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

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

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

Overview of the BioWatch System

The BioWatch Program is the nation's only federally-managed, locally-operated nationwide biosurveillance system designed to detect the intentional release of select aerosolized biological agents. Deployed in more than 30 metropolitan areas throughout the country, the system is a collaborative effort between preparedness and public health personnel at all levels of government. The program is operated by a team comprised of field operators, laboratory technicians, and public health officials from city, county, state, and federal organizations. This coordinated team is responsible for installing bio-collectors, collecting daily samples, analyzing and reporting laboratory results, and responding to the detection of a positive signal, known as a BioWatch Actionable Result (BAR).

The current detection capabilities used by the BioWatch Program consist of outdoor and select indoor aerosol collectors whose filters are retrieved for subsequent analysis in state or county public health laboratories that are members of the CDC Laboratory Response Network (LRN). BioWatch works with jurisdictional personnel to determine collector locations, and has an initiative that looks at optimizing locations. A BAR is declared by the director of that public health laboratory or their designee. A BAR simply means that DNA of a selected agent is present. To be clear, a BAR does not mean a terrorist attack has occurred, a viable agent has been released, or that people have been exposed. Additional analysis is needed to determine if a release has occurred and if there is a risk to public health.

Federal-State-Local Partnership

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

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

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

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

Providing Tools for Preparedness

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

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

Robust Quality Assurance

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

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

Innovation for the Future

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

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

Conclusion

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