

STATEMENT BY

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ON BEHALF OF THE
ASSOCIATION OF PUBLIC HEALTH LABORATORIES

DIRECTOR OF THE BUREAU OF LABORATORIES OF THE
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

ON

One Year Later – Implementing the
Biosurveillance Requirements of the ‘9/11 Act’

BEFORE THE

SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND
SCIENCE AND TECHNOLOGY, OF THE
COMMITTEE ON HOMELAND SECURITY
UNITED STATES HOUSE OF REPRESENTATIVES

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Dear Mr. Chairman and members of the Subcommittee:

Thank you for inviting me to testify about the State and local government experience with the Department of Homeland Security's BioWatch program. I am Dr. Frances Pouch Downes, the director of the State of Michigan public health laboratory –in the Michigan Department of Community Health. State and local public health laboratories are an essential infrastructure program that support testing for public health programs and serve as the reference laboratory to hospital and clinical laboratories nationwide. Michigan is one of 24 public health laboratories that host the BioWatch program. I am also the current President of the Association of Public Health Laboratories (APHL). APHL is a national non-profit located in Silver Spring, Maryland, that is dedicated to working with its members to strengthen governmental laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure need to protect the health of US residents and to prevent and control disease globally.

In March 2003, the Michigan Bureau of Laboratories became a host laboratory for the BioWatch program. The security climate in the US was very different than it is today. Public health labs had just come off the intensive testing demands of the 2001 intentional anthrax exposures. Biological weapons caches were still a purported threat. DHS contacted state security officials in states with major urban centers and determined that the BioWatch testing program would be a security asset. When the public health laboratories were asked to install the BioWatch testing program, we did what we always do: meet the challenges to protect the public's health, which in this instance meant devoting considerable resources to receiving and installing equipment and supplies, being trained, training the contractors who would perform the testing and participating in the development of response plans. The response plans made it clear that I would be responsible for result interpretation and initiating the cascade of events that ensue after a positive result. Therefore, I was willing to take on the burden of hosting the program, if I could control the safety of the testing personnel and assure quality of testing. I accepted the program with the caveats that the program did not divert us from other essential public health testing priorities and I controlled quality and safety of the testing program. Unfortunately, we have never hit this mark and are moving further away from it.

At that time verbal promises were made regarding support for hosting the program. Did we get these promises in writing? No. We are not contractors or vendors. We function in a culture of partnership. Public health laboratories are part of a system that for over a century has been committed to providing the services in the interest of the health of our communities.

The technology and the mechanisms for acquiring testing personnel have evolved since the inception of the BioWatch program but the contribution of the host laboratories has never been considered by DHS nor have the safety and quality responsibilities of the host laboratory.

First, space demands have grown at an unrestricted pace. The image you see on the monitors indicates the initial footprint of the BioWatch program in the Michigan lab in 2003. The red space is exclusively for BioWatch use and cannot be used for Michigan public health testing priorities; the yellow space is shared between BioWatch and Michigan public health testing. This next image shows the BioWatch footprint in 2008 and you can see the significant growth in the red space that is dedicated to BioWatch. These images from the first floor of the Michigan laboratory are followed by images that display the growth on the second floor over the same period of time. More equipment, dedicated sample receipt area, server, and supplies. The demands are limitless.

To give you a better visual perspective of the impact BioWatch has had on the Michigan laboratory, I've also brought along some pictures that show how much of our space is used to store BioWatch supplies, equipment and other materials. All of the items displayed in these pictures are only for use in the BioWatch program. None of these pictures show the actual equipment used to perform testing on BioWatch samples or the space that equipment occupies.

Mr. Chairman, APHL has provided you with correspondence that details the significant concerns related to the BioWatch program and its presence in public health laboratories. I would like to briefly give voice to some of our major concerns:

- No agreed upon roles and responsibilities between DHS, its contractor and Public Health Laboratories: At present, DHS and its BioWatch contractor have no contractual relationship or legal authority, regulatory or otherwise, with State and local public health laboratories for the operations of the BioWatch program. Yet, DHS is contractually obligated to the BioWatch contractor to provide laboratory space (Section 4.1 of Task Order No. HSHQDC-08-F-00016).

Because there is no agreement of any sort between the State and local public health laboratory and DHS or BioWatch contractor, there is no ability to require adherence to site specific quality assurance practices, standard operating procedures and policies – even those that relate to laboratory safety. Furthermore the absence of any agreement has spurred State and local government legal offices into action because of their concern over the exposure to these governments, including unresolved liability and worker's compensation issues.

DHS has distributed a draft Memorandum of Agreement (MOA) to address this matter, but the details included in the draft make it unlikely that State and local governments will enter into an agreement soon. For starters, ***DHS has said they will not reimburse for the use of laboratory and storage space – an issue they say is non-negotiable.*** Again, the draft MOA does not limit the space and administrative demands that the BioWatch program can place on a laboratory. Also, while DHS proposes one MOA that will be utilized nationally, the unique legal issues in each State and local government must be recognized and they demand individual resolution.

- Uncompensated Laboratory Costs: State and local public health laboratories have not received funding from DHS to support the cost of housing and overseeing the BioWatch program whereas the state agencies collecting the samples and transporting to the public health laboratories daily are reimbursed for their expense. I have already mentioned the key non-negotiable element of reimbursement as it relates to the draft MOA. The message transmitting that draft MOA asserts:

DHS cannot enter into an arrangement to reimburse for space, due in part to funding limitations, and in large part to the anti deficiency act, which precludes long term commitments without sufficient funds appropriated.

To be blunt, this amounts to nothing less than the federal government demanding a match from State and local governments to defray the expenses of a federal program with no limits, no control on the direction of the program but almost total responsibility for response. The State and local public health laboratories absorb costs associated with administration, training, and safety for BioWatch-contracted personnel. These costs include laboratory space with utilities, removal of infectious waste material, support services, training, computers, telephones and cell phones, vaccinations, and on-site scientific direction and expertise on questionable results. As I've shown you, the BioWatch footprint continues to expand in the host laboratories, often taking up extensive space in multiple rooms.

For example, in one public health laboratory, the BioWatch program occupies 975 square feet of laboratory space in 8 rooms on 4 floors. In addition to the costs of providing space and administrative oversight, laboratories may need testing personnel to maintain daily testing or to support intensive testing that occurs during high profile special events (like political party conventions, sporting events). Two public health laboratories only have one BioWatch-contracted employee and must use State laboratory employees to complete BioWatch testing despite informing DHS of this workforce shortage over a year ago. In plans to prepare for intensive testing or contract employee vacancy, the BioWatch contractor is to establish a contract and pay State employees to provide additional testing capacity. However, the contractor has been slow to sign, or has not signed these state employees on. Also, the contractor is on record of approving an insufficient amount of time for training and other quality assurance activities that will prepare the State employees for the situation when they are needed. Finally, these employees may not be available in the event of a bioterrorism emergency and great testing demand because their primary responsibility is to fulfill their role to the Laboratory Response Network (LRN). As the primary and career employer, the State laboratory director will determine the individuals assignment; not a contractor.

Further, the draft MOA would require that the State and local laboratories pay for the cost of maintaining certification on laboratory equipment used in BioWatch testing – costs that were previously covered by DHS.

Most alarming is the situation in one state where the current BioWatch contractor has been very reluctant to address any of the problems related to the daily operation of the BioWatch laboratory. When the new contract was awarded, payment for the internet connection service used by the BioWatch program was terminated. When the new contractor was informed of this problem, they suggested that the State laboratory pay for the service – an option the laboratory declined. This problem has yet to be resolved. With State and federal preparedness budgets shrinking at the same time, the burden of the costs incurred for hosting BioWatch will reach critical mass in the near future.

Although the lack of any contractual relationship or legal authority precludes BioWatch from being considered an unfunded federal mandate, its effect on State and local obligations is the same.

- Management and Oversight of Contract Employees at the Local Level: In January 2008, DHS awarded the BioWatch staffing contract. In May 2008, public health laboratories hosting the BioWatch program received a communication from DHS (attached) explaining that the non-personal services nature of the BioWatch contract greatly restricts the roles of DHS and the public health laboratories in the management of the BioWatch-contracted personnel. I would call attention to this portion of the DHS explanation which compounds the challenges for State and local public health laboratories hosting the BioWatch program:

The current contract that the Department of Homeland Security (DHS) has with A-TEK, Inc. is a nonpersonal services contract. The following definition of a nonpersonal services contract comes from the FAR, Part 37.101: “Nonpersonal services contract’ means a contract under which the personnel rendering the services are not subject, either by the contract’s terms or by the manner of its administration, to the supervision and control usually prevailing in relationships between the Government and its employees.”
(Emphasis added)

The host laboratories are neither federal government nor employees of the federal government.

Since the transition of BioWatch-contracted personnel to the new contractor, public health laboratory directors have struggled to maintain open lines of communications with the contractor, BioWatch-contracted personnel located in our labs and DHS. Communication has been constrained by contractor issued directives that prohibit BioWatch-contracted personnel and supervisors from fully communicating with their public health laboratory counterparts and fail to understand how fully integrated BioWatch operations and personnel are with public health laboratory operations and employees.

Contract employees are instructed to contact the contractor in the event of quality control failures or positive results. There is no reason for this communication to occur since the contractor is not involved in response and CDC provides quality

assurance consultation. It is imperative that lines of communication are seamless and totally unrestrained to assure the most efficient and effective laboratory operations. The advice and direction by the contractor will only confuse the response and is not welcome nor needed.

Prior to the issuance of the January 2008 BioWatch contract, the State and local laboratories were able to create salary parity between the BioWatch-contracted personnel and State laboratory employees based on prevailing local compensation; and they were able to have the final say on which interviewees received job offers, contribute to performance evaluations, and determine disciplinary actions to be taken by the contractor. Under the proposed MOA described previously, these oversight roles are lost. In fact the current contractor instructs their employees not to communicate with host laboratory personnel on many issues including wages. Public health labs have other contract employees and federal assignees working in our facilities and provide oversight without interfering with employer rights and responsibilities. It is only this contract that has put us at odds with the contractor.

Public health laboratory directors are legally responsible under State and federal law for the safety of all activities that occur within their laboratory, including all who work within their laboratory. This includes determinations on who has access to and is working in the laboratory (laboratory security), what analytical procedures are undertaken and how they are performed (laboratory safety and practice), and fair and equitable treatment and supervision among all laboratory staff (laboratory operations and employee morale), among others. BioWatch needs to run in parallel to the existing State and local public health laboratory infrastructure and it must not undermine that infrastructure with determinations on the internal operations of these laboratories, like whether the BioWatch-contracted personnel should be registered in the CDC's Select Agent program. The work location alone suggests Select Agent registration.

- Science and Technology: To date, State and local public health laboratory directors have not been provided with the performance data (sensitivity, specificity, limits of detection) that are necessary for them to make the best judgment possible on any BioWatch Actionable Result (or BAR) . In addition, many of these laboratories have expressed interest in providing input into the evaluation and implementation of new technologies as this has a direct impact on the use of laboratory space, personnel, and utilities as well as BAR response. New technologies have simply been foisted upon the laboratory without adequate preparation, including the performance data referenced above. Additionally, some public health laboratory scientists are concerned that there may be naturally-occurring background levels of some pathogens in surveyed cities, such as *Francisella tularensis* in Houston, Texas, leading to positive findings in the BioWatch program which do not result from bioterrorism. Other than descriptive data from studies conducted in Houston, and Virginia, public health laboratories

have not been privy to data depicting the background levels and types of organisms in the environment.

- Other Issues: In the draft MOA, DHS continues the practice of asserting that BioWatch-contracted personnel do not have to go through the Department of Justice's Security Risk Assessment (SRA) clearance process. The SRA is required for any individuals who may have access to select biological agents and toxins. This is in direct conflict to the statement in the draft MOA that the contract employees may spend up to 25% of their time working on Category A and B agent testing. The biological select agents are all included in Category A. Due to the space demands of the BioWatch program, contract employees may be working in areas that provide them access to select agents. The draft MOA provisions on cross-training that restrict BioWatch-contracted personnel to only perform testing on environmental samples and not work on clinical specimens is overly restrictive. This greatly reduces the utility of having BioWatch-contracted personnel cross-trained for public health emergencies, such as the ongoing nationwide Salmonella outbreak.

State and local public health laboratories work closely with the CDC's Laboratory Response Network (LRN) to provide analytical support for the BioWatch program. Many of these laboratories have limited interactions with DHS. The public health laboratory personnel who perform LRN testing also would perform follow up or Phase 1 Response testing on a BAR. It is important for both the staff of the public health laboratory and any BioWatch-contracted personnel to work closely together and fully understand all testing procedures.

The State and local public health laboratories would prefer to work with the BioWatch program in a more constructive and direct manner and recommend that DHS consider the following options for the BioWatch program:

- I. Fund State and local public health laboratories through a DHS cooperative agreement mechanism to manage the BioWatch program. This mechanism could either be with APHL or directly with the jurisdictions. With direct funding to the State and local jurisdictions, the BioWatch-contracted personnel would become employees of the State or local laboratory and can be easily cross-trained and integrated into the public health laboratory. This would allow the public health laboratory director to fulfill their responsibilities to their jurisdictions (and comply with all applicable federal and State regulations pertaining to the laboratory). A cooperative agreement would allow for significant programmatic involvement by DHS and collaboration by the public health laboratory.
- II. Provide funding to States to via the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement – it is important to note that PHEP Cooperative Agreement funds are shrinking and State and local public health laboratories cannot take on additional activities, such as

BioWatch without an adequate investment from DHS. Using the PHEP Cooperative Agreement mechanism, a designated sum of money can be set aside for each BioWatch host laboratory.

- III. Remove the limitation on the ability of State and local public health laboratories to cross-train BioWatch-contracted personnel that limits them to testing environmental samples. Cross-training of BioWatch-contracted personnel should be more broadly applied to testing clinical specimens and environmental samples of public health significance, such as the work done under the CDC Public Health Emergency Preparedness cooperative agreements. This would allow for more effective and robust testing capacity in a surge situation and would increase employee morale as they would be integrated into the laboratory operations.
- IV. Investigate the use of contractor incentives to foster integrated management of BioWatch-contracted personnel.
- V. Until such time when an improved mechanism is in place, DHS must work directly with State and local public health laboratories and other vested partners to ensure that BioWatch-contracted personnel applicants and hires (a) meet minimum hiring qualifications equivalent to public health laboratorians performing the same work; (b) accept the hiring recommendation of the public health laboratory director or designee; (c) can interact effectively and productively with the public health laboratory staff; (d) are subject to public health laboratory policies and procedures, and (5) abide by all public health laboratory safety and security rules and policies. Further, DHS should require the BioWatch contractor to consult with the public health laboratory director when evaluating BioWatch-contracted personnel so that the public health laboratory directors can provide input into employees' evaluations with respect to laboratory productivity, safety, and security, and interaction with co-workers.

APHL members and staff met with the senior DHS BioWatch leadership in the Office of Health Affairs on November, 19, 2007, to ensure they understood the role of State and local public health laboratories and APHL in homeland, including BioWatch and need for continued and enhanced communications. Once the BioWatch contract was awarded, APHL sent the attached January 17, 2008 letter to Dr. Runge outlining concerns about a number of personnel matters that developed with the award of the new contract and suggesting options for improvements. No reply has been received to this letter as of today's date.

Additionally, the association has documented our communication to DHS regarding the public health laboratory community's interest on communicating its recommendations concerning BioWatch. The process of developing memoranda of agreement with the public health laboratories may ultimately address these concerns; however because of the urgent need for some immediate solutions an interim approach is also needed.

APHL works to safeguard the public's health by strengthening public health laboratories in the United States and globally. We advance laboratory systems and practices, and promote policies that support healthy communities. APHL and its State and local public health laboratory membership are committed to working with DHS to assure that laboratories are adequately funded to support the BioWatch program and to improve the overall management of BioWatch-contracted personnel.

With funding and increased management oversight, public health laboratory directors would be able to improve workflow, promote cross-training among laboratorians to adequately utilize staff and improve quality laboratory practices by implementing standard quality control measures in all BioWatch locations.

The BioWatch program has been variously described by my fellow State and local laboratory directors as a parasite to the public health laboratory and squatters in valuable public health laboratory space. I am hard-pressed to disagree.

This concludes my testimony, and I thank you again for inviting me to participate in this hearing.



January 17, 2008

Dr. Jeffrey Runge
Office of Health Affairs
Department of Homeland Security
245 Murray Lane, SW
Washington, DC 20528

Dear Dr. Runge:

Thank you very much for the meeting we had with Drs. Jon Krohmer, Donald Noah, and Jeffrey Stiefel. We found the meeting very productive and we were quite pleased to have had the opportunity to meet briefly with you and Dr. Henry Falk from the Centers for Disease Control and Prevention in the building lobby as we left.

We enjoyed discussing a variety of preparedness issues including the developments for the next generation of BioWatch, which has an obvious and significant impact on public health laboratories in many states. Foremost in our conversation was our mutual interest in sharing information in a timely manner on all of these issues. Therefore, it came as quite a surprise when we first learned from several worried public health laboratory directors that the contract to employ BioWatch laboratory personnel had been awarded and that the contractor had sent out personnel materials containing their first notification of drastic benefit and in some cases salary changes. This deeply troubled the current BioWatch staff and host laboratory directors are concerned about the plans of these employees to continue employment with the new BioWatch personnel contractor.

The compensation and benefits changes proposed by the contractor were so alarming to the BioWatch staff across the country that they quickly organized themselves through email and identified the areas of greatest mutual concern. Fortunately for the BioWatch program, most of these concerns were immediately addressed in a revised version of the contractor's frequently asked questions document that was subsequently released this past Saturday. This experience underscores the value of creating and maintaining regular and direct lines of communication between the program and the host public health laboratories. Had we known of the contract award and the contractor's plan to make dramatic personnel changes directly, we could have offered advice that would have avoided much of the frustration caused by these recent actions.

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Please understand that we are most interested in assuring that the BioWatch program operates as intended with a highly-trained and reliable laboratory workforce. Unfortunately, however, this experience has shaken the confidence of that workforce considerably and could result in greater staff turnover. While there are reports of a large pool of potential replacements for these workers, the actual process of integrating such replacements into the program could lead to dramatically reduced public health preparedness by requiring more samples to be analyzed by the Lawrence Livermore National Laboratory facility, instead of in a BioWatch facility, during the new staff integration process.

Moving forward, we reiterate our interest in working collaboratively with you on issues of mutual interest, like BioWatch. Hopefully, an open line of communication will forestall the recurrence of these types of incidents and together we will find ways to stabilize management of the BioWatch staff working so effectively in our public health laboratories.

Sincerely,



Frances Pouch Downes, Dr.P.H.
President, APHL
Laboratory Director, Bureau of Laboratories
Michigan Department of Community Health

