to exclude that bacteria. Dr. Pillai agreed that the assay should have been redesigned back in 2005. It was not until recent years, after the National Academies of Science reports, that DHS and CDC started working together to find ways to design new assays to distinguish *francisella tularensis novicida* from the target *francisella tularensis* pathogens. As a result of this delayed response, during the period of 2005-2011, BioWatch and its state and local public health authorities had to contend with well over 100 BioWatch Actionable Results (BARS), positive hits attributed to naturally occurring bacteria (mostly *francisella tularensis novicida*), since the 2005 study.

B. Implementation and Quality Control Problems in the BioWatch Program

In addition to not dealing with the near neighbor problem in a timely manner, the BioWatch program suffered from serious implementation and quality control flaws. These problems have included inappropriate placement of the collectors themselves, the deployment of assays without appropriate testing or approval, and the deployment of certain assays that were less effective than previous assays.

For example, in the rush for deployment, many BioWatch collectors were co-located with preexisting EPA air quality monitors. However, the criteria for placement of EPA air quality monitors are different from those for the placement of BioWatch collectors. EPA monitors are designed to assess the impact of potential pollutant sources for detection. As a 2003 Congressional Research Service report noted, because of the different criteria for biological detection, the location of the EPA air quality monitors did not place the BioWatch collectors in an optimal configuration for a given area.³⁴ Another concern with placing BioWatch collectors at EPA sites is that EPA monitors were not equally spaced within a city or area. Thus, the irregularity of placement and potential gaps in coverage may have caused them to be inappropriate for security concerns.³⁵ In addition, the placement would have made it more difficult to determine the exact areas impacted by the release. It wasn't until several years later that DHS finally changed locations of its collectors from EPA sites to new locations to better reflect risk assessment.

In addition to improper placement, the quality control of BioWatch components has also experienced problems. In January 2007, the DHS' Inspector General Office issued a report criticizing the chain-of-custody procedures and quality control involving the handling and transportation of BioWatch filters.³⁵ Among the problems found:

- At 84 percent of the labs, exposed filters were improperly transferred from the field.
- At 74 percent of the labs, bags holding the filters were improperly decontaminated.

³⁴ Dana A. Shea and Sarah A. Lister, "The BioWatch Program: Detection of Bioterrorism, Congressional Research Service, November 19, 2003 available at <http://www.fas.org/spp/crs/terror/RL32152.html>.

³⁵ Department of Homeland Security, Office of Inspector General, *DHS' Management of BioWatch Program*, OIG-07-22 (January 2007) available at http://www.oig.dhs.gov/assets/Mgmt/OIG_07-22_Jan07.pdf.

- In 65 percent of the cities checked, procedural errors were made during handoffs from field workers to lab technicians.³⁶

Transportation and handling issues were not the only problems with the BioWatch filters. The EPA's Inspector General Office found that EPA did not provide adequate oversight of the sampling operations of the BioWatch program to ensure quality assurance guidance was adhered to, potentially affecting the quality of the samples taken.³⁷ Both agencies stated they corrected the deficiencies. However, such deficiencies could have jeopardized DHS' ability to detect biological agents and may well have impacted the validity of results in the early years of the program. Questions relating to the reliability or usefulness of performance data for BioWatch during its first three years of deployment should be examined at the June 18th hearing.

The kinds of assays used in the BioWatch system, and their relative effectiveness over different generations of the BioWatch technology, has also been a source of controversy in the program. In 2006 through 2008, BioWatch was involved in the development and the deployment of an autonomous detection system in a pilot program known as Gen 2.5 or the Autonomous Pathogen Detection System (APDS). This system used multiplex assays, which can detect several different organisms in a single sample, and thus would be generally more efficient, as they require less time and reagents.³⁸

In 2007, based on work conducted at DHS and the Lawrence Livermore National Laboratory (LLNL), DHS moved forward with initial deployment of the multiplex assays into the field, and DHS began a limited transition from single-plex assays.³⁹ In 2008, when multiplex assay performance data was shared with CDC, the agency raised concerns with DHS about potential limitations in the performance of those assays. In 2008, DHS OHA requested that the S&T conduct an evaluation of the multiplex assays that were developed by LLNL and deployed in the BioWatch Program.⁴⁰ S&T established a BioWatch Technical Advisory Committee (BTAC) that encompassed technical experts from half a dozen agencies and sub-agencies, with the goal of determining the robustness of the multiplex assays for use in the BioWatch program to meet the intended use and application.⁴¹ BTAC members evaluated reports and data generated by LLNL and the Pacific Northwest National Laboratory (PNNL).

According to an internal DHS document, it was the unanimous opinion of the BTAC that Gen 2.5 assays did not provide an improvement over the previously deployed single-plex real-time polymerase chain reaction (PCR) testing.⁴² In fact, it was the unanimous observation of the

³⁶ *Id.* at 5.

³⁷ EPA, Office of Inspector General, *EPA Needs to Fulfill Its Designated Responsibilities to Ensure Effective BioWatch Program*, 2005-P-00012 (March 23, 2005) available at <http://www.epa.gov/oig/reports/2005/20050323-2005-P-00012.pdf>.

³⁸ Hon. Nelson Peacock, DHS Assistant Secretary for Legislative Affairs, to The Honorable Fred Upton, Chairman, Committee on Energy and Commerce, U.S. House of Representatives, January 25, 2013.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Pillai and Drabkowski, BioWatch, December 2011, slide 15.

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BTAC that the results of the BioPlex study demonstrated a 10 to 500 times loss in sensitivity of the Gen 2.5 assays which represented a decreased capability to detect a widespread release of biological agents.⁴³ As a result of these findings, the BTAC recommended to OHA on July 16, 2009, that BioWatch revert back to single-plex real-time PCR assays for sample analysis. BioWatch laboratories transitioned back to the single-plex real-time PCR assays by August 2009. However, a DHS document showed that New York and another location had transitioned back a year before in August 2008, before the other 12 affected jurisdictions.⁴⁴ The two political conventions in 2008 also both used real-time assays. Thus, it appears that DHS let 12 jurisdictions use assays for a year that were already in question, and ultimately found to be 10 to 500 times less sensitive than the assays used in the other BioWatch jurisdictions.

Moreover, internal CDC documents indicate that DHS deployed these assays without consulting CDC and without proper authorization. According to an internal CDC email from 2008, the following was noted about the deployment of Gen 2.5 or APDS:

- Senior-level DHS personnel become aware/discovered that DBPR (CDC's Division of Bioterrorism Preparedness and Response) leadership did NOT accept or approval [sic] Multiplex Panel 1/Panel 2 Equivalency.
- It was then revealed that Dr. Meyer [CDC scientist on detail to DHS] had accepted them.
- It was clearly stated that Dr. Meyer was not authorized to accept/approve such decisions but that authority resides within the BRRAT [Bioterrorism Rapid Response and Advanced Technology] lab.
- The reason BW Program is in its current situation . . . is bcs CDC/DBPR/SME [subject matter experts] have not been involved in the decision process for selecting Panel 2, Panel 3 or the acceptance of APDS.
- DHS leadership have made key multiplex panel-selection decisions based on misinformation/mis-placed authority w/o the approval or authorization of DBPR's leadership.
- DHS has chosen not to directly engage with DBPR's leadership related to Panel 2 and 3 selection.⁴⁵

According to an October 23, 2012, Los Angeles Times article, Dr. Meyer acknowledged that he lost his contracting role with Homeland Security because of dissatisfaction over how the multiplex assays performed once installed.⁴⁶

⁴³ Id.

⁴⁴ Attachment to Peacock letter, *supra* note 44.

⁴⁵ Harvey Holmes of CDC to Harvey Holmes, September 12, 2008, 9:51 am.

⁴⁶ David Willman, *Test fail to detect lethal germs: Scientists say the U.S. biodefense system used a faulty tool for two years to check for threats in 30 cities*, L.A. TIMES, October 23, 2012. According to a June 13, 2013 email from

Moreover, the DHS official who oversaw deployment of Gen 2.5 was removed from working on BioWatch. In a November 13, 2012, request letter to DHS Secretary Napolitano, the Committee asked for a written explanation for why the federal official who oversaw installation of the multiplex assays was removed from his position of responsibility in the BioWatch program and the date he was removed. In his interview with Committee staff, the DHS official said he was the subject of an internal investigation, he was reassigned from his BioWatch duties, told he was not allowed to work on BioWatch or even use the word “bio.” This official believed he was the subject of three different investigations, but DHS later told staff that there was only one investigation and that it was closed in June 2012.⁴⁷

While DHS has confirmed to Committee staff that its internal investigation found mismanagement of BioWatch, DHS has refused to provide documents relating to this investigation or to otherwise explain the mismanagement that occurred. DHS’ refusal to provide this information has prevented the Committee from better understanding the management problems facing the program and whether they have been addressed or corrected.

DHS’ approach on Gen-3 acquisition has also been problematic. A September 2012 GAO report found that, in October of 2009, DHS approved Gen-3 acquisition, but did not engage in the appropriate steps leading up to its acquisition.⁴⁸ GAO stated that DHS had a responsibility to ensure that Generation-3 provided an optimal solution to the problems with Generation-2 and that Gen-3 was successful based on the costs and benefits associated with the program. Those involved in the program claim that leadership directed them to develop the program quickly for the 2009 decision and as a result, critical early phases were bypassed and DHS did not follow their own guidance and requirements in order to grant Gen-3 acquisition. As a result, quality assurance of the program was compromised.

It should be noted that DHS acquisition is also one of several management functions that fall under the Implementing and Transforming DHS category in the GAO’s High-Risk Series, which highlights programs that are at high risk for waste, fraud, abuse, mismanagement, or in need of broad reform.⁴⁹

III. Continuing Concerns Over BioWatch

This section of the memorandum examines continuing concerns about BioWatch. These include: lack of data supporting the effectiveness of the current BioWatch technology, concerns

CDC Office of Legislative Affairs to Committee staff, Dr. Meyer retired from CDC on January 3, 2008. He then went to work for the Tauri Group, a contractor that works in the BioWatch program.

⁴⁷ The impression of multiple investigations may have arose because the investigator for the first investigation was himself removed for misconduct, and another DHS investigator was brought in to redo the investigation.

⁴⁸ U.S. Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 (September 10, 2012) available at <http://www.gao.gov/assets/650/648026.pdf>.

⁴⁹ Id. at 4 n.6; see also GAO *High-Risk Series*, April 2013.

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with the credibility of DHS statements about BioWatch, and the relationship between CDC and DHS.

A. Lack of Data Supporting Effectiveness of Current BioWatch Technology

After more than a decade of operation, BioWatch still lacks critical data about the Gen-2 technology currently used in its system. For example, DHS scientists noted among the following limitations with BioWatch Generation 1 and 2 that system sensitivity was unknown at the current time.⁵⁰

Internal documents reflect issues over lack of data availability on BioWatch Generation 2. A DHS S&T document showed the information gaps itemizing the areas of Generation 1 and 2 where there was a lack of understanding: system capture efficacy, agent degradation rate, sample processing efficacy, presence of PCR inhibitors and its impact on PCR inhibition for detection, and the true cost to operate Gen 1/2.⁵¹

In an October 22, 2012, email to a CDC official, DHS BioWatch Acting Deputy Director Linda Beck wrote: “We do not have data that show how the filters and extraction from the filters affects LOD [Limits of detection].”⁵² During his staff interview, DHS BioWatch Program Manager Michael Walter stated that OHA now had the data. However, there were no documents provided that substantiated the existence of the data or whether it had been shared outside of OHA.

In addition, internal DHS emails show that on January 13, 2012, and January 20, 2012, DHS S&T scientist Douglas Drabkowski asked Michael Walter and Robert Hooks of DHS OHA to provide the following information: available data that informs the current (Gen-2) system sensitivity; whether or not Dugway chamber testing was performed to understand current (Gen-2) system sensitivity for the five (or six) BioWatch agents; what the current sample processing efficiency is for the five (or six) BioWatch agents.⁵³ Dr. Drabkowski sought this information to help “understand the current Gen-2 system sensitivity in order to better inform robust biomonitoring systems of the future.”⁵⁴ On August 6, 2012, Dr. Drabkowski emailed Dr. Segaran Pillai at DHS S&T that as of that date “we have not received a response from OHA.”⁵⁵ Dr. Pillai told Committee staff during his June 6, 2013, interview that he still had not received that data.

The lack of data or data-sharing is of particular concern because of the limited understanding about the effectiveness of the current BioWatch technology. As noted in a November 17, 2011, email, Dr. Toby Merlin wrote: “. . . It’s interesting. I don’t think anyone

⁵⁰ Pillai and Drabkowski, BioWatch, December 2011, slide 31.

⁵¹ Attachment of BioWatch read ahead for USST 3 Jan12, email from Kristin Willner to Segaran Pillai, January 3, 2012, 4:14 pm.

⁵² Email from Linda Beck of DHS to Michael Farrell of CDC, October 22, 2012, 5:13 pm.

⁵³ Email from Douglas Drabkowski to Michael Walter and Robert Hooks, January 20, 2012, 12:11 pm.

⁵⁴ Id.

⁵⁵ Email from Douglas Drabkowski to Segaran Pillai, August 6, 2012, 11:38 am.

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actually knows the sensitivity of the current PSU [Portable Sampling Unit] system for detecting bacteria or viruses in actual aerosol.” In fact, according to DHS, BioWatch sponsored a study at the U.S. Army, Dugway Proving Grounds (DPG) to further characterize the sensitivity of the BioWatch operational system (including the Portable Sampling Unit aerosol collector, filter media, sample extraction method and reagents, assays, and algorithm for detection). In addition, this study enabled the measurement of particulate distribution across aerosol collector filter medium. DPG is currently analyzing the results of this study, and is expected to deliver the findings to DHS in Fall 2013.⁵⁶

In addition to the lack of sensitivity data for Biowatch Gen-2, DHS scientists have noted other data gaps such as sample capture and preservation efficacy is limited or unknown, and sample processing and extraction efficacy is unknown.⁵⁷ Members may want to question whether a proper assessment can be conducted about Gen-3 when there is still limited or missing data related to Gen-2.

B. Credibility of DHS Statements About BioWatch

Where data and statements about BioWatch have been provided by DHS, in several cases serious questions have been raised about credibility.

CDC scientists believed DHS made a misleading statement about BioWatch’s ability to make trace detections. In a July 26, 2012, email in regard to this issue, CDC scientist Angela Weber wrote:

I realize that much attention has been placed on the issues related to Ft. [francisella tularensis]. However, I would like to also bring up issues related to how DHS OHA has referred to BioWatch’s ability to detect ‘traces of dangerous pathogen’

Since we are being asked about this, I think it’s critical that we provide clarification as to why this is misleading. In the course of working on Biowatch, I have heard OHA repeatedly sell this capability as a way to tout how sensitive the assays are at detecting low concentrations of organisms. This is flawed as there is supporting data showing that the collection system is not capable of detecting trace concentrations of organisms (the collector itself is known to leak around the filter). This is an important point to make from the public health standpoint as the system (regardless of whether you are addressing the current system or Gen 3) is not capable of detecting the lower concentrations associated with infectious doses. This is true of all the agents and not only Ft as it relates to sampler collection efficiency, etc.

⁵⁶ Email from DHS Office of Legislative Affairs to Committee Staff, June 11, 2013, 1:02 pm.

⁵⁷ Segaran Pillai and Douglas Drabkowski, DHS S&T, BioWatch, December 2011, slides 6 and 7.

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The other critical point to bring up related to this is based on basic industrial hygiene practice. DHS OHA should not be claiming that the Ft BARs were associated with trace detections because they have absolutely no way of knowing what was in the environment (airborne) at the time the organism was collected. Most likely, there was a very large aerosol present when it was detected as BioWatch requires large concentrations to be present⁵⁸

CDC scientists have also raised concerns with the DHS action to lower the threshold (known as Ct or cycling threshold used for the PCR test) for what would qualify as a BAR for *francisella tularensis*. This new cut-off was implemented in August 2011.⁵⁹ In an August 16, 2012, email, CDC scientist Angela Weber wrote:

. . . This is another reason for treating the Ct values as only qualitative – who knows how much air is actually being collected from day to day. Another concern this brings up is lowering the cut-off Ct value for Ft to get around the analytical problems and false positives. In doing so, you are making the assay even less sensitive when already the LOD is very high . . . (this is not a trace level as claimed by DHS).⁶⁰

This view was supported by Dr. Stephen Morse during his staff interview on May 23, 2013. Dr. Morse called the changes to eliminate the *francisella tularensis* BARS by lowering the threshold “artificial.”

CDC personnel have expressed concerns generally about BioWatch, with serious doubts about Generation-3.

In a June 19, 2012, email, Dr. Ali Khan , the CDC Director for the Office of Public Health Preparedness and Response, wrote to Dr. Beth Bell, CDC Director of NCEZID:

As discussed earlier today, your professional judgment of the BioWatch program including the new Gen-3 expansion would be very helpful and appreciated for my upcoming conversation with Tara. Recognizing that DHS money is not going to be diverted to CDC, is there anything we see worthwhile in that program? Although the cost is an abomination and a positive reading will still require somebody to go get the canister and cut into the purported timeliness.⁶¹

In June 20, 2012, email, Dr. Beth Bell, CDC Director of NCEZID, wrote:

⁵⁸ Email from Angela Weber (CDC/OID/NCEZID) to Toby Merlin and Stephen A. Morse of the CDC, July 26, 2012, 1:21 pm.

⁵⁹ Email from Jasmine Chaitrum, CDC’s LRN Program Office to Toby Merlin and Geoffrey Jackson, May 10, 2012, 10:42 am.

⁶⁰ Email from Angela Weber to Stephen A. Morse, August 16, 2012, 3:03 pm.

⁶¹ Email from Ali Khan to Beth Bell, June 19, 2012 5:37 pm.

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1) Currently CDC and others (DHS S&T) have identified serious problems with the specificity and sensitivity in the Gen3 system under development On a day to day operational basis, we are most immediately concerned about the risk for false positives which could be a regular occurrence.

2) The Gen3 system generates positive results which would require investigation and confirmation before action could be taken on these results. There is currently no concept of operations for how this investigation and confirmation would take place.

3) The Gen 3 system is being deployed to Biowatch sites before the device has been shown to work effectively.⁶²

It should be noted during his staff interview, Dr. Toby Merlin, who communicated the concerns to Dr. Bell, confirmed that Items 1 and 2 were still concerns, while Item 3 did not actually occur.

In response, Dr. Ali Khan wrote: "This is very helpful. So tactically, this specific device appears to be premature for deployment for various reasons. . . ."⁶³

Dr. Bell answering Dr. Khan wrote: ". . . I would say that the operational and technical problems may not be surmountable, ie I am not sure there is a technology good enough to work the way DHS has envisioned BW Gen 3 to function. . . ."⁶⁴

CDC officials have also expressed concerns over the cost-effectiveness of Gen-3. In a July 26, 2012, email to Dr. Toby Merlin, CDC scientist Dr. Stephen Morse wrote: ". . . I heard that BioWatch is considering deploying Gen3 in indoor environments (They may have decided not to but I don't know for sure). Their mantra has been 'detect to treat' in order to reduce morbidity and mortality in the event of a release. Thus, it becomes even more important to have high confidence assay results if public buildings are to be evacuated in the event of a BAR, and prior to confirmation."⁶⁵

On the same date, Dr. Merlin replied: "I am not sure there is much of a long term future for Gen3 in the current budgetary environment. That said, Biowatch has already deployed into select indoor environments, where it is problematic to send teams in for phase 1 sampling without evacuating the building."⁶⁶

Dr. Morse wrote back:

⁶² Email from Beth Bell to Ali Khan, June 20, 2012, 6:05 am.

⁶³ Email from Ali Khan to Beth Bell, June 20, 2012, 12:02 pm.

⁶⁴ Email from Beth Bell to Ali Khan, June 20, 2012, 7:09 pm.

⁶⁵ Email from Stephen Morse to Toby Merlin, July 26, 2012, 9:54 am.

⁶⁶ Email from Toby Merlin to Stephen Morse, July 26, 2012, 10:19 am.

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With the current BioWatch system, filters are collected and analyzed in a laboratory. Thus, there is a delay between when the release occurred and when it was detected through laboratory analysis. Confirmation may occur in the same laboratory facility. In Gen3, they envision that the release would be detected by the autonomous collection/analysis unit and the results sent to a central site where some action would be initiated. I think there is more time for a thoughtful consideration of the data with the current system than what they envision (or hyped) with Gen3. I agree there is little 'bang for the buck' with Gen3 and it is likely to be a casualty of the Country's current fiscal situation.⁶⁷

In reaction, Dr. Merlin stated: "Candidly, I do not believe that a high consequence action can be initiated based only on a BAR, even if the test methodology conforms to PHAA [Public Health Actionable Assay, a stronger standard than PSAA, Public Safety Actionable Assay, favored by DHS OHA]. There are many other potential sources of error than just cross reactivities."⁶⁸

Dr. Morse concluded: "I agree with your comment whole heartedly. Unfortunately, the hype is different than reality."⁶⁹

OHA's views about BioWatch Gen-3 seem out of the step with the preponderance of evidence and external reviews. For example, in a February 7, 2012, Acquisition Decision Memorandum, the DHS Acquisition Review Board determined that the Gen-3 program's lack of maturity and compliance of Management Directive 102-01 were cited as significant risk. Nevertheless, an internal DHS email indicates that DHSOHA leadership in June 2012, continued to view Gen-3 as not "high risk," despite the weight of contrary opinion. According to a June 19, 2012, email, DHS Undersecretary Tara O'Toole wrote:

... The GAO report now circulating in DHS for accuracy (release date in August) is highly critical of the acquisition process. There is another report on the state of the biowatch technology by HSSAI which the Secretary requested (have not seen it). S&T's written comments to the IRB [DHS's Investment Review Board] express a lot of skepticism about whether the technology works and whether we are getting our money's worth. The House Approps bill does not include money for BW operational testing until the Secretary 'certifies' that it is prudent to do so and provides an alternate plan (essentially an analysis of alternatives, which S&T also wants to see done).

Alex Garza [then DHS Assistant Secretary for Health Affairs], on the other hand, told me this morning that he does not regard the BioWatch

⁶⁷ Email from Stephen Morse to Toby Merlin, July 26, 2012, 10:34 am.

⁶⁸ Email from Toby Merlin to Stephen Morse, July 26, 2012 10:44 am.

⁶⁹ Email from Stephen Morse to Toby Merlin, July 26, 2012, 10:52 am.

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acquisition to be ‘high risk’ and he has aggressively sought permission to proceed⁷⁰

Moreover, the HSSAI report issued in August 2012, found that the deficiencies in the CONOPS (concept of operations) in Gen-3 presented “high risk to overall program success; specifically, they may hinder proper development of operational requirements.”⁷¹

DHS scientists believed that OHA used new operational requirements for Gen-3 technology that were “very confusing and misleading.”⁷² No information was provided as to the rationale for weakening operational system sensitivity. DHS scientists estimated that these changes would lower the probability of detection to 30 percent with the new indoor standard and less than 20 percent for the outdoor standard.⁷³ One DHS scientist was concerned enough with these changes that he wrote: “What kind of game are they playing with these system-level sensitivity numbers?”⁷⁴

Information obtained during the investigation raises questions about the accuracy of DHS statements concerning the performance of BioWatch. For example, in a DHS blog responding to a July 2012 Los Angeles Times article, DHS Assistant Secretary Alexander Garza wrote: “Out of these more than 7 million tests, BioWatch has reported 37 instances in which naturally-occurring biological pathogens were detected from environmental sources.”⁷⁵ However, information provided by DHS and CDC shows the total number of BARS that have occurred in the BioWatch program were 149 instances in which the BioWatch monitor detected environmental organisms.⁷⁶ This discrepancy should be examined at the June 18 hearing.

C. CDC-DHS Relations

Internal documents from CDC and DHS revealed tensions over CDC’s inclusion and approach to BioWatch scientific issues. Even after the Gen 2.5 matter and beyond BioWatch, the CDC still had concerns about insufficient inclusion into DHS decisions. In a May 23, 2012, email, Dr. Toby Merlin wrote: “There is a lot that happens at DHS S&T that has profound impact on public health downstream, and we could better understand and mitigate these decisions if we had some sort of seat at the table. Here are some examples: 1) The material threat assessments (MTA) which DHS is required to perform by statute. These drive the

⁷⁰ Email from Tara O’Toole to Brian de Vallance, June 19, 2012 3:03 pm.

⁷¹ HSSAI Report, *Revised BioWatch Gen-3 Program Acquisition Assessment: Executive Summary and Annotated Briefing*, at 54.

⁷² DHS S&T Chem-Bio Division Review and Comments, BioWatch Documents – June 14, 2012 at 5.

⁷³ *Id.*

⁷⁴ Email from Doug Drabkowski, DHS S&T Directorate, to Segaran Pillai, April 23, 2012, 12:37 pm.

⁷⁵ Posting of Alexander Garza, Assistant Secretary for Health Affairs, to DHS blog, “The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack,” <http://www.dhs.gov/blog/2012/07/12/truth-about-biowatch> (July 12, 2012).

⁷⁶ June 10, 2013 email from DHS Office of Legislative Affairs to Committee staff; May 29, 2013 email from CDC Office of Legislative Affairs to Committee staff: “Total BARS to date=149; Total for 2012=5; Total for 2013 to date =0. Email from Jasmine Chaitram of the CDC to Toby Merlin, October 9, 2012, 12:04 pm: “We now have 149 BARS.”

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downstream decisions about medical countermeasure acquisition, diagnostic test development, Biowatch testing, and preparedness plans. But the MTAs seems to be developed without input from people who really understand the agents, diseases, or practical implications of these decisions.”⁷⁷ During his May 15, 2013, interview with Committee staff, Dr. Merlin confirmed that this was still a concern.

Another source of tension between CDC and DHS has been over the definition of a BAR. This is illustrated in a series of emails from Dr. Toby Merlin of the CDC. In a June 24, 2011, email, he wrote: “I understand the disposition of this, but it illustrates to me the squishy definition of a BAR. What is the action here? Who has made the final determination of the action to take? What is that determination? It’s obviously not urgent, but I would like to discuss. There seem to be different definitions of a BAR, according to the jurisdiction (e.g. NYC versus Houston).”⁷⁸ Several months later, Dr. Merlin wrote: “BioWatch Program and CDC agree on the need to develop federal guidance for how jurisdictions should handle a single BAR. Mike Walter is going to take the lead with CIDRAP in setting up a focus group with BioWatch, CDC, NYC and a few other large cities to work on this.”⁷⁹ Yet, on June 29, 2012, Dr. Merlin wrote: “We have been trying to get the Biowatch program to better define what a BAR is.” Support for CDC’s concern about the term “BAR” is found in the 2010 report by the National Academies of Science (NAS) on BioWatch. The NAS Committee concluded:

The committee considers the term ‘BioWatch Actionable Result,’ or BAR, misleading because the term implies that action can be taken immediately, but further investigation and deliberation are generally needed. A BAR indicates only that genetic material consistent with a target pathogen was present on a BioWatch filter. A BAR does not confirm that a terrorist attack has occurred, that a viable pathogen was detected, or that people have actually been exposed. Thus, the committee sees a BAR alone as unlikely to be a sufficient basis to automatically trigger a specific response by public health authorities.⁸⁰

One continuing issue of controversy is over “false positives.” This controversy refers to the times that BioWatch has shown a positive hit for one of the targeted bioterrorism agents, but upon further analysis has turned out to be a near neighbor to the agent that exists in the environment. In July 2012, the Los Angeles Times published an article about BioWatch’s false alarms, detailing instances of such positive hits at high-profile events over the last decade. In response, then DHS Assistant Secretary for Health Affairs, Dr. Alexander Garza, published a blog on July 12, 2012, called, “The Truth About BioWatch: The Importance of Early Detection of a Potential Biological Attack.” In that blog, Dr. Garza wrote: “Recent media reports have incorrectly claimed that BioWatch is prone to ‘false positives’ or ‘false alarms’ that create confusion among local officials and first responders. These claims are unsubstantiated. To date,

⁷⁷ Email from Toby Merlin to Beth Bell and Tracee Treadwell, May 23, 2012, 9:53 am.

⁷⁸ Email from Toby Merlin to Michael Farrell, Richard Kellogg and Harvey Holmes, June 24, 2011, 9:16 am.

⁷⁹ Email from Toby Merlin to Colin Stimmler (NYC Dept. of Health & Mental Hygiene), Isaac Weifuse, and Beth Maldin, November 17, 2011, 2:51 pm.

⁸⁰ National Academy of Sciences, *supra* note 1 at 55.

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more than 7 million tests have been performed by dedicated public health lab officials and there has never been a false positive result.”

In defense of this position, DHS scientist Dr. Segaran Pillai told Committee staff that if the BioWatch assay was designed to detect a category of bacteria that included the near neighbor to the francisella tularensis select agent, then the detection of the near neighbor was not a false positive because the assay was designed to detect it. In addition, Dr. Garza was reiterating a position taken by DHS during the Bush Administration that BioWatch had never had a false positive.

Nevertheless, questions may still be raised at the hearing about DHS’s insistence that BioWatch has never had a false positive. There is substantial scientific disagreement with DHS’ position. For example, CDC emails show CDC scientists considered the BARs as false positives. In addition, the National Academies of Science, disagreed with the DHS characterization of the BARS, by stating in its 2010 report:

From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been ‘BAR false positives,’ meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.⁸¹

Given the NAS report commentary, DHS may be questioned about why it continues taking a hard-line “no false positives” stance that is controversial and risks further undermining DHS credibility with the CDC and public health laboratories.

Moreover, there is another basis to question Dr. Garza’s statement. According to the GAO, in order to build user confidence in the system, BioWatch has established a stringent threshold of 1 in 10 million for the false positive rate – that is, the rate at which the system is allowed to indicate a pathogen is present when one is not.⁸² According to a Gen-3 operational requirement document, the definition of the “probability of false positive” is “[t]he probability that the Gen-3 BioWatch detector will issue a positive signal for a BioWatch agent when that agent is not present.”⁸³ The same document states that system specificity “is defined as the ability of the Gen-3 BioWatch System to detect strains of the target species without detecting near-neighbors or background organisms.”⁸⁴ Under these definitions for Gen-3 requirements, the current BioWatch has had false-positives. Using the number of positive hits for background

⁸¹ National Academy of Sciences, *supra* note 1 at 50-51.

⁸² U.S. Government Accountability Office, *Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition*, GAO-12-810 36 (September 10, 2012) available at <http://www.gao.gov/assets/650/648026.pdf>. GAO states, that according to BioWatch documentation, 33.5 years of operational testing would be required to fully demonstrate that the system meets the established false positive rate.

Thus, BioWatch uses lab data to extrapolate the probability.

⁸³ BioWatch Gen-3 Autonomous Detection System ORD 2.0, May 16, 2011, Appendix C, C-2.

⁸⁴ *Id.*, Appendix C, C-3.

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organisms cited in Dr. Garza's blog (37 in over 7 million tests), the approximate false-positive rate is 1 in 189,000. While CRS notes that such a rate meets or exceeds requirements for other detection systems, it is about 50 times worse than the false-positive rate requirement for Gen-3.⁸⁵ Dr. Walter confirmed during the staff interview that this is still the Gen-3 requirement.

Prior mismanagement by DHS and extended scientific disputes with DHS may have also negatively impacted the confidence of CDC and the public health laboratories in working with BioWatch Gen-3. For example, in a 2011 email, CDC scientist Michael Farrell wrote:

Bottom line for me is that despite whatever changes they have done, or assay or systems validation that they perform, the Gen 3 system with these assays is going to be dead on arrival at the Public Health Service Labs, especially and importantly at NYC. This will be simply because of a lack of confidence due to previous experience with environmental cross reactivity and the problematic APDS [Gen-2.5] deployment. Confidence in the system is going to be paramount with the current 'actionable' nature of the signal that is intended. I just don't see how this is going to be possible.⁸⁶

Another email from Dr. Toby Merlin stated the historical tensions in the BioWatch program: ". . . I think the bottom line is that NYC public health feels that public health is struggling to be heard in a program that is dominated by DHS and law enforcement but which has huge implications for public health departments. . . ."⁸⁷

In addition, CDC was concerned that the multiplex technology and many of the signatures were the same or similar to Gen 2.5 "which was not found to be acceptable."⁸⁸

Such views underscore the need for DHS to have proven science that supports Gen-3 technology to engender the necessary confidence from CDC and the public health laboratories. However, over the past two years, DHS and CDC have been unable to resolve their disagreement on the appropriate testing standard to be used for the Gen-3 assays.

DHS favors the Public Safety Actionable Assay (PSAA) standard. This standard is intended to support the evaluation of field screening assays for first responder use. The actions taken in response to positive results are safety-related actions such as evacuation of building, decontamination of potentially exposed individuals, expediting the transfer of samples to the LRN for confirmation. In addition to such actions, regardless of whether a sample is positive or

⁸⁵ Congressional Research Service memorandum, *supra* note 30 at 8. As previously discussed, the 37 BARs cited in Dr. Garza's blog is considerably less than the 149 BARs that were actually reported by DHS and CDC to the Committee staff.

⁸⁶ Email from Michael Farrell to Toby Merlin, May 26, 2011, 12:15 am.

⁸⁷ Email from Toby Merlin to Beth Bell, May 6, 2012, 11:11 am.

⁸⁸ Email from Toby Merlin to Harvey Holmes, Richard Kellogg, Jasmine Chaitram, and Michael Farrell, May 25, 2011, 4:57 pm.

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negative, the sample is still forwarded to an LRN laboratory for secondary testing to eliminate False Positives and False Negatives.⁸⁹

CDC favors the Public Health Actionable Assay (PHAA) standard. This standard is specifically to support the assay development, evaluation, validation and certification of the assays deployed and employed throughout the CDC LRN.⁹⁰ “These assays are intended to be highly robust for use in a LRN laboratory to evaluate environmental samples that come into the lab, support [epidemiological] investigation associated with a bioterrorism event as well as clinical samples to support medical and clinical intervention.”⁹¹

The depth of the CDC’s support for PHAA is illustrated in an email from Dr. Dan Sosin of the CDC. He wrote: “I shared support for the PHAA model developed over multiple years of deliberation and [DHS official] asked if it was ‘too rigorous.’ I find it hard to believe that when it comes to taking actions involving human life we can be too rigorous, the cost balance does seem to be an issue. . .” Interestingly, Dr. Jeffrey Stiefel, the DHS BioWatch program manager from 2004-08, told Committee staff during his interview that he unequivocally supported the PHAA standard for Gen-3. His opinion was consistent with the pro-PHAA position he took during a lecture before the NIH in 2005, when he was the program manager for BioWatch.

On November 22, 2011, the White House Office of Science and Technology Policy (OSTP) convened a meeting including DHS and CDC scientists. Although the purpose of the meeting was not clear to some of the participants, it appears one purpose was to facilitate a resolution on the federal testing standard to be used in Gen-3. According to Dr. Pillai during his staff interview, the OSTP asked Dr. Paul Jackson of LLNL and Dr. Stephen Morse to provide advice on the appropriate testing standard. These scientists recommended the PHAA standard. However, even the OSTP meeting and the advice provided did not resolve the dispute. As a result of the impasse, Dr. Michael Walter has recently requested the National Academies of Science, as an outside and independent body, to conduct a consensus study about the testing standards and to resolve the issue.

Another unresolved issue is CDC’s concerns over a breach in informational security concerning sensitive CDC and LRN (Laboratory Response Network) information. According to CDC Office of Legislative Affairs, CDC scientists discovered that the Generation 3 Phase 1 device had incorporated nucleic acid signatures from LRN assays into the Generation 3 device.⁹² It was unclear to CDC how the Gen-3 contractor had obtained these signatures, although CDC assumed it was through Lawrence Livermore National Laboratory, which was involved in the assay development for DHS.⁹³ CDC pursued this matter for several months through the offices of the general counsels of DHS and DOE. DOE was involved because DOE

⁸⁹ Based on information in email from Segaran Pillai of DHS S&T to Toby Merlin of CDC, October 13, 2011, 10:07 am.

⁹⁰ Id.

⁹¹ Email from Dr. Segaran Pillai of DHS S&T to Dr. Toby Merlin of CDC, October 13, 2011, 10:07 am.

⁹² Email from CDC Office of Legislative Affairs to Committee staff, June 12, 2013.

⁹³ Id.

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oversees Lawrence Livermore National Laboratory. The matter was never fully resolved and CDC has not further pursued.⁹⁴

Internal CDC documents underscore the seriousness of CDC's concerns in the matter. For example, in a June 9, 2011, email, Dr. Richard Kellogg wrote:

. . . Although Inger and Mike may have more detailed information, it appears that sensitive information that may have been shared with LLNL (and which should have at least been controlled by Non Disclosure Agreements to protect intellectual property and sensitive national security information related to detection of biological threat agents) was "tossed over the fence" (i.e. unauthorized transfer with no strings attached) to a commercial platform developer How this transpired is a conundrum to me since all previous work we have done with LLNL for these type [sic] of projects (e.g. Bionet Study) was protected by highly structured and signed NDAs as standard practice.

. . . We need to understand exactly what transpired that resulted in the current situation and then take actions to institute better informational security/intellectual property protections as well as remediate the known likelihood for generating false positive results in the BioWatch Program (to which CDC is currently a principal partner).⁹⁵

It is important that CDC and the public health departments have trust and confidence in the BioWatch program. In the event of an actual attack, these public health officials would be responsible for advising and taking high-consequence decisions such as activating the Strategic National Stockpile, and dispensing medications to millions of individuals. Members may want to ask about ways on how to resolve the ongoing concerns in order to strengthen the working relationship between DHS and CDC.

In addition to the ongoing disputes between CDC and DHS, there are also internal disputes within DHS over BioWatch. As noted in an email, DHS Undersecretary O'Toole stated, ". . . I think S&T and OHA have conflicting views of the [BioWatch] program."⁹⁶ Dr. Toby Merlin wrote: "We at CDC often seem to be caught in the middle of the DHS OHA S&T dispute. I actually think a lot of this could be resolved, at least in regard to the substantive issues, if the parties put their minds and hearts to it. . . ."⁹⁷ In response, Dr. James Hayslett of CDC wrote: "Agree. The amount of animosity between the 4th and 6th floor is pretty evident from time to time."⁹⁸ Likewise, Dr. Ali Khan of CDC, with regard to the BioWatch program in DHS, wrote: "There are some very severe politics in DHS right now."⁹⁹

⁹⁴ Id.

⁹⁵ Email from Richard Kellogg to Toby Merlin, Harvey Holmes, Michael Farrell, June 9, 2011, 1:54 pm.

⁹⁶ Email from Tara O'Toole to Erin O'Connor of DHS, June 19, 2012, 2:49 pm.

⁹⁷ Email from Toby Merlin to James Hayslett, October 19, 2011, 5:23 am.

⁹⁸ Email from James Hayslett to Toby Merlin, October 19, 2011, 7:48 am.

⁹⁹ Email from Ali Khan to Beth Bell, June 21, 2012, 1:43 pm.

Majority Supplemental Memorandum for the June 18, 2013, Oversight and Investigations
Subcommittee Hearing
Page 27

Conclusion

Dr. Michael Walter, the DHS program manager for BioWatch, and Dr. Toby Merlin, CDC's principal contact for Biowatch issues, will be testifying at the committee's hearing. Members will have an opportunity to question these witnesses about issues arising from the information presented in this memorandum.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (2011-2012)
Minority (2011-2012)

July 10, 2012

Dr. Michael Walter
BioWatch Program Manager
Office of Health Affairs
U.S. Department of Homeland Security
245 Murray Lane, S.W.
Washington, D.C. 20528

Dear Dr. Walter:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, June 18, 2013, to testify at the hearing entitled "Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism."

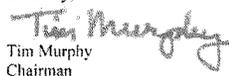
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on July 24, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at brittany.havens@mail.house.gov and mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

Question#:	1
Topic:	BAR 1
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

**Dr. Michael Walter, BioWatch Program Manager, Office of Health Affairs, U.S.
Department of Homeland Security**

Question: The Department of Homeland Security has asked the National Academies of Science to organize workshops to develop locally-owned jurisdictional response plans for response to BioWatch Actionable Results. Is that an indication that local authorities do not have sufficient guidance for handling a BAR?

Response: DHS did not ask the National Academies of Science to organize workshops to develop jurisdictional response plans. Rather, DHS requested that the National Academies of Science review and assess existing guidance to assist State and local development of response plans, including specific considerations for indoor locations, for the current technology.

The DHS request to the National Academies of Science does not reflect insufficient guidance among local authorities for handling a BAR. To the contrary, guidance documents have been published by the BioWatch Program with the full participation of all BioWatch Jurisdictions and the Federal BioWatch Working Group since 2004. As the BioWatch Program continues to evolve, the Guidance documents are updated to reflect these changes. The current BioWatch Program Guidance document was released on March 18, 2013.

Question: Why has DHS allowed this lack of guidance to occur for so many years?

Response: As discussed above, there has been no gap in DHS guidance for use by the State and Local Jurisdictions. Guidance documents have been published for use by State and Local Jurisdictions since 2004 and are updated periodically.

Question: Is there any discussion inside the Department of Homeland Security to redefine what constitutes a BAR?

Response: There are no DHS plans to redefine a BioWatch Actionable Result (BAR). A BAR is defined as one or more polymerase chain reaction (PCR)-verified positive result(s) from a BioWatch collector that meets the algorithm for one or more specific BioWatch agents. A BAR is one piece of information provided to Federal, State, and local decision-makers as they review findings from other collectors and additional relevant information in order to determine the cause of the BAR and whether there is a risk to public health.

Question#:	2
Topic:	BAR 2
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: The National Academies of Science, in its 2011 report on BioWatch, wrote: “From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been ‘BAR false positives,’ meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.” Do you agree with this statement?

Response: There is common agreement on what a BAR does and does not determine, however the term “false positive” has been used inconsistently. DHS’s use of the term “false positive” refers to a BAR being declared for a specific BioWatch agent, when in fact the DNA from that agent was not actually present. Other groups, including the CDC, consider a “false positive” to refer to a BAR being declared for a specific BioWatch agent, where the DNA is detected for the agent but the specific strain of agent is not a threat to public health. Both DHS and CDC are working to coordinate our use of scientific terminology when communicating with our stakeholders.

As discussed above, the occurrence of a BAR indicates that there is evidence of a *potential* occurrence of a terrorist attack, in that certain DNA has been detected, requiring further investigation. In every case to date, that detection has been accurate. A BAR sets in motion a series of steps to determine whether that potential attack is real. In the case of each BAR to date, the system has successfully and accurately determined that no terrorist attack was under way.

Question#:	3
Topic:	BAR 3
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Even though Dr. Garza said there had never been a false positive, does BioWatch really want to detect near-neighbors or background organisms?

Response: No. DHS's use of the term "false positive" refers to a BAR being declared for a specific BioWatch agent, when in fact the DNA from that agent was not actually present. Other groups, including the CDC, consider a "false positive" to refer to a BAR being declared for a specific BioWatch agent, where the DNA is detected for the agent but the specific strain of agent is not a threat to public health.

BioWatch detects the actual biothreat agents responsible for causing diseases of concern, and DHS and CDC have worked to minimize the occurrence of BARs due to near-neighbor organisms. BioWatch has also improved its analytical capability to rule out non-pathogenic sub-species of bioterrorism agents.

As technology improves, the BioWatch program is working to increase its specificity and accuracy in detecting target organisms. For example, it has recently improved the specificity of the assays for *Francisella tularensis*, enabling them to detect only the sub-species of the organism that are responsible for causing human disease.

Question: Even if the BioWatch detection of near-neighbors are true-positives, aren't the Department of Homeland Security and the Centers for Disease Control and Prevention working to minimize the number of BARs for near-neighbors?

Response: Yes. As discussed above, DHS and CDC have worked together with State and local partners to improve detection by continually reviewing and updating the best available assays to screen samples, tightening the analytical criteria for defining a detection, and in the case of *Francisella tularensis*, introducing assays capable of identifying the subtypes that actually cause disease.

Question#:	4
Topic:	cost
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: What was the total cost of Generation-2.5?

Response: The total cost of Generation 2.5 (APDS) was approximately \$27,853,918. Please see chart below for detail.

Fiscal Year	APDS
2003	
2004	
2005	
2006	12,985,852*
2007	
2008	14,868,066
2009	
2010	
2011	
2012	
Total to Date	27,853,918

* \$12,985,852 was spent on APDS prior to the formal transfer of the BioWatch program to the Office of Health Affairs in 2008.

Question#:	5
Topic:	Gen-3
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How much money has been spent on testing and evaluation of the Gen-3 system to date?

Response: For FY2009 through FY2012, \$77,921,217 was available for obligation by the BioWatch Program for testing and evaluation of the Gen-3 candidate systems. All Gen-3 funding thus far has been for testing and evaluation. In FY 2012, \$24,000,000 was originally appropriated, \$21,600,000 was available for obligation, but only \$4,437,681 has been obligated (the remainder has been placed on hold). Therefore, the total of past allocations plus the FY 2012 obligations is \$61,938,898, a more precise measure of what has been "spent." No funds have been appropriated for Gen-3 in FY 2013.

Fiscal Year	Gen-3 Available for Obligation	Gen-3 Obligated
2009	34,498,000	34,498,000
2010	10,100,000	10,100,000
2011	12,903,217	12,903,217
2012	20,420,000	4,437,681
Total to Date	\$77,921,217	\$61,938,898

Question: How much money has been spent on R&D by both the Department of Homeland Security's Science and Technology Directorate and the Office of Health Affairs on the testing and evaluation of Gen-3?

Response: OHA does not have the authority to perform R&D for testing and evaluation of Gen-3 and has not spent any money on R&D related to the testing and evaluation of Gen-3. The OHA funds for testing and evaluation are separate from the funds spent by S&T on R&D testing and evaluation.

S&T has spent \$ 51,893,040 on Research and \$ 12,444,489 on T&E for Gen-3. S&T conducted research and development on a next-generation biodetector from 2004-2008. This program, known as the Bio-Agent Autonomous Networked Detector or BAND, focused on the development of a fully autonomous sampling and analysis instrument capable of detecting a large number of bio-agents (>20 agents) with a higher sensitivity and specificity and lower operating costs than the deployed BioWatch systems. The BAND units were never operationally deployed but the prototype from Microfluidics Systems Inc. (MFSI) was one of the two technologies evaluated for the Gen-3 acquisition. Overall, S&T spent \$145,935,768 on R&D and \$ 14,309,205 on T&E.

Question#:	5
Topic:	Gen-3
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Is the Department of Homeland Security still spending money on Gen-3? If so, how much?

Response: No money for Gen-3 was appropriated for FY13. However, there are ongoing activities, such as an Analysis of Alternatives (AoA) study that have been utilizing FY2012 funds. The AoA will include a comparison of the current operations technology, an autonomous identifier, health surveillance, and a sentinel system. The AoA will summarize benefits and capabilities, as well as cost benefit analysis for the alternatives. Of the \$20.42M provided for Gen-3 in FY2012, only \$4,437,681 has been obligated and the remaining funds are on hold.

Question: How much will it cost for workshops and the study to be conducted by the National Academies of Science on Gen-3?

Response: A public workshop was held by the National Academies of Science Standing Committee on Health Threats and Workforce Resilience on June 25-26, 2013 to explore alternative cost-effective systems that would meet requirements for BioWatch as an automated detection system for aerosolized agents. During this workshop, multiple classes of alternative technologies for autonomous detection were discussed. The final cost for this workshop was \$292,285.

An additional independent study written by an ad hoc committee is focused on determining appropriate standards for the validation and verification of polymerase chain reaction (PCR) tests and assays used in the laboratory. The results of this study will be relevant for all nucleic acid/PCR technology. The cost for this PCR Study is estimated at \$599,469.

Question#:	6
Topic:	certification
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Before making a certification on the science of Gen-3, will the Secretary of DHS rely on information from the study and report by the National Academies of Science that is to be conducted over the next year?

Response: The Department plans to use all available information, including the proceedings of the June workshop referenced in response to question 6 and the Analysis of Alternatives (AoA) as the future of an automated detection acquisition is discussed this fall.

Question#:	7
Topic:	comparison
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How can an Analysis of Alternatives be done by this fall that includes a cost-benefit comparison between Generation 2 and Generation 3, when the Department of Homeland Security will not have Generation 2 data from Dugway Proving Ground until fall of this year?

Response: The assessment of the Current Operations Program (Gen-2) technology conducted at Dugway Proving Grounds (DPG) is solely intended to generate information regarding the sensitivity of the current collection technology and analytical processes. Gen-2 information has been shared with the AoA study team to compare with the proposed autonomous detection system (Gen-3), and therefore, there should be no need to wait for the DPG data to complete this effort. The costs of the Gen-2 Program have been tracked historically, and that information has also been provided for the AoA.

Question#:	8
Topic:	current plan
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Under the current plan for Gen-3, what is the concept of operations for confirming that a sample is actually a bio-threat once there is a BAR?

Response: Since there is no current Gen-3, there are no local response plans specific to an automated detection system that would be executed at the state or local level in response to a BAR. The decision-making process for what to do in response to a BAR would likely not change substantially from current practices, should the BioWatch program integrate autonomous detection technology; autonomous detection simply provides earlier warning to enable a faster response. It is important to note that guidance for any concept of operations for Gen-3 would be developed in partnership with the local responders in each jurisdiction where the system would be deployed. As a result, there will not be one single concept of operations for autonomous detection, because the guidance developed by BioWatch would be used by each jurisdiction to develop the appropriate response plans for its area of responsibility.

Question#:	9
Topic:	PSAA
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Does the Department of Homeland Security recommend the Public Safety Actionable Assay (PSAA) for Gen-3?

Response: As Generation 3 (Gen-3) is still in the acquisition phase and the performance and concept of operations of deployment has not yet been established, DHS has not formally recommended the PSAA standard for Gen-3 or any future acquisition. The BioWatch program is supportive of any standards that improve the accuracy of our detection capabilities, and DHS and its partners, including the CDC, will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

Both the PSAA standard and Public Health Actionable Assay (PHAA) standard are sufficiently robust to support their respective intended uses though it is important to note that the two standards were developed for different purposes and are used in distinct ways.

The PSAA standard is intended to apply to technologies that would be used in the field by individuals with first responder training to accomplish the initial detection of a biological threat agent. Results from these technologies under this standard are intended to support “immediate” Public Safety Actions that include closure and evaluation of a facility or area, and decontamination of individuals. An additional sample of the suspect material would then be sent to a CDC LRN laboratory for confirmatory testing. The PSAA was developed by DHS S&T in collaboration with other Federal partners to support the commercial/private sector development of technologies and/or assays for use by First Responders and the private sector for screening of suspicious materials (environmental samples only) for biological threat agents.

The final verification test panel necessary for a BioWatch Actionable Result (BAR) to be declared is done using CDC LRN assays which use the Public Health Actionable Assay (PHAA) standard. Also developed by DHS S&T in collaboration with other Federal partners, PHAAs are required to have the specificity, sensitivity, and robustness to provide critical information on agent-specific detection to support public health actions and decisions such as initiating a national or local health alert warning, initiating a public health investigation, conducting risk assessments to support distribution of post exposure prophylaxis, and initiating public health risk communications.

Question: During his interview with Committee staff, a prior BioWatch program

Question#:	9
Topic:	PSAA
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

manager, Dr. Jeffrey Stiefel, said that he unequivocally supported the PHAA standard for Gen-3. He took the same position publicly when he was BioWatch program manager in 2005 in a lecture before the NIH. Why don't you agree with Dr. Stiefel?

Response: The BioWatch program is supportive of any standards that improve the accuracy of our detection capabilities. However, the PHAA standard referenced by Dr. Stiefel in 2005 is not the PHAA standard currently being proposed and utilized in certain LRN laboratories, which began development in 2008. DHS and its partners, including the CDC, will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

Question: Why won't the Department of Homeland Security accept the Public Health Actionable Assay (PHAA) for Gen-3?

Response: The BioWatch program is supportive of any standards that improve the accuracy of our detection capabilities. As Gen-3 is still in the acquisition phase and the performance and concept of operations of deployment has not yet been established, it cannot be said that DHS will not accept the PHAA standard for Gen-3. DHS and its partners, including the CDC, will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

Question: If the National Academies study recommends the PHAA standard, would that standard be too rigorous for Gen-3 to meet the requirements for certification by the Secretary?

Response: If the National Academies recommends the PHAA standard for any future acquisitions, the BioWatch Program would determine cost and schedule impacts in order to utilize PHAA and provide this information to DHS leadership.

Question: Which testing standard would give the public health community and the public the most confidence in Gen-3?

Response: Both the PSAA standard and PHAA standard are sufficiently robust to give the public health community and the public confidence in the BioWatch program, however, it is important to note that the two standards were developed for different purposes and are used in distinct ways.

Currently, the PSAA standard is intended to apply to technologies that would be used in the field by individuals with first responder training to accomplish the initial

Question#:	9
Topic:	PSAA
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

detection of a biological threat agent. Results from these technologies under this standard are intended to support "immediate" Public Safety Actions that include closure and evaluation of a facility or area, and decontamination of individuals. The final verification test panel necessary for a BioWatch Actionable Result (BAR) to be declared is done using CDC LRN assays which use the PHAA standard.

Therefore, the PHAA, as a verification of the initial results, gives public health officials more information, because the PSAA standard is an initial indicator meant to detect potential threats to public health. However, as Gen-3 is still in the acquisition phase and the performance and concept of operations of deployment has not yet been established, DHS has not recommended either standard for Gen-3 or any future acquisition.

Question: Do you believe that with a PSAA standard, you would need to have confirmatory testing?

Response: In BioWatch current operations, the results of PCR analysis always include initial screening and verification testing. In the event of a BAR, jurisdictional response plans would guide local public health officials in determining the appropriate response including, but not limited to, the decision to conduct additional testing.

Question#:	10
Topic:	drawbacks
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: What are the drawbacks for having a largely outdoor detection system?

Response: There are identified exposure vulnerabilities to the American public in indoor and outdoor venues, and detection systems are valuable for both outdoor and indoor applications. A largely outdoor detection system provides less capacity to cover vulnerable locations with a large concentration of people, i.e., high-throughput transportation nodes, such as mass transit systems and international airports. The largest of these indoor facilities accommodates the passage of several hundred thousand passengers per day, making them the highest density target where a bad actor could inflict the greatest amount of harm with the smallest amount of biological agent.

Question: What are the drawbacks for having a largely indoor detections system?

Response: There are identified exposure vulnerabilities to the American public in indoor and outdoor venues, and detection systems are valuable for both outdoor and indoor applications. While indoor detection systems enable early detection of an attack against our highest density targets (such as mass transit systems and international airports), it is unlikely that an indoor system will be able to detect a large outdoor attack without a significant passage of time.

Question: What are the advantages for an indoor detection system?

Response: An indoor detection system enables early detection of an attack against our highest density targets (such as mass transit systems and international airports). Indoor detection systems can help reduce the number of exposures by closing or limiting access to contaminated facilities.

Question: Are you aware that Dr. Stiefel favors only deploying Gen-3 indoors? Do you agree with this?

Response: Dr. Stiefel has stated that, with limited budget and resources, an automated system should be at a minimum deployed indoors. OHA, through the Analysis of Alternatives, continues to evaluate whether the indoor requires the same specifications as requirements in Gen3 for outdoor environments, or whether tailoring detectors to the indoor environment could result in more cost-efficient and cost-effective options.

Question#:	11
Topic:	President's directive
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Tim Murphy
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Has DHS produced a strategic implementation plan in response to the President's directive last July when he released the National Strategy for Biosurveillance?

Response: The National Strategy for Biosurveillance included the Presidential Directive to complete a National Implementation Plan. Individual Departmental plans were not directed in the Strategy, but specific Departmental actions are likely to be part of the National Implementation Plan once it is finalized. The DHS Office of Health Affairs is involved in the interagency process led by the National Security Staff to write the National Implementation Plan. As active participants in the process, the National Biosurveillance Integration Center (NBIC) is also working to align implementation of its Strategic Plan to the National Implementation Plan. In the year since the NBIC Strategic Plan was finalized and released, the Center continues to undergo a transformation in its processes and products. Specifically, among a number of activities, NBIC is: 1) improving the data and analytics it uses for biosurveillance based on new capabilities developed in its Innovation Section; 2) conducting an independent stakeholder and customer analysis to identify ways to improve our operational products; and 3) preparing new processes and product lines for evaluation starting this fall. These and other activities form the core of NBIC's implementation actions following the Strategic Plan's release last year.

Question: If so, what are the projected costs of this plan?

Response: Since NBIC's mission in statute is to support and serve the Interagency regarding biosurveillance, we consider our contributions to the NSS in developing its plan as part of our staff responsibilities covered by base salaries and expenses. NBIC's Strategic Plan, which aligns with the National Implementation Plan, is designed to be successfully executed within our anticipated appropriated resources.

Question#:	12
Topic:	BioWatch cost
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Steve Scalise
Committee:	ENERGY & COMMERCE (HOUSE)

Question: How much money has been spent on BioWatch?

Response: Since formal transfer of the BioWatch program to the Office of Health Affairs in 2008 and as of July 31, 2013, \$566,129,697 was allocated and available for obligation, and \$547,432,959 has been obligated ("spent") or committed (Purchase Request submitted to spend). These totals are for the entire BioWatch Program to include Current Operations (Gen-1/ 2), APDS (Gen-2.5), and Gen-3. The difference between what was available and what has been obligated is primarily the FY 2012 Gen-3 funds that the Program has put on hold.

In addition to OHA's expenditures, S&T has spent a total of \$145,935,768 on research and development and \$ 14,309,205 on testing and evaluation.

Question#:	13
Topic:	update
Hearing:	Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism
Primary:	The Honorable Gus M. Bilirakis
Committee:	ENERGY & COMMERCE (HOUSE)

Question: Once the analysis of alternatives report comes out, please give us an update on any efforts to measure the cost-effectiveness of the BioWatch program.

Response: As part of the analysis of alternatives, OHA requested that a cost benefit analysis also be conducted. OHA expects to receive a draft report by the end of September 2013, which will be shared with Federal stakeholders for review and comment. These comments will be incorporated into the final report, which OHA expects to be completed this fall.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
15 July 2013 5:18:28 PM
Monday, 7/23/2013 10:54:11 AM

July 10, 2012

Dr. Toby Merlin
Director
Division of Preparedness and Emerging Infections
Centers for Disease Control and Prevention
395 E Street, S.W.
Washington, D.C. 20024

Dear Dr. Merlin:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, June 18, 2013, to testify at the hearing entitled "Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on July 24, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at brittany.havens@mail.house.gov and mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

**Centers for Disease Control and Prevention
Subcommittee on Oversight and Investigations
Hearing: "Continuing Concerns Over BioWatch and
the Surveillance of Bioterrorism" (June 18, 2013)
Questions for the Record**

The Honorable Tim Murphy

1. Do you agree that expanding BioWatch with Gen-3 would increase the financial strain of state and local health departments?

a. Do you agree that an additional financial strain could negatively impact the capability of these state and local departments to respond to an actual bioterrorism event?

It is hard to predict the financial impact on state and local health departments since Generation 3 (Gen-3) is still in the acquisition phase and the performance, concept of operations, and cost of deployment has not yet been established.

Considering the impact a Gen-3 system could have on the operational capability of state and local health departments, CDC believes that the state and local health departments' capabilities should be a consideration in the final decision to deploy.

2. Given the reductions in the capacity of the state and local health departments to respond, do you think the country is worse off in this regard than we were five years ago in preparing against bioterrorism?

Preparedness is a process of continual improvement of capabilities. The past five years have seen advances in preparedness planning and countermeasure development and stockpiling at a Federal level. However, reduced funding at all levels has led to staffing and other reductions at state and local public health agencies, which adversely impacts public health preparedness.

State and local health departments rely heavily on the CDC-administered Public Health Emergency Preparedness (PHEP) cooperative agreement to build and sustain preparedness capabilities and to develop and exercise their all-hazards preparedness and response plans. This funding to state and local health departments for public health preparedness has decreased 17 percent since 2008 and 42 percent since the terrorist attacks and anthrax letters in 2001.

3. Do you know what the sensitivity is for the current BioWatch technology?

CDC does not have sensitivity information on the BioWatch assays. CDC previously provided to the Committee sensitivity information on the Laboratory Response Network (LRN) assays that are used as a single component in the Generation 2 system.

4. Do you agree with the Department of Homeland Security's Assistant Secretary Alexander Garza that BioWatch has never had a false positive result?

There is common agreement on what a BioWatch Actionable Result (BAR) does and does not determine. However, the term "false positive" has been used in different ways. DHS's use of the term "false positive" refers to a BAR being declared for a specific BioWatch agent, when in fact the DNA from that agent was not actually present. Other groups, including the CDC, consider a "false positive" to refer to a BAR being declared for a specific BioWatch agent, where the DNA is detected for the agent but the specific strain of agent is not a threat to public health. Both DHS and CDC are working to coordinate our use of scientific terminology when communicating with our stakeholders.

Since its inception in 2003, the BioWatch program has experienced a number of BARs. To date, none of these BARs represented the release of a biologic threat agent and thus would be considered "false positive" tests for a biologic agent in CDC's view. However, these are the type of infrequent results that can be expected in testing for any rare condition.

Although initial positive results do occur, it is important to note that BioWatch has implemented an overall detection resolution protocol to ensure these results do not inadvertently lead to a high-consequence action. Also, the BioWatch program has modified its sampling methods and equipment to reduce the number of these positive test results.

5. When the BioWatch has a BioWatch Actionable Result (BAR) and that BAR is not a detection of the threat agent but a detection of a near-neighbor bacteria that exists naturally in the environment, is the adjudication of a BAR a draft or burden on federal, state and local authorities?

The adjudication of a BAR does create work for the jurisdiction and for their Federal partners. If the adjudication of BARS is an infrequent occurrence, the process of adjudication could be a good exercise for all parties. If there are too many false positives, on the other hand, the adjudication takes too much time and people could lose faith in the sampling process.

6. Isn't it true that there were some problems with the APDS (autonomous pathogen detection system) deployment regarding environmental cross reactivities?

a. What were some of the problems with the "previous experience with environmental cross reactivity and the problematic APDS [Gen 2.5] deployment?"

CDC has had no direct involvement with the APDS deployment and we have no data on its performance in the field.

7. The National Academies of Science, in its 2011 report on BioWatch, wrote: "From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have

been 'BAR false positives,' meaning they have signaled the potential occurrence of a terrorist attack when none has occurred." Do you agree with this statement?

CDC concurs with the language in the National Academies of Science 2011 report on BioWatch that all BARs to date have been BAR false positives. CDC and DHS believe that the BioWatch tests provide preliminary screening results that always require additional review and testing before a conclusion about the occurrence of a terrorist attack can be made.

a. And when a BAR is caused because the tests have detected near-neighbors or background organisms, rather than the targeted bioterrorism agent, in your professional judgment, is that a false-positive?

CDC believes the detection of a near neighbor organism, rather than the targeted bioterrorism agent, should be considered a false positive. DHS and CDC have worked to minimize the occurrence of BARS due to near neighbor organisms, and BioWatch has improved its analytical capability to rule out non-pathogenic sub-species of bioterrorism agents.

It is important to note that BioWatch has implemented an overall detection resolution protocol to ensure these results do not lead directly to a high-consequence action.

8. If BioWatch had been in place in 2001, would BioWatch have detected the anthrax letter attacks?

BioWatch was not designed or intended to detect that type of small scale release of biological agents.

**9. How important is it to have a complete assay validation before deployment of Gen-3?
a. Is there a completely validated Gen-2 assay?**

Assay validation before deployment of a Gen-3 system is critical. One must know the performance characteristics of the system, in order to make the correct decision about its deployment, to develop the appropriate concept of operations, and to interpret results. BioWatch current operations (a/k/a Gen-2) uses screening (initial testing) reagents from the Department of Defense Critical Reagents Program (CRP). Any sample that produces a screening positive result is subjected to a verification panel using the CDC LRN assays. As an element of the BioWatch Gen-3 assay characterization effort, DHS conducted validation of the CRP and LRN assays against the Stakeholder Panel on Agent Detection Assays. Standard Method Performance Requirements published in the *Journal of Association of Analytical Communities International*. The data from this validation was shared with us.

There has been substantial progress to improve BioWatch's analytical capability, including a robust quality assurance program, launched in FY 2010. This program ensures, on a daily basis at every facility, the technical validity of field and laboratory operations and monitors the performance of reagents that are used for analysis in the laboratory.

10. What are some of the perceived limitations of the current Gen-2 system?

a. What would be some improvements?

In CDC's view, enhancements to the current Generation 2 system might include the following. Use of more specific nucleic acid signatures for some organisms to decrease the possibility of false positive results. The volume of air sampled could be increased to improve the sensitivity of detection. Improvement of the current filtering process with another method of particulate concentration could reduce collection of substances that interfere with the PCR testing. The frequency of PCR testing of a collected sample could be increased.

11. With respect to the Gen-3 autonomous "robot" system, do you believe that the public health laboratories will have confidence to take action on one test result from a Department of Homeland Security robot that does not use LRN assays?

Generation 3 is still in the acquisition phase, so it is difficult to tell how confident LRN laboratories, including those laboratories in the states, will be in the results from a Gen-3 system. To be confident in the results, the scientific community, including CDC and the LRN laboratories, will want the performance of the system to be adequately assessed, and they will want to see this performance data themselves. They will also want to see the system field tested, to ensure the accuracy of results.

12. What is the difference between the Public Safety Actionable Assay (PSAA) standard and the Public Health Actionable Assay (PHAA) testing standard?

a. Which testing standard would you support?

b. Why is the testing standard important?

Testing standards are important in order to understand how assays perform (e.g., sensitivity, specificity, robustness) and how this impacts the interpretation of the results. Both the PSAA standard and PHAA standard are sufficiently robust to support their respective intended uses. However, the two standards were developed for different purposes and are used in distinct ways.

The PSAA standard is intended to apply to technologies that would be used in the field by individuals with first responder training to accomplish the first detection of a biological threat agent. Results from these technologies under this standard are intended to support "immediate" Public Safety Actions that include closure and evaluation of a facility or area, and decontamination of individuals. An additional sample of the suspect material would then be sent to a CDC Laboratory Response Network (LRN) laboratory for confirmatory testing. The PSAA standard was developed by DHS S&T in collaboration with other Federal and private sector partners to support the commercial/private sector development of technologies and/or assays for use by First Responders and the private sector for screening of suspicious materials (environmental samples only) for biological threat agents.

The final verification test panel necessary for a BAR to be declared is done using CDC LRN assays, in affiliation with a CDC LRN Laboratory, which uses the PHAA standard. Also developed by DHS S&T in collaboration with other Federal partners, PHAAs are required to have the specificity, sensitivity, and robustness to provide critical information on agent-specific

detection to support public health actions and decisions such as initiating a national or local health alert warning, initiating a public health investigation, conducting risk assessments to support distribution of post exposure prophylaxis, and initiating public health risk communications.

CDC, DHS, and other Federal partners will continue to review and update standards that can be applied to improve and enhance the specificity of biosecurity technologies.

13. Why is it important to detect these agents as early as possible before citizens begin to develop symptoms?

a. Is it true that PHAA would give public health officials more information to base decisions for prescribing clinical remedies (e.g., vaccinations) in the event there was an attack.

Early detection allows public health to take measures to minimize further exposures, and earlier begin the processes of identifying persons at risk, and deploying and administering countermeasures. This could potentially save many lives.

The PSAA standard, as an initial indicator, is meant to provide a good screening assay to detect organisms that might constitute a threat to public health. The PHAA, as a verification of the initial results, would give public health officials more information. Specific panels of organisms have been developed and are used to validate assays intended for use with clinical specimens, and environmental (e.g., BioWatch), food, and water samples positive results with tests that conform to the PHAA standard are more likely to be true positives and thus will provide better information to inform public health decisions, like the administration of vaccines.

14. In the event of a BAR, what additional information will the Centers for Disease Control and Prevention look for before taking public health actions with the distribution and dispensing of medical counter-measures?

The declaration of a BAR is just one step in a process of responding to a positive environmental test. The process includes subsequent steps that are used to determine if a high-consequence action (such as dispensing medical countermeasures) would be warranted. These steps include many local, states, and national partner agencies that would be involved in making decisions about what actions are needed and when they should be taken.

DHS has provided guidance to BioWatch jurisdictions on how to respond to a BAR. In the event of a BAR, a national conference call is convened by DHS and BioWatch representatives where CDC works with DHS and HHS/ASPR, the local jurisdiction, and other agencies to gather as much additional information as possible to determine whether the BAR represents an anomaly or a threat. During this call, CDC will ask the local jurisdiction to do additional testing on the sample that they have on hand. We may ask them to go out and perform environmental sampling in the area where the detector was located or other areas where the organism might be found. In addition, the national conference call will query intelligence agencies and law enforcement agencies to find out whether there is any indication that there might be a threat with this agent. Finally, the CDC will ask subject-matter experts in the field if there are other factors they think

might be causing this to be positive, and public health authorities will intensely scrutinize disease surveillance activities for evidence of unusual disease.

