



**Testimony**

of

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before the

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Committee on Homeland Security  
Subcommittee on Emergency Preparedness, Response & Recovery

**Defending The Homeland From Bioterrorism: Are We Prepared?**

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Good morning Chairman Payne, Ranking Member King, and Members of the Subcommittee. I am Dr. Jennifer Rakeman, Assistant Commissioner and Laboratory Director of the Public Health Laboratory at the New York City Department of Health and Mental Hygiene (NYC Health Department). On behalf of Mayor Bill de Blasio and Health Commissioner Dr. Oxiris Barbot, thank you for the opportunity to testify on New York City's (NYC) biothreat detection efforts and ongoing work to prepare for and respond to public health emergencies.

### **Public Health and Emergency Preparedness**

I am here today to discuss the vital role that public health plays in biothreat detection efforts and how the NYC Health Department collaborates with city agencies and coordinates with state and federal partners to prepare for and respond to emergencies.

Our nation's public health and health care infrastructure play a critical role in protecting people from a range of hazards, including bioterrorism and infectious diseases. Local public health departments and their partners are on the front lines and are often the first to detect and respond to disease outbreaks. What we do every day at the local level is backed by our partners at the federal level, such as the Centers for Disease Control and Prevention (CDC) and the Department of Homeland Security (DHS). For this system to work, each piece must be appropriately resourced and engage in ongoing transparent communication and collaboration.

A robust public health infrastructure saves lives and is crucial for all jurisdictions. Core public health infrastructure at the local level requires state-of-the-art laboratories and electronic surveillance systems. We also need highly skilled staff such as laboratory leadership, bench technologists, epidemiologists, informatics specialists, and emergency management and response experts who enable the people and systems to operate effectively during emergencies. Core public health infrastructure is essential to detect and respond to emerging diseases and outbreaks. Without it, we risk the rapid spread of disease, increased illness and death. It is therefore critical to our nation's security that local health departments receive the necessary resources to maintain these capabilities.

Public health and health care system readiness noticeably expanded and improved after 9/11, with an influx of federal preparedness funding from the CDC and the Assistant Secretary for Preparedness and Response (ASPR). Public health departments and health care systems have used these funds to invest in staff, purchase equipment and instrumentation, implement critical information technology (IT) systems, and create response plans. Adequate funding allows operators to train and exercise these plans to prepare for a broad range of emergencies and maintain a strong, experienced workforce necessary for a robust response.

### **New York City Context**

As the largest, most densely populated city in the United States, NYC is an international hub for business, media, and tourism. Consequently, we face a high risk of both intentionally disseminated and naturally occurring hazards. A biological attack or large-scale infectious disease outbreak in NYC would significantly impact the health, security, economy, and political stability of not only the City, but the rest of the country, and will have international impact. The NYC Public Health Laboratory (PHL) serves a population larger than that of most states. It has been central to the NYC response to the Amerithrax letters in 2001, H1N1 outbreak in 2009, Ebola in 2014, Zika virus in 2016, and the recent, unprecedented measles outbreak. In addition, the NYC PHL, in coordination with the CDC's Laboratory Response Network (LRN), provides local diagnostic testing for emerging and highly pathogenic diseases including Ebola virus disease and Middle East respiratory syndrome corona virus (MERS-CoV).

Seven days after the 9/11 attacks in 2001, letters tainted with *Bacillus anthracis* were sent to media companies and Congressional offices. The investigation that followed resulted in a nationwide focus on

bioterrorism and identified significant gaps in our ability to protect the public's health. In 2003, as a result of this investigation, BioWatch was created and quickly rolled out to a number of jurisdictions, including NYC. BioWatch is intended to serve as an early warning system of a widespread attack with one of a small number of potential biological threat agents.

As the lead scientific agency for the NYC BioWatch program, the NYC Health Department is responsible for the day to day technical oversight of BioWatch laboratory testing and is responsible for the development of environmental sampling plans to be deployed in the event of a BioWatch detection. While the NYC PHL hosts the BioWatch laboratory, neither the NYC PHL nor the NYC Health Department has input regarding the standard operating procedures and testing reagents used for BioWatch testing. Further, the local jurisdictions do not have detailed information regarding basic performance characteristics of the tests to which we are asked to respond. However, as the PHL Laboratory Director, I am responsible for determining that a BioWatch result is valid and is a "BioWatch Actionable Result" (or BAR) to be reported to local and federal partners to determine what response actions will be taken.

In 2010, after NYC experienced an unacceptable increase in the number of false positive BioWatch testing results, the NYC PHL revised the testing algorithm to differ from the national BioWatch program standard to require additional verification to minimize the threat of a false positive BAR. The same BioWatch reagents and testing standard operating procedures are used, as required by the BioWatch program, but part of the test is repeated in the NYC algorithm as a check of the initial positive result.

### **Cooperation with Federal Partners**

NYC has taken a leadership role nationally in pushing for a better system that provides reliable results, and has worked closely with the CDC, DHS, and other jurisdictions to inform the building of a biothreat detection architecture with acceptable performance characteristics required in urban and civilian settings. As the Committee is aware, DHS is proposing to replace BioWatch with a new detection system, BioDetection 21 (BD21), the intention of which is to detect a potential release in near real-time. BD21 will use real-time detectors of "biological anomalies" in the field to signal the initiation of additional sample collection and testing. A biodetection program is an essential public health tool for a global city like NYC. We understand the need for a reliable biodetection system and applaud the efforts to improve upon the current system, both in the timing of detection and the reliability of the assays. However, both BioWatch and the proposed BD21 systems fail to meet even minimum standards that any other test deployed in a public health laboratory would need to meet.

While we support advancing the current BioWatch program to take advantage of modern biothreat detection technology, we have concerns about the deployment of this new program and the options under evaluation as part of BD21. Instruments currently deployed for military use, which have generated regular false alarms, are being considered for implementation in NYC and throughout the country. Biothreat detection system requirements for urban settings like NYC fundamentally differ from the requirements for those used in military settings. The implications for launching a substantial response based on a false-positive biothreat detection could have profound economic consequences and will have associated morbidity and mortality.

DHS has communicated very little about the program and has made it clear that jurisdictions will need to develop response plans without any input or consideration to the technology deployed, evaluation plans, or access to evaluation data. Local public health agencies have been left out of the conversation and, at best, are receiving very limited information and no data. Active, ongoing collaboration between local, state, and federal partners is critical to the development and deployment of a successful biodetection program. It is imperative that DHS has an ongoing dialogue with other federal partners, such as CDC and ASPR, and, critically, with state and local jurisdictions throughout this process. The local end users must be confident that the system is based on scientifically sound principles, that it will be used appropriately,

and that the technology will generate information with sufficient fidelity for an actionable response. We are grateful for the Subcommittee's interest in this matter.

### **Importance of Federal Emergency Preparedness Funding**

A strong public health and health care system preparedness and response infrastructure is an essential component of national security to any biodetection program. However, significant cuts in federal funding have hampered state and local readiness at a time when emerging diseases are spreading faster than ever before. NYC relies on federal funding to prepare for, detect, and respond to public health emergencies. Over the past 14 years, this funding has been significantly reduced – including a 34% cut to the Public Health Emergency Preparedness (PHEP) program and 39% cut to the Hospital Preparedness Program (HPP) funding since FY 2005. The most drastic impact of these cuts has been the significant reduction in the public health preparedness and response workforce in NYC. If there are no public health laboratory scientists, epidemiologists, environmental health specialists, emergency managers, and risk communication experts to build the local alarm system, and then hear the alarm and respond when it goes off, we cannot protect the health of the American public. This critical workforce needs an infrastructure to enable them to do their work – state of the art public health laboratories that are flush with instrumentation, reagents, and supplies, information technology solutions for the analysis of data, and interoperable electronic systems to share that data are all also basic necessities for protecting Americans.

Additionally, funding for the CDC Epidemiology and Laboratory Capacity (ELC) Infection Control and Laboratory BioSafety Officer (BSO) programs ended in March 2019. These programs provided critical support for infection control and clinical laboratories at health care facilities. The BSO network ensured that clinical laboratory staff across the country were trained to safely handle and test specimens from patients that may have a highly infectious disease. This program is critical to ensuring the safety of the health care workforce and to ensure that all patients are able to receive appropriate life sustaining care, and allows NYC and the rest of the country to maintain these capabilities. This loss of funding threatens to waste years of investment and relationship-building with critical partners.

In 2014, Congress appropriated funding to prepare public health and health care systems to respond to cases from the Ebola outbreak in West Africa that reached the U.S. and prevent further transmission. This funding has helped sustain the capacity of 10 Regional Ebola and Other Special Pathogen Treatment Centers (RESPTC), state-designated Ebola Treatment Centers (ETCs) as well as frontline hospitals, health departments, and emergency medical services (EMS). With this funding, the capability to identify and safely care for patients with viral hemorrhagic fevers and other high-consequence infectious diseases was built and maintained. These funds supported joint planning and regional coordination between public health, health care, EMS, and law enforcement to rapidly respond, and were critical to the replacement of aging laboratory equipment and instrumentation, initially purchased with post-9/11 funding, in public health laboratories. As a result, our country is substantially more prepared to manage cases of Ebola than ever before. However, there is no plan to continue funding when it expires in 2020. Local health departments, public health laboratories, and health care systems around the country cannot continue to function on sporadic funding. We cannot wait for the next major public health emergency to maintain critical infrastructure.

Chairman Payne and Ranking Member King, thank you once again for inviting me to testify today. Our concerns regarding BioWatch, the BD21 system, and the need for stable investment in public health preparedness are shared by cities across our nation. Federal investment and collaboration is critical to ensuring local government's ability to stay ahead of emerging threats. I look forward to your questions.