

BIOWATCH AND PUBLIC HEALTH SURVEILLANCE: EVALUATING SYSTEMS
FOR THE EARLY DETECTION OF BIOLOGICAL THREATS

Statement of

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Good afternoon, Mr. Chairman and members of the Subcommittee. My name is Bernard Goldstein. I am a professor in the Department of Environmental and Occupational Health in the Graduate School of Public Health at the University of Pittsburgh. I am here today as the chair of the Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, which was convened by the Institute of Medicine (IOM) and the National Research Council (NRC). The Institute of Medicine and National Research Council are part of the National Academies, originally chartered by Congress in 1863 to advise the government on matters of science and technology.

As the committee knows, the BioWatch program began in 2003 with the rapid deployment of air samplers, principally in outdoor locations, in about 30 major urban areas to aid in earlier detection of an airborne biological attack. The filters from these devices are usually collected once a day and taken to a laboratory where they are processed to test for the presence of genetic material from a few biological agents of particular concern. With this sampler technology and deployment (known as Generation 2), as much as 36 hours may elapse between the collection of genetic material of interest and the availability of essential laboratory test results showing its presence. Plans for a new system—Generation 3—call for deploying new air sampling devices that are capable of on-board automated analysis, which would permit more rapid and more frequent testing of air samples. The aim with Generation 3 is also to deploy additional devices in current BioWatch jurisdictions, to increase the number of jurisdictions in the program, and to eventually have the capability to test for a greater number of biological agents. The Department of Homeland Security (DHS) is responsible for BioWatch, but the program operates as part of a broader system that involves collaboration with the states and

localities where BioWatch air samplers are deployed, and with other federal agencies, including the Department of Health and Human Services (HHS).

My testimony is drawn from the publicly available version of the summary of the report *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats*. This report is the product of a study conducted between mid-2008 and mid-2009 in response to congressional direction to the Office of Health Affairs (OHA) in DHS in conjunction with the Consolidated Appropriations Act, 2008 (P.L. 110-161). The essential elements of the task for this study were

- to evaluate the effectiveness of BioWatch, including comparing the benefits and costs for the current system (Generation 2) and an anticipated BioWatch upgrade (Generation 3);
- to examine the costs and benefits of an enhanced national surveillance system that relies on U.S. hospitals and the U.S. public health system; and
- to reach a conclusion as to whether BioWatch and surveillance through the public health and health care systems are redundant or complementary.

Given this task, we focused on the detection of infectious diseases that might pose a significant threat to the civilian population in the United States. The breadth of this study task resulted in findings and recommendations regarding not only DHS and BioWatch, but also HHS and public health and health care at the federal, state, and local levels. For this hearing, I am focusing primarily on those concerning BioWatch and DHS.

I also want to note certain features of our work. First, it was beyond our study's scope to examine the basis for estimates of the likelihood and magnitude of a biological attack, or how the

risk of a release of an aerosolized pathogen compares with risks from other potential forms of terrorism or from natural diseases. However, these estimates are crucial in judging the value of the BioWatch approach. Second, our study focused on the role of BioWatch as a tool for the detection of biological threats; we recognize, however, that it may also have other purposes, such as aiding forensic analysis. Third, we saw having the capability to respond to the detection of a biological threat with appropriate public health and health care services (e.g., mass dispensing of medications or establishing mass treatment centers) as essential to be able to benefit from any improvements in detection. However, assessing this capability in the public health and health care systems was beyond our charge. Finally, we found it challenging to compare BioWatch, a relatively well-defined federal program, with infectious disease surveillance in the health care and public health systems, which is the product of a diverse mix of activities by state and local government agencies and public- and private-sector participants in what are very loosely linked “systems.”

FINDINGS AND RECOMMENDATIONS

Overall, our committee concluded that DHS needs to conduct systematic technical and operational testing and evaluation of both current and future BioWatch technologies, and to evaluate the effectiveness of the BioWatch system from a risk-management perspective. No expansion of the BioWatch program should be made without a very clear understanding of the contribution it will make to the opportunity to reduce mortality or morbidity. Moreover, the BioWatch system requires better collaboration with the public health system to improve its usefulness as part of a variety of efforts to protect against biological threats. The proposed enhancements to the BioWatch system are appropriate but very ambitious. They will be possible

only if significant advances can be made against long-standing scientific and technical challenges, and against important organizational and operational concerns.

Conduct Systematic Testing and Evaluation of Current and Planned BioWatch Technology

The rapid initial deployment of BioWatch did not allow for sufficient testing, validation, and evaluation of the current system and its components. The suspension of plans for the deployment of an interim technology (Generation 2.5) and a delay in the acquisition and deployment of a Generation 3 system provide DHS with a needed opportunity to establish a more systematic, scientifically sound, and stakeholder-approved approach to technology acquisition, development, testing, and deployment than was possible when the BioWatch program began.

Our review of the plans that DHS had developed for testing and evaluation for Generation 3 (as presented to us in spring 2009) revealed that technology goals for Generation 3 will be very difficult to achieve, and the planned test and evaluation timeline may be too short. There was little allowance for delays to respond to problems that often emerge during testing, and there was limited provision for operational testing under diverse environmental conditions. Moreover, the operational test results should be evaluated against measures of effectiveness that should be developed through a genuine collaboration between the BioWatch program office and the public health community. The results of this and other BioWatch testing should be thoroughly documented and made available to public health stakeholders.

With the continued use of Generation 2, a clearer understanding of its capabilities is critical, and operational testing of Generation 2 should be undertaken now to provide agent-specific performance specifications that can be used to refine Generation 3 requirements.

Improvements are needed in the laboratory assays as well. The committee endorses the DHS collaboration with CDC, EPA, and the FBI to develop validated and consistent assays and assay platforms that will be used in continued operation of Generation 2.

Projections done for our study suggest that the average annual direct costs over the next 10 years will be approximately \$80 million for continuing the BioWatch program in its current form (Generation 2). This estimate includes some allowance for financial and in-kind costs incurred by states and localities in supporting BioWatch, but data on these costs are poorly defined. The analysis commissioned for our study suggested an annualized direct cost of about \$200 million for acquisition, deployment, and operation of the proposed Generation 3 system, with its new technology and expanded coverage. However, our estimate appears to have been based on a higher unit cost for Generation 3 detectors than is being used in the FY 2011 budget proposal that you are now considering.

Make BioWatch Planning Risk-Based and Responsive to User Needs

DHS should ensure that the BioWatch program evaluates its planning within the framework of both a careful analysis of the risks of an airborne biological attack *and* the most effective ways to manage these specific risks. The biological agents being monitored vary widely in their time course, health effects, and responsiveness to treatment. Comprehensive modeling and analysis that takes these factors into account should be done to evaluate the potential contributions of the BioWatch system to public health decision making and outcomes. Where appropriate, a Bioterrorism Risk Assessment (BTRA) that has been modified according to the recommendations in a 2008 National Research Council report, should be used.*

* NRC (National Research Council). 2008. *Department of Homeland Security Bioterrorism Risk Assessment: A call for change*. Washington, DC: The National Academies Press.

This evaluation should include all risk scenarios, each pathogen that BioWatch monitors, and the use of BioWatch in outdoor versus indoor settings. The BioWatch program should not expand its coverage of biological agents or jurisdictions without a clear understanding of such an expansion's contribution to reducing mortality or morbidity in conjunction with clinical case finding and public health surveillance.

As part of this effort, DHS should actively solicit input from and collaborate closely on all aspects of the program with key partners and stakeholders at the federal, state, and local levels because the assessment should consider the responsibilities that fall to state and local public health officials for additional information gathering to confirm and characterize a BioWatch signal (a BioWatch Actionable Result or BAR); for communication with varied federal, state, and local authorities and with the public; and for response planning and training.

Strengthen the BioWatch Interface with State and Local Jurisdictions

DHS has tended to assess BioWatch in terms of its technology, but the assessment must be based on a broader perspective that emphasizes the program's stated goal of aiding timely response to mitigate illness and deaths from a biological attack, not just successful detection of genetic material that may indicate a terrorist event. To contribute to saving lives, BioWatch requires not only appropriate technology but also effective coordination and communication with the public health decision makers and responders who must be able to determine with confidence whether BioWatch signals call for administering medications or other actions before clinical evidence of illness is evident.

Public health officials need greater assistance in developing the necessary capabilities to interpret and respond to BioWatch Actionable Results (BARs). A BAR signals detection of

segments of the DNA of a target organism, but our committee finds the term to be misleading because it sees a BAR alone as unlikely to be a sufficient basis for public health action.

Detection of DNA consistent with that of a bioterrorism agent does not automatically mean that an attack has occurred, that an infectious agent has been released, or that people have been exposed. Our committee concluded that local officials will generally need to gather and assess additional information to determine the proper response to a BAR.

The apparent lack of systematic assessment of dozens of BARs that have occurred—none of which has been associated with bioterrorism or human illness—is a missed opportunity to capture and share lessons learned among the BioWatch jurisdictions and to inform program planning and development in DHS, CDC, and other federal partners. A formal mechanism is needed for the creation and sharing of BAR after-action reports. Local jurisdictions would also benefit from improved decision-support tools to help in the synthesis and analysis of information relevant to decisions after a BAR is declared. DHS should continue its efforts to develop such tools.

Establish a Source of External Expert Advice

In the continued development of the BioWatch system, DHS and HHS should work collaboratively, and their joint effort should be guided by advice from an independent panel of external stakeholders and subject matter experts who have a mix of operational, decision-making, and technical expertise. This panel should advise on setting program goals and objectives, evaluating progress toward them, and decision making and planning for the BioWatch system. These advisors should include state and local public health officials who have decision-making roles in response to a BAR.

In addition, DHS should be a partner in an array of continuing research and development efforts needed to optimize environmental monitoring technologies, to lower the cost of biodetection, and to improve knowledge of BioWatch jurisdictions' natural microbial ecology to aid in interpretation of surveillance results.

Complementary Surveillance Roles for BioWatch and Public Health and Health Care

We concluded that, in principle, BioWatch and surveillance through the public health and health care systems are complementary. Emphasizing the need for more and better testing of the BioWatch system's ability to meet its technical and operational requirements, BioWatch has the *potential* to provide a more timely alert than the public health and health care systems. But this potential for earlier detection exists only under certain circumstances: *that is, if a large-scale aerosol attack using certain pathogens were to occur in the localities where BioWatch is deployed, and if BioWatch successfully detects the pathogen.*

Although surveillance through the public health and health care systems certainly needs improvement, it is broader and more flexible than BioWatch, permitting detection of a wider range of infectious diseases and diseases resulting from sources of exposure that BioWatch is not designed or deployed to detect. With or without BioWatch, the public health system needs to be capable of monitoring disease trends and accessing information from multiple sources to identify or characterize situations that may signal a public health emergency. At best, BioWatch is only one source of such information.

Develop and Evaluate New Opportunities in Infectious Disease Surveillance and Detection

Detecting and responding to infectious disease threats is a core function for public health agencies and the health care system. But they face significant challenges in achieving more effective infectious disease surveillance and capabilities for analysis and exchange of information.

Among local and state health departments, surveillance capabilities vary widely, contributing to inefficiencies and the potential for gaps. Investments, especially increases in federal funding since 2001, have brought improvements; but further improvements are needed and current funding in state and local health departments is limited. Our report calls for HHS, in partnership with state and local public health agencies, to coordinate research, testing, and evaluation of improved public health surveillance methods. There is a need to identify and address evidence gaps, unevenness in the geographic deployment and quality of public health surveillance, its costs and effectiveness, and the integration and harmonization of approaches across the many surveillance programs used by CDC and the public health community.

Early detection of a bioterrorism event or the emergence of a naturally occurring disease threat also depends on the ability of astute clinicians to diagnose the first few cases, or recognize suspicious cases that require special scrutiny. To aid health care providers, federal efforts are needed to advance the development and evaluation of clinically useful, bidirectional, and modifiable decision support tools for use in acute care settings. Other technologies under development, such as rapid point-of-care diagnostic testing, may also enhance timely case recognition.

Achieve Better Information Sharing and Situational Awareness

Infectious disease surveillance of all types, including the BioWatch system, should be better linked to a broader and more effective national biosurveillance framework that will help provide state and local public health authorities and the health care system with the information needed to determine the appropriate response if a biological threat is detected.

Much of the information that enables detection, characterization, and ongoing management and mitigation of natural and bioterrorism-related infectious disease outbreaks is generated by health care providers and laboratories, collected at the local or regional level, assembled at a statewide level, and then reported to CDC at the federal level. However, geographic and programmatic compartmentalization of this information can impede identification of regional, national, and international health events. Better approaches to information sharing can be expected to contribute to faster and more effective outbreak detection, improved communication between public health officials and clinical providers, and improved situational awareness and response capabilities. Ensuring that information from BioWatch is effectively integrated into such systems will help maximize its value.

Federal efforts to improve situational awareness are still evolving, and both DHS and HHS should be working to facilitate the development of an interoperable, secure, bidirectional, nationwide information-sharing infrastructure and ensure that local and state health officials have ready access to the system.

Thank you for this opportunity to testify. I would be pleased to answer any questions the Subcommittee may have.