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

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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 to36 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

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 2013[2] (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.

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[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?

IV. STAFF CONTACTS

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