



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

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

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

As you know, 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 of health personnel at all levels of government.

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

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

Each BioWatch jurisdiction has a BioWatch Advisory Committee (BAC) made up of state, local and federal partners who operate the program and are responsible for leading response efforts.

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

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

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

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

Automated detection will eliminate the need for manual filter retrieval and is intended to provide continuous collection and analysis of samples within the unit. The results of this automated

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

analysis would be transmitted electronically to public health officials. With Gen-3, the time to detect could be reduced to 4-6 hours, handing back precious time to public health officials faced with responding to a potential bioterrorism event.

Moving from the manual analysis of a filter towards what would essentially be a “laboratory in a box,” marks a true sea change, bringing DHS to the forefront of state of the art biological detection technology. However, acquiring a first-of-kind technology requires a robust and agile acquisition strategy that can accommodate iterative improvements and open competition, while ensuring rigorous performance standards are met.

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

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

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

This course of action addresses the core of GAO’s recommendations which call for a re-evaluation of the mission need and an AoA based on cost-benefit and risk information, as well as updates to acquisition documents to consider cost-benefit and risk information. As a result of the guidance provided in the last IRB, we are in the process of updating the Mission Need Statement,

commissioning an independent organization to conduct the AoA, which will include a cost-benefit analysis, and updating all the required documents to ensure they comply with the current Departmental guidance for acquisitions as outlined in Management Directive 102-01.

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