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Chairman Brooks, Ranking Member Payne, and distinguished members of the Subcommittee, thank you for inviting us to speak with you today. We appreciate the opportunity to testify on biological defense and specifically the Department of Homeland Security's BioWatch program. We're honored to testify alongside Acting Under Secretary Cummiskey as well as our colleagues from the Government Accountability Office (GAO) and the Institute for Defense Analysis (IDA).

The Bioterror Threat

More than a decade after anthrax was mailed to Members of Congress and to media organizations, dozens of policy, intelligence, and technical reports have affirmed the viability of terrorist groups and violent extremists using biological weapons to cause death, suffering, and socio-economic disruption on a calamitous scale. In 2008, the congressional Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism stressed the near-term and growing threat that terrorist use of biological weapons pose. The DHS Office of Health Affairs (OHA) and the Science and Technology Directorate (S&T) have worked diligently to increase understanding of the full spectrum of potential threats and their consequences as well as countermeasures and means of prevention.

In 2001, the Defense Science Board affirmed that "there are no technical barriers to a large-scale bioattack." We are living in the midst of a biotechnology revolution in which the knowledge and tools needed to acquire and disseminate a biological weapon are increasingly accessible. It is possible today to manipulate pathogens' characteristics (e.g., virulence, antibiotic resistance) and even to synthesize viruses from scratch. These procedures will inexorably become simpler and more available across the globe as technology continues to mature. Thankfully, the combination of technical expertise required and the restrictions limiting the acquisition of the materials necessary for production still make this a challenging task.

Even small-scale attacks, however, could be highly lethal and disruptive, and as has been noted, there is a real possibility of a campaign of bioattacks on multiple targets (the "reload" phenomenon) – because some of these weapons are self-replicating organisms. Moreover, it is not necessary for a nation-state to maintain a large stockpile of bioweapons as the development of a significant offensive bioattack capability could occur within weeks or months.

Biological threats, including bioterrorism, pandemics, emerging infectious diseases, and animal and plant diseases, remain a top homeland security risk. A biological attack could impact any sector of our society and would place enormous burdens on our Nation's public health, security, and critical infrastructures. The 2014 Quadrennial Homeland Security Review includes a review of the biological threat landscape and the Department's strategy to counter these threats. One aspect of our overarching strategy includes robust biosurveillance capabilities that provide situational awareness and early detection. These capabilities are important because in a biological event, every moment counts. The faster we detect an event, the faster we can take life-saving steps such as providing medical countermeasures and containing the threat.

Biosurveillance

It is challenging to recognize early indications of a biological attack because its release is invisible, and because of the global availability of pathogenic organisms, the dual-use nature of the required materials, and the small operational footprint necessary to produce the agents. Advance detection and disruption of a bio-weapons program will continue to be difficult and, as such, cannot be relied upon as the main focus of U.S. defenses against biological attacks. Instead, the United States has made a deliberate strategic choice to detect an attack through bio-agent release detection technology programs such as BioWatch and mitigate its affects by enhancing the capabilities of first responders and public health professionals to detect bioagents in the field and conduct reliable lab analyses. Other investments to improve our early detection capability include working to create sensors capable of automatically initiating protective actions (e.g., altering a building's airflow patterns) and developing rapid diagnostic capabilities to guide our response.

Effective management of biological threats and hazards depends on early warning and shared situational awareness, which in turn support response and recovery decision making that is timely, well-informed, and ultimately saves lives. The United States has numerous biosurveillance capabilities across human health, plant, animal, food, water, and environmental domains distributed broadly across federal, state, tribal, territorial, and local government and the private sector. The National Biosurveillance Integration Center (NBIC), operated through the DHS Office of Health Affairs (OHA), is the designated government entity charged with integration, analysis, and dissemination of the Nation's biosurveillance information in order to advance national safety, security, and resilience.

NBIC is a 24/7 operation that collaborates daily with the BioWatch program as well as other National Biosurveillance Integration System (NBIS) federal department and agency partners and state, local, tribal, and territorial entities. At this time, NBIC is monitoring and reporting on, among other biological events, avian influenza H7N9 in China; Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in a number of countries now including the United States; Chikungunya Fever in the Caribbean; Ebola Virus Disease in West Africa; and the highly pathogenic avian influenza H5N1 worldwide.

Biological Detection and the BioWatch Program

Early detection of a biological attack and identification of the biological agent involved are critical to containing the spread of the agent as well as the successful treatment of affected populations. Early detection is part of a multi-layered approach to providing public health decision makers more time – and thereby more options – in responding to, mitigating, and recovering from a bioterrorist event or other threat to public health. If release of a bioagent is detected and assessed in a timely fashion, an appropriate prophylactic treatment can be started prior to the widespread onset of symptoms resulting in more lives saved.

BioWatch is the only civilian-managed, nationwide surveillance and detection system for aerosol biological releases, and it is intended as an interface for state and local public health and responder communities to jointly respond to a bioterrorism event. The sampling technology used by the BioWatch program is designed to detect the intentional catastrophic release of the most threatening aerosolized biological agents. The BioWatch system consists of units that collect air samples in more than 30 cities and a network of local, state, and federal laboratories that analyze samples on a daily basis with a goal of providing warning of possible biological attacks within 12 to 36 hours of an agent's release. The BioWatch program has a robust quality assurance element that includes laboratory and field audits to ensure accuracy. BioWatch has conducted 37 laboratory and 20 field audits to date. For more than 10 years, BioWatch has operated 24 hours a day, 365 days a year. It is a proven asset to the Nation's overarching biodefense architecture.

The initial deployment of BioWatch in 2003 was intended to provide the most comprehensive detection network possible within budgetary, time, logistical, operational, and technical constraints. The complex coordination required to achieve the successful rollout of BioWatch across a broad range of government and private entities was a difficult and hard-earned achievement. The BioWatch program was designed to be able to advance its technological capabilities to meet an evolving threat. Although technology can always be improved; the challenge is to do so cost-effectively and in pace with the evolving threat.

Autonomous detection acquisition activities

As the *National Strategy for Biosurveillance* states, we must foster innovation and facilitate new biosurveillance activities – including new detection technologies. In 2008, as directed by Congress, the BioWatch program began examining new technologies to shorten operational timelines, increase coverage, and decrease costs. Acknowledging the benefit of early warning of a biological attack and the prompt distribution of medical countermeasures, the program began exploring technologies that could reduce detection and response times in a cost effective manner.

For this reason, BioWatch began a technology acquisition process – known as Generation 3, or Gen-3 – to provide autonomous detection capability that would eliminate the time-consuming steps of collecting filters by hand and transporting them to a laboratory for analysis. An autonomous detector is designed to be a "lab-in-a-box" where the sampling and analysis processes will take place within the device, generating results as soon as 4 to 6 hours after the release of a biological agent, rather than the 12 to 36 hours needed by current operations. The BioWatch program began a phased acquisition for automated detection technology. Phase I was

completed in June 2011 and assessed the maturity and technical capability of the biodetection technology market against a robust set of system requirements. These requirements included technical assay/characterization testing of two candidate systems and limited field testing of one vendor's candidate autonomous detection system.

In September 2012, the Government Accountability Office (GAO) recommended that BioWatch perform an Analysis of Alternatives (AoA) as well as re-evaluate its mission needs statement to ensure acquisition requirements were well grounded and that the BioWatch program was pursuing an optimal and cost-effective solution. In an Acquisition Decision Memorandum issued September 7, 2012, the Acquisition Decision Authority (ADA) directed the BioWatch program to prepare a solicitation/request for proposal (RFP) for an AoA study, consistent with GAO's recommendation.

The AoA study, conducted by the Institute for Defense Analysis, was concluded on August 30, 2013, and the final report was released on December 20, 2013. Following an exhaustive market survey, the AoA report analyzed four different methodologies, not favoring one over another. The intent of the AoA was not to issue a recommendation but to help inform DHS's decision to proceed with any acquisition of BioWatch technology.

Cancellation of Gen-3 Acquisition

The AoA determined that an autonomous detection capability would be a valuable addition to current BioWatch operations. However, it did not find an overwhelming benefit to justify the cost of a full technology switch (one to one replacement and expanded coverage within jurisdictions). Following a thorough review of the Gen-3 acquisition of record, the AoA and other studies on future biodetection technology, OHA, in consultation with S&T, the Management Directorate, and the Office of Policy, concluded that the autonomous detection system under consideration would not meet program objectives at a reasonable cost and recommended that DHS leadership cancel its acquisition. Secretary Johnson then directed Acting Under Secretary for Management Cummiskey to cancel the BioWatch Gen-3 technology acquisition. In accordance with this guidance, and per the Department's Management Directive 102 on acquisition procedures and processes, Acting Under Secretary Cummiskey convened the Acquisition Review Board for the BioWatch Gen-3 acquisition to formally cancel the acquisition of record on April 24, 2014. This cancellation reflects the need to implement cost-effective solutions, as it is critical that any upgrades to the technology be acquired and deployed in a staged manner and in parallel – not in place of – the current operational program.

The Path Forward

Cancellation of the Gen-3 acquisition of record in no way reduces the capability of existing BioWatch operations or the need to investigate potential advancements in biodetection capabilities. OHA and S&T are working closely on the development of a systems approach to next-generation biodetection, including joint development of requirements moving forward. Evaluation of the existing operational BioWatch system is underway and will guide near and long term investments in new or updated capabilities. A full range of potential investments is under consideration from near-term incremental improvements to longer-term shifts such as a

distributed, networked, sensor-agnostic biosurveillance architecture currently under development at S&T with potential for capability well beyond what the Department initially envisioned for Gen-3.

Using newly delegated prize authority[1], S&T and OHA have a platform for engaging and harvesting non-traditional government performers through a biosurveillance grand challenge on this issue of national importance. S&T is also exploring a "Beyond BioWatch" Apex Lite[2] program that will, in partnership with OHA and other national biodefense stakeholders, work toward implementation of an integrated national systems approach to biodetection. We would be happy to share this vision and strategic approach to biosurveillance research with the Subcommittee as it takes shape in the near future.

Conclusion

We want to emphasize that the Secretary, the Department, and our offices remain committed to the operational BioWatch Program, the role of vigilant biosurveillance as part of the layered approach to the Nation's biodefense, and the advancement of innovative technological capability as part of an integrated systems approach to surveillance. In the coming years, we intend to focus our limited developmental resources on capacities to detect bioattacks in near-real time in order to enhance protective response actions. However, we will also have to consider future needs for detection of a wider range of potential threat agents, including genetically-altered, synthetic, or unanticipated agents, and possibly to enable detection of food and surface contamination. Faster, more detailed, and more reliable characterization of bioevents will be necessary to improve situational awareness and inform response. We must continue to develop an agile approach that accommodates possible epidemics of emerging disease or attacks using unforeseen bioagents or agents not addressed by stockpiled countermeasures. Strategies for coping with and stopping bioterror campaigns must be developed. Mechanisms of international cooperation in dealing with infectious disease outbreaks and collaborative approaches to financing and refining needed biodefense technologies and countermeasures must evolve.

OHA and S&T are committed to working together with our colleagues across the interagency to address these challenges. We are deeply appreciative for this Subcommittee's continued support for our shared goals of health and homeland security.

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[1] The America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Reauthorization Act of 2010 (America COMPETES Reauthorization Act P.L. 111-358) outlines authority s for all federal agencies to conduct prize competitions to engage broadly the American public to stimulate innovation that may potentially advance their agency mission.

[2] Apex projects are cross-cutting, multi-disciplinary efforts requested by DHS Components that are high priority, high-value, and short turn-around in nature. They are intended to solve problems of strategic operational importance identified by a Component leader. Apex Lite projects will be a middle ground between traditionally managed projects and Apex efforts, building off lessons learned from previous Apex projects and scaling critical Apex elements to different timelines, scopes, and foci.