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).

- 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

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.

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."

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.

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] HHSAI 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.

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 mis-understandings.
>
> I hope this addresses the concerns you raised.

[19] Id. at slide 31.
[20] Id. at slide 10.

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.

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.

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 directon [sic] of the President. 2. One has to take the immediate political and intelligence [sic] climate into account, befor judgement is passed on the fielding of BW. We were ablout [sic] to go to war with a foe that stated unequivically [sic] that they would use biological and chemical weapons againt [sic] the US and it's [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.

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-pathogenic[32] 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. 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/sgp/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.

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.

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-20 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.

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.

> 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 . . . . [58]

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.

> 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.

> 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.

> acquisition to be 'high risk' and he has aggressively sought permission to proceed . . . .[70]

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."

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.

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.

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.

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.

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 Kellog 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.

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.