

# CRS Report for Congress

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## **The BioWatch Program: Detection of Bioterrorism**

**November 19, 2003**

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# The BioWatch Program: Detection of Bioterrorism

## Summary

The anthrax mailings of 2001 increased public and governmental awareness of the threat of terrorism using biological weapons. The federal response to this threat includes increases in countermeasure research funding, greater investment in public health infrastructure, and greater preparation of first responders who might be the first to encounter such weapons in an event. The new Department of Homeland Security (DHS) has made preparation against biological weapon attack a priority and deployed the BioWatch Program to provide early warning of a mass pathogen release.

The BioWatch Program uses a series of pathogen detectors co-located with Environmental Protection Agency air quality monitors. These detectors collect airborne particles onto filters, which are subsequently transported to laboratories for analysis. It is expected that this system will provide early warning of a pathogen release, alerting authorities before victims begin to show symptoms and providing the opportunity to deliver treatments earlier, decreasing illness and death.

The BioWatch Program, funded and overseen by DHS, has three main elements each coordinated by different agencies, sampling, analysis, and response. The Environmental Protection Agency (EPA) maintains the sampling component, the sensors that collect airborne particles. The Centers for Disease Control and Prevention (CDC) coordinates analysis, the laboratory testing of the samples, though testing is actually carried out in state and local public health laboratories. Local jurisdictions are responsible for the public health response to positive findings. The Federal Bureau of Investigation (FBI) is designated as the lead agency for the law enforcement response if a bioterrorism event is detected. The BioWatch Program has raised concerns in some quarters, with questions about its general effectiveness, the siting of pathogen detectors, the reliability of its results, its cost and workforce requirements, and the ability of public health officials to respond to BioWatch results. Efforts to develop integrated response plans, lower the system cost, and develop complementary and next-generation systems continue.

Some aspects of the BioWatch Program may be of particular interest to policymakers. For example, Congress may be interested in whether these types of detection systems can substitute for or supplement other mechanisms in protecting the general populace; whether this detection system was implemented optimally; how the success of this system is to be evaluated; whether the implementation, operational, and expansion costs for the BioWatch Program make it a cost-effective federal investment; and how to optimize and streamline performance in the future. Since the BioWatch Program is a federal program implemented using state infrastructure, Congress may wish to examine how this new program coordinates with already existing public health and counterterrorism programs, as well as consider the roles and responsibilities of the federal government and coordination with state governments in an actual bioterrorism event.

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# The BioWatch Program: Detection of Bioterrorism

## Introduction

During the 2003 State of the Union address, President Bush announced that the federal government was “deploying the nation’s first early warning network of sensors to detect biological attack.”<sup>1</sup> The newly formed Department of Homeland Security (DHS), is responsible for deploying this network, the BioWatch Program, reportedly as part of the Biological Warning and Incident Characterization System.<sup>2</sup> Funded and overseen by DHS, the program has three main elements each coordinated by different agencies, sampling, analysis, and response. The Environmental Protection Agency (EPA) maintains the sampling component, the sensors that collect airborne particles. The Centers for Disease Control and Prevention (CDC) coordinates analysis, the laboratory testing of the samples, though testing is actually carried out in state and local public health laboratories. Local jurisdictions are responsible for the public health response to positive findings. The Federal Bureau of Investigation (FBI) is designated as the lead agency for the law enforcement response if a bioterrorism event is detected. The installation of the sensor network is ongoing, with over 30 cities chosen as locations for these sensors.<sup>3</sup>

The detection of a covert act of bioterrorism, unless detected by the BioWatch Program, is likely to occur through the diagnosis of ill victims. Detection is delayed from the time of the actual event by the time required to develop symptoms and report them. For many pathogens, early treatment, preferably before symptoms develop, is key to preventing casualties. If early detection is achieved, it is predicted that therapeutic agents could be provided in a timely manner to those exposed, reducing the effectiveness of such an attack and averting the potentially catastrophic nature of mass pathogen releases. While pathogen detection systems are employed by the military, such systems were not previously deployed on such a scale in the civilian sector.

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<sup>1</sup>“State of the Union Address,” Executive Office of the President, The White House, January 28, 2003, found online at [<http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html>].

<sup>2</sup>For a short description of the Biological Warning and Incident Characterization System, see the statement of Under Secretary Dr. Charles E. McQueary, Department of Homeland Security, Science and Technology Directorate, before the House Select Committee on Homeland Security Subcommittee on Cybersecurity, Science, and Research and Development, at a hearing titled “Homeland Security Science and Technology: Preparing for the Future,” on May 21, 2003.

<sup>3</sup>The White House, *Progress Report On The Global War On Terrorism*, September 2003, p. 14.

A fundamental question to be asked of the BioWatch Program is whether it is an appropriate federal response to the threat of bioterrorism. The historic cases of bioterrorism within the United States have been small in scope, and likely would not be detected by the current system. Additionally, the Central Intelligence Agency has reported that while al-Qaeda maintains the goal of mass casualties, most attacks will be small scale.<sup>4</sup> The deployment of a bioterrorism detection system with a primary goal of detecting large releases of pathogen may not be viewed as the optimum response to the current threat.

The BioWatch Program garners public and Congressional interest for a variety of reasons, including its cost, the future development and testing of similar systems, the effectiveness of the currently deployed system, the process by which this program was chosen and deployed, and the consequence-management process envisioned in response to a BioWatch warning. These issues may raise questions about the role that the Department of Homeland Security plays with respect to the public health infrastructure, aspects of federal and state communication and coordination, and the role of the federal and state governments in protecting the populace against biological attack.

## What is the BioWatch Program?

The function of the BioWatch Program is to detect the release of pathogens into the air, providing warning to the government and public health community of a potential bioterror event. While there is limited federal government description of the BioWatch Program, there have been media reports describing the functional concept.<sup>5</sup> According to these reports, aerosol samplers mounted on preexisting EPA air quality monitoring stations collect air, passing it through filters. These filters are manually collected at regular, reportedly 24-hour, intervals<sup>6</sup> and are analyzed for potential biological weapon pathogens using polymerase chain reaction (PCR) techniques.<sup>7</sup> While filters from the BioWatch program were initially shipped to and tested at a federal laboratory in California, state and local public health laboratories now perform the analyses.<sup>8</sup> News reports suggest that the system tests for the

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<sup>4</sup>Directorate of Intelligence, Central Intelligence Agency, *Terrorist CBRN: Materials and Effects*, June, 2003.

<sup>5</sup>For example, see Judith Miller, "U.S. Deploying Monitor System For Germ Peril," *The New York Times*, January 22, 2003, p. A1; Kathy Sawyer, "Biowarfare Monitors Are Deployed in U.S.," *The Washington Post*, January 23, 2003, p. A6; and Julie Deardorff, "City's Air Monitored for Bioterror Attack: Early Detection System Criticized," *Chicago Tribune*, April 6, 2003, p. 1C.

<sup>6</sup>This interval could be changed at the operator's discretion. Dina Cappiello, "'BioWatch' to Sound Alarm; Monitors Screen Air Quality for Bacteria Attack," *Houston Chronicle*, July 29, 2003, p. A11.

<sup>7</sup>PCR is a common method of creating many copies of specific fragments of DNA. In theory, PCR could allow the detection and identification of just a few pathogens on a given filter.

<sup>8</sup>See Michael Lasalandra, "Boston Joins National Bio-warfare Alert Network," *Boston* (continued...)

pathogens that cause anthrax, smallpox, plague, and tularemia (a bacterial illness, sometimes called “rabbit fever”), but the entire list of pathogens is not publicly available.<sup>9</sup>

The BioWatch equipment is fielded in select cities, reportedly including Philadelphia, New York City, Washington, DC, San Diego, Boston, Chicago, San Francisco, St. Louis, Houston, and Los Angeles.<sup>10</sup> The Department of Homeland Security has not confirmed the exact number of cities engaged in the BioWatch program, nor the number of pathogens that are detected using BioWatch equipment.<sup>11</sup> It is reported that at least 31 cities are included in the BioWatch program, while according to the minutes of a Centers for Disease Control and Prevention (CDC) Information Council meeting, the program may expand to as many as 120 cities.<sup>12</sup> While the exact cost of this program is unknown, the capital costs for installation in a single city are estimated at \$1 million and the yearly budget for operation at \$1 million per city.<sup>13</sup>

The press has reported that the state and local public health labs conducting BioWatch testing are all part of the national Laboratory Response Network for Bioterrorism (LRN).<sup>14</sup> The LRN is a nationwide network composed primarily of local, state, and federal government laboratories that provide confirmatory testing of potential bioterrorism pathogens, using consensus protocols. It was developed by Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation, and the Association of Public Health Laboratories prior to the anthrax mailings of 2001. It provides confirmatory testing in all 50 state public health labs, and in additional locations.<sup>15</sup> There are currently 118 member labs in the LRN.

<sup>8</sup>(...continued)

*Herald*, March 14, 2003, p. 5.

<sup>9</sup>*Ibid.*

<sup>10</sup>City list compiled from the following news articles: David B. Caruso, “Devices Sniff Out Bioterror, But Experts Question Effectiveness,” *The Associated Press*, July 11, 2003; and Dina Cappiello, “‘BioWatch’ to Sound Alarm; Monitors Screen Air Quality for Bacteria Attack,” *Houston Chronicle*, July 29, 2003, p. A11.

<sup>11</sup>David B. Caruso, *op cit.*

<sup>12</sup>Comments made in “Meeting Minutes,” CDC Information Council, February 27, 2003, found online at [<http://www.cdc.gov/cic/minutes/CIC%20minutes%202-27-03.pdf>].

<sup>13</sup>“Nationwide Monitoring System Planned For Detecting Bioterror Attack,” *The Associated Press*, January 22, 2003.

<sup>14</sup>“BioWatch Program Aims For Nationwide Detection of Airborne Pathogens,” *CIDRAP News*, February 26, 2003, revised March 10, 2003.

<sup>15</sup>For background on the LRN, see M. J. R. Gilchrist, “A National Laboratory Network for Bioterrorism: Evolution from a Prototype Network of Laboratories Performing Routine Surveillance,” *Military Medicine*, Vol.165, Supplement 2, 2000, and A.P. Perkins, T. Popovic, and K. Yeskey, “Public Health in the Time of Bioterrorism,” *Emerging Infectious Diseases*, Vol. 8, Oct. 2002, available at [<http://www.cdc.gov/ncidod/EID/vol8no10/02->

BioWatch equipment is heavily based on the Biological Aerosol Sentry and Information System (BASIS), a system developed within the Chemical and Biological National Security Program of the National Nuclear Security Administration (now part of the Department of Homeland Security) by scientists at Lawrence Livermore and Los Alamos National Laboratories.<sup>16</sup> BASIS is comprised of an air collector coupled to a series of filters. Airborne particles passing through the system are captured on a filter. The filter mechanism is designed to roughly determine when an attack occurred by using sequential filters automatically rotated on an hourly basis. Filters are removed and tested using PCR for the presence of select pathogens.

BASIS was deployed for both indoor and outdoor monitoring at the Salt Lake City Olympics in 2002, and was also tested and characterized in urban settings.<sup>17</sup> Some conclusions about instrument performance based on these tests were released. BASIS was characterized as having high specificity, with fewer than 0.005% false positives per filter measurement,<sup>18</sup> and high sensitivity.<sup>19</sup> However, BASIS was noted to be labor intensive, requiring people to collect filters and perform PCR testing and analysis.

The first incident of a positive BioWatch result was reported on October 9, 2003 in Houston, Texas. The Houston Department of Health and Human Services reported detecting low levels of the bacterium that causes tularemia. According to a press release, positive results were detected on three consecutive days, with negative results on subsequent days.<sup>20</sup> The response to the positive result was a modest one with precautionary measures being taken by the local and state public health agencies, including increased surveillance for human illness; additional environmental sampling and testing; and assessment of activities in the area that may have caused the sensors to pick up the organism. There are no indications that this

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<sup>15</sup>(...continued)

0444.htm]. See also Department of Health and Human Services, *Public Health Emergency Preparedness: Transforming America's Capacity to Respond*, Fact Sheet, September 11, 2003.

<sup>16</sup>Vin LoPresti, "Guarding the Air We Breathe," *Los Alamos Research Quarterly*, Spring, 2003. See also United States General Accounting Office, *Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Ability To Respond To Public Health Emergencies*, GAO-03-139, May 2003.

<sup>17</sup>"Technology Will Be Used at 2002 Winter Olympics," *Newsline*, February 8, 2002.

<sup>18</sup>A false positive rate refers to how often a system signals the presence of a pathogen when no pathogen exists. A false positive rate of less than 0.005% corresponds to less than one false positive result per 20,000 tests. Vin LoPresti, *op cit*.

<sup>19</sup>Test methods are described according to *sensitivity*, the ability to detect an agent when it is present, and *specificity*, the ability to yield a negative result when the agent is not present. Specificity requires that the method does not detect closely related organisms, but only the organism(s) of interest.

<sup>20</sup>Houston Department of Health and Human Services, "Officials Following Up on Bacteria Detection," Press Release, October 9, 2003, found online at [<http://www.ci.houston.tx.us/departme/health/bacteria%20detection.htm>].

signal was the result of an intentional pathogen release, but investigation is ongoing with federal, state and local agency participation.<sup>21</sup> The Director of the Houston Department of Health and Human Services stated, “We are investigating to determine if the bacteria was always present or newly present and if it represents a health threat to the community.” These findings may likely reflect natural “background” levels of the organism in the environment, and authorities have chosen to enhance surveillance rather than distributing antibiotics in the affected community.<sup>22</sup>

## Reactions to the BioWatch Program

The BioWatch program has received a mixed reaction from experts. While acknowledging the program may address a noted homeland security vulnerability, commentators and analysts have raised concerns in a number of areas. This section presents some of these concerns, including overall strategy, sensor siting, detector performance, and public health response.

### Strategic Issues

Countering the threat of terrorist use of weapons of mass destruction against civilians has taken on new priority since the anthrax mailings of 2001. President Bush, when announcing the deployment of the BioWatch program during the 2003 State of the Union Address, stated,

Today, the gravest danger in the war on terror, the gravest danger facing America and the world, is outlaw regimes that seek and possess nuclear, chemical, and biological weapons. These regimes could use such weapons for blackmail, terror, and mass murder. They could also give or sell those weapons to terrorist allies, who would use them without the least hesitation.<sup>23</sup>

A goal of the BioWatch program is detection of large releases of biological weapons, some of which might potentially cause thousands of casualties.<sup>24</sup> Early notification of a biological attack is presumed to provide a significant advantage in preventing and treating casualties. Such a “detect to treat”<sup>25</sup> warning system may

<sup>21</sup>*Ibid.*

<sup>22</sup>See also Eric Berger, “Suspicious Bacteria Detected: Security Monitors Spot Germ; Terrorism Discounted,” *Houston Chronicle*, October 10, 2003, p. A27, and Robert Roos, “Signs of Tularemia Agent Detected in Houston Air,” *CIDRAP News*, October 10, 2003.

<sup>23</sup>“State of the Union Address,” Executive Office of the President, The White House, January 28, 2003, found online at [<http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html>].

<sup>24</sup>For an overview of the impacts of weapons of mass destruction, see Office of Technology Assessment, U.S. Congress, *Proliferation of Weapons of Mass Destruction; Assessing the Risks*, OTA-ISC-559, (Washington, DC, U.S. Government Printing Office) August 1993.

<sup>25</sup>A “detect to treat” technology provides early notification of a biological attack, so that effective treatment for those made ill can be provided. This differs from a “detect to warn” technology which provides warning of an event before infection occurs. “Detect to treat”

(continued...)

limit casualties and fatalities by allowing earlier medical service to the exposed, avoiding disease progression. A modeling study concludes that while the earliest possible detection of a hypothetical urban anthrax release still cannot prevent all deaths, the proportion of lives saved by detection and intervention within the first day after the event (before symptoms appear in those exposed) is approximately 40%.<sup>26</sup> With increasing delay between detection and treatment, greater casualties occur.

Some experts question whether mass biological attack is the most probable terrorist threat, and suggest that more localized attacks are more likely.<sup>27</sup> It is suggested by some that the BioWatch monitors would not likely detect indoor or underground releases, such as within a building or a subway system.<sup>28</sup> There are historical examples of both indoor releases, the U.S. anthrax mailings in 2001, and outdoor releases, such as the suspected accidental anthrax release at Sverdlovsk (now Ekaterinburg), Russia in 1979.<sup>29</sup>

Factors influencing the choice of locales to be monitored are another area of discussion. BioWatch monitors are reportedly deployed in major cities. A successful mass biological attack on a large city would likely cause high casualties. The perceived prestige conferred upon a terrorist group following a successful, large-scale attack may lead terrorist groups to preferentially target cities.<sup>30</sup> Some posit that these factors, among others, require special consideration for major cities. For example, in the debate over homeland security spending, some have asserted that homeland security funds should be allocated using formulas that take into account threats, population density, and the presence of critical infrastructure, rather than on a per capita basis.<sup>31</sup> In contrast, some have claimed that successful aerosol dissemination

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<sup>25</sup>(...continued)

and “detect to warn” technologies differ in timescale, with “detect to warn” technologies having to detect in real time, a much more difficult task. For a discussion of these issues, see Jeffery H. Grotte, *Frequently Asked Questions Regarding Biological Detection*, Institute for Defense Analysis, Alexandria, Va., November 2001.

<sup>26</sup>Lawrence M. Wein, David L. Craft, and Edward H. Kaplan, “Emergency Response to an Anthrax Attack,” *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 100, April 1, 2003, and Lawrence M. Wein, personal communication, September 8, 2003.

<sup>27</sup>For a representative view, see Amy Smithson and Leslie-Anne Levy, *Ataxia: The Chemical and Biological Terrorism Threat and the US Response*, The Henry L. Stimson Center, Report No. 35, October 2000.

<sup>28</sup>Julie Deardorff, “City’s Air Monitored for Bioterror Attack: Early Detection System Criticized,” *Chicago Tribune*, April 6, 2003, p. C1.

<sup>29</sup>For a discussion of the anthrax epidemic of Sverdlovsk, see Matthew Meselson, Jeanne Guillemin, Martin Hugh-Jones, *et al.*, “The Sverdlovsk Anthrax Outbreak of 1979,” *Science*, Vol. 266, November 18, 1994.

<sup>30</sup>For an overview of factors which may influence a terrorist group to use chemical or biological weapons, see CRS Report RL31831 *Terrorist Motivations for Chemical and Biological Weapons Use: Placing the Threat in Context* by (name redacted).

<sup>31</sup>See Laurence Arnold, “Less Populated States Receive More Money per Capita for (continued...)”

near a major city is less likely due to the higher probability that such an event would be noticed by officials or citizens.<sup>32</sup>

Some feel that the existence of bioterrorism countermeasures can themselves serve as a deterrent to the use of these agents. In theory, the BioWatch program might have this effect, with potential bioterrorists knowing that cities have early warning capability due to the BioWatch program being deterred from using biological weapons. Some may conclude that this deterrent value is enhanced by the general secrecy surrounding BioWatch program details, such as monitor locations and pathogen lists. The deterrence value may be difficult to measure, and may alternately direct terrorists toward locations lacking such detectors. Also, the general secrecy surrounding the BioWatch program details may lead potential bioterrorists to underestimate the system's true capability, decreasing the deterrent effect.

## Sensor Siting Issues

Technical issues regarding placement of BioWatch monitors are raised as potential limitations to the system's effectiveness. Some BioWatch monitors are reportedly co-located with preexisting EPA air quality monitors,<sup>33</sup> though potentially the monitors could be relocated should the need arise.<sup>34</sup> Regulations regarding placement of EPA air quality monitors are found at 40 CFR 58, and, among other criteria, placement is designed to assess the impact of potential pollutant sources for a given area. Since these criteria are different from those designed for biological detection, the placement of the EPA air quality monitors may not place the BioWatch monitors in an optimal configuration for a given area. Some outdoor pathogen releases, particularly those that might be small, reportedly might avoid detection due to gaps or limitations in coverage due to siting, even though the monitors themselves were very sensitive.<sup>35</sup>

The exact locations of the BioWatch monitors are not public knowledge. The Department of Homeland Security does not confirm the locations of BioWatch monitors.<sup>36</sup> If the locations of these monitors were known with great certainty, it might become possible to avoid them, to degrade their detection capability, or to provide them false signals or information. The locations of the BioWatch monitors

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<sup>31</sup>(...continued)

Security," *The Associated Press*, June 29, 2003.

<sup>32</sup>"San Diego Monitored By Bioterror Sensors; Experts Question Effectiveness," *NBC San Diego*, July 10, 2003.

<sup>33</sup>Doug Tsuruoka, "Web Is Key Homeland Security Element – A Revamp of Civil Defense," *Investor's Business Daily*, February 20, 2003, p. A10.

<sup>34</sup>Dan McKay, "Is Our Air Toxic?" *Albuquerque Journal*, July 3, 2002, p. A1.

<sup>35</sup>Stacy Finz and Alan Gathright, "S.F.'s Bio-Warfare Sentries; City Marshals Devices to Give Early Warning of Anthrax, Smallpox Attacks," *The San Francisco Chronicle*, April 3, 2003, p. A14.

<sup>36</sup>Geoff Dutton, "Ohio Says Security Requires Secrecy On Tests For Air Toxins," *The Columbus Dispatch*, March 21, 2003, p. 3A.

determine the detection coverage areas and the security of the monitors. Some law enforcement concerns which may have been employed in developing priorities for placing and operating BioWatch monitors include: assuring the physical security of the monitors so that no tampering occurs; guaranteeing that monitor filters arrive at the testing location in the same condition as when they were removed from the monitor; and providing that the chain of custody for potential forensic evidence is established.

A further concern regarding placement of some BioWatch monitors near EPA air quality sites is that EPA monitors are not equally spaced within a city or an area. Even if the EPA monitors meet the above criteria with respect to security, privacy, and access, the irregularity of placement and potential gaps in coverage between these sites may cause them to be not entirely appropriate as BioWatch monitors. It is suggested by some that an outdoor biological warning system would require the placement of monitors as closely spaced as 300-500 meters.<sup>37</sup> Neither the official rationale for BioWatch monitor placement nor who established the placement criteria has been disclosed. It may be that the reported choice of sites reflects an effort to provide maximal coverage for the population in a particular metropolitan area. An unnamed spokesman for the Department of Health and Human Services stated that the goal of BioWatch siting is to provide coverage for 80% of the population of a particular area.<sup>38</sup> Alternately, cost and ease of access are suggested as possible additional reasons for the reported use of EPA co-locations.<sup>39</sup>

Following a positive signal from a BioWatch monitor, the likely affected area might be determined through analysis and modeling of potential releases. Those determined to be inside areas affected by the release might receive priority treatment. A recent Congressional hearing<sup>40</sup> cast light on the diversity of programs able to model gaseous releases, but also highlighted that there is not a single, acknowledged best method for determining the area of effect of a given release, especially in urban areas where wind patterns and the effects of turbulence from building geometries is only partially known.<sup>41</sup> Thus, determining the exact areas impacted by the release,

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<sup>37</sup>See Gary Eifried, "Detecting Biological Terrorism; Evaluating the Technologies," in *The Role of Biotechnology in Countering BTW Agents*, A. Kelle, et al., Eds. (Kluwer Academic Publishers) 2001, and Philip J. Wyatt, "Early Warning and Remediation: Minimizing the Threat of Bioterrorism," *Journal of Homeland Security*, April 2002, found online at [<http://www.homelandsecurity.org/journal/Articles/wyattearlywarning.htm>].

<sup>38</sup>"BioWatch Program Aims For Nationwide Detection of Airborne Pathogens," *CIDRAP News*, February 26, 2003, revised March 10, 2003.

<sup>39</sup>Ian Hoffman, "Air Monitors To Sniff For Biowarfare Agents," *The Oakland Tribune*, January 24, 2003.

<sup>40</sup>U.S. House of Representatives, Committee on Government Reform, Subcommittee on National Security, Emerging Threats and International Relations, *Following Toxic Clouds: Science and Assumptions in Plume Modeling*, 108<sup>th</sup> Congress, June 2, 2003.

<sup>41</sup>For a representative view, see National Research Council, *Tracking and Predicting the Atmospheric Dispersion of Hazardous Material Releases: Implications for Homeland Security*, (Washington, DC: National Academies Press) 2003.

and hence those individuals requiring priority treatment, may be more difficult if the monitors are sub-optimally deployed.

## Analytical Issues

As stated above, the BioWatch Program is built from the successes of BASIS, developed by the Department of Energy.<sup>42</sup> BASIS, which employs similar technology, was tested by the Department of Energy in a variety of situations, including laboratory environments and deployment at the Salt Lake City Winter Olympics in 2002.<sup>43</sup> It is not fully known what potential changes were made to the BASIS equipment when it was adapted to serve BioWatch, and how applicable previous testing results for BASIS are to BioWatch. Some question the ability of the BioWatch test methods to detect pathogens in a large city environment, especially one with considerable pollution and airborne particulate matter that might affect analysis.<sup>44</sup>

Some are concerned that there may be naturally-occurring background levels of some pathogens in surveyed cities, leading to positive findings in the BioWatch program which do not result from bioterrorism.<sup>45</sup> While PCR is a sensitive technique, it reports the presence or absence of a DNA sequence, providing only a coarse scale of the amount of initial material. The diseases caused by anthrax, plague, and tularemia bacteria, all on CDC's Category A list of biological terrorism agents, are not commonly found in humans, but they are diagnosed as naturally-occurring infections each year in the U.S.<sup>46</sup> Certain of these agents are considered endemic, regularly present in the environment, in certain parts of the country. The BioWatch Program appears to be premised upon the assumption that all positive detections merit further investigation, even if there may be a detectable background level of these pathogens in some areas. In this regard, the BioWatch Program is a simpler methodological design than surveillance systems that detect deviations from an anticipated background event level. Such systems have the added burden of determining thresholds above background which are significant. Those concerned about detection of naturally occurring background pathogens question how response

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<sup>42</sup>The General Accounting Office, for example, states that BASIS was adapted to process samples from the BioWatch program. United States General Accounting Office, *Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Ability To Respond To Public Health Emergencies*, GAO-03-139, May 2003. See also Vin LoPresti, *op cit*.

<sup>43</sup>Statement of Mary Anne Yates, Senior Advisor, Threat Reduction, Los Alamos National Laboratory before the New Mexico Legislature, Committee on Information Technology Oversight, September 18, 2002.

<sup>44</sup>For example, see Mark Baard, "Bio-Whatchamacallit," *The Village Voice*, March 12-18, 2003.

<sup>45</sup>David B. Caruso, *op cit*.

<sup>46</sup>Centers for Disease Control and Prevention, "Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response: Recommendations of the CDC Strategic Planning Workgroup," *Morbidity and Mortality Weekly Report*, Vol. 49 (RR04), April 21, 2000.

plans might take this possibility into account. When airborne tularemia bacteria was detected by BioWatch sensors in Houston, Texas, other information, such as the appearance of human illness, was sought to clarify the BioWatch result.

Further concerns with BioWatch implementation relate to the verification of positive results and the use of further testing to guide governmental response. While the number of false positives arising with BASIS was determined to be very small,<sup>47</sup> it is unknown whether that rate is directly applicable to BioWatch equipment. The BioWatch collection filters, under vacuum airflow for several hours, have the potential to desiccate and kill organisms collected on them, yielding positive PCR results that cannot be directly confirmed by growth of a pathogen in culture.<sup>48</sup> PCR methods are based on the detection of DNA signatures; they do not require that the organisms be viable, nor do they distinguish whether organisms are viable or not. For many pathogens of bioterrorism concern, the “gold standard” confirmatory test is based on growth of the sample in culture. Besides providing clear confirmation of preliminary results, growing the organism provides options for further testing. For example, having viable samples of the pathogen allows for molecular “fingerprinting” and other techniques to support epidemiologic and law enforcement investigations, as well as allowing determination of antibiotic resistance. There may be analytical techniques, other than culture, used to clarify PCR results from BioWatch, and other activities that could be undertaken to corroborate initial findings, but whether protocols for these activities are established and communicated to the state and local authorities that would implement them is not publicly known.

The public health testing model for bioterrorism, in place during the anthrax attacks of 2001, incorporates confirmatory testing as one of its operational cornerstones. LRN laboratories use trained personnel to expedite testing that confirms or refutes preliminary findings. One goal of the LRN is to minimize the time between an initial signal, such as a “positive” on a field-screening device that is expected to yield some false positive findings, and a confirmed result. This process is designed to launch a public health response swiftly when it is needed, and avoid doing so when it is not. A large-scale aerosol release of biological agents would necessitate a public health emergency response of the highest order. While the BioWatch program is designed to detect a potential aerosol release quickly, if confirmatory testing is not available, it could lead to triggering response activities erroneously, potentially consuming limited resources and damaging public confidence.

A final concern is the threshold for pathogen detection in the BioWatch system. Since PCR can amplify very small amounts of DNA, such a system could be very sensitive, theoretically able to detect a single pathogen. On the other hand, the pathogen deposition onto the filter depends on the rate of air flow into the monitor. Thus, the pathogen release detection limit is a combination of at least three factors: the concentration of aerosols passing over the detector; the duration that the aerosol mist is passing over the detector; and the amount of air collected through the filters

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<sup>47</sup>Vin LoPresti, *op cit.*

<sup>48</sup>“BioWatch Program Aims For Nationwide Detection of Airborne Pathogens,” *CIDRAP News*, February 26, 2003, revised March 10, 2003.

during that time.<sup>49</sup> Since these three parameters of equipment performance are not publicly available, the actual detection limit for BioWatch is not publicly known. As a consequence, analyst opinion is mixed as to the utility of these monitors, with some expressing confidence that small releases could be detected, and others expecting that smaller outdoor releases would fall below the detection limit.<sup>50</sup> A very low detection limit is desirable because for some of the potential agents of bioterrorism, the infective dose in some individuals may also be very low.<sup>51</sup>

The BioWatch program is considered labor intensive.<sup>52</sup> Collection of filters from the monitors, processing of the filters, and laboratory analysis all require human intervention. Additionally, the required laboratory work regularly consumes chemical reagents and disposable equipment, incurring significant operational cost. Finally, there are additional costs in administering, overseeing, and managing personnel and mandatory reporting related to this program. Initial estimates of the costs of the BioWatch program are reported to be approximately \$1 million in initial equipment costs per city, followed by operational costs of \$1 million per city per year.<sup>53</sup> Since the BioWatch Program was launched in January 2003, it is likely that a more exact accounting of the recurring costs of this program will become available in the future.

## Public Health Response Issues

If an aerosol release of a biological agent were detected, a two-pronged response would be initiated, with state and local public health agencies in charge of an epidemiologic investigation, and the Federal Bureau of Investigation (FBI) in charge of a law enforcement investigation.<sup>54</sup> The public health consequence management plan for the BioWatch program is not publicly available, but based on a generic model for public health activities following a bioterrorism event, it is likely to

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<sup>49</sup>For an overview of issues related to biological weapon detectors see *Biological Detection System Technologies, Technology and Industrial Base Study – A Primer on Biological Detection Technologies*, North American Technology and Industrial Base Organization, February 2001.

<sup>50</sup>David B. Caruso, *op cit*.

<sup>51</sup>For example, see T.V. Inglesby, *et al.*, “Anthrax as a Biological Weapon 2002,” *Journal of the American Medical Association*, Vol. 287, No. 17, May 1, 2002, noting evidence from primate studies that the infective dose of anthrax may be as low as one spore, and D.T. Dennis, *et al.*, “Tularemia as a Biological Weapon,” *Journal of the American Medical Association*, Vol. 285, No. 21, June 6, 2001, noting evidence that as few as 10 inhaled *Francisella tularensis* organisms may cause disease.

<sup>52</sup>“BioWatch Program Aims For Nationwide Detection of Airborne Pathogens,” *CIDRAP News*, February 26, 2003, revised March 10, 2003.

<sup>53</sup>Laura Meckler, “Government Deploys Early Warning System For Bioterror Attack,” *The Associated Press*, January 22, 2003. It is likely that this estimate includes salaries for state public health laboratory workers who perform required sample analysis.

<sup>54</sup>Lawrence O. Gostin, *et al.*, “The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases,” *Journal of the American Medical Association*, Vol. 288, (2002) pp. 622-628.

include such activities as: expanded laboratory investigation, identification of affected populations, guidelines for countermeasure distribution, considerations for management of mass casualties, and potential restriction of movement of individuals in the case of a communicable agent.<sup>55</sup> A likely first step would be aimed at further sampling to quickly confirm and clarify any positive results from the BioWatch system, including an attempt to isolate viable organisms, but with an urgency to minimize the time spent between an initial alert and a decision to launch a public health response. The public health response to a suspected aerosol pathogen release is likely to be massive and difficult to implement in a limited manner. It is, in fact, the intent of the BioWatch program that the public health response be launched as quickly as possible following a detected release. An often cited theoretical model of casualties following mass exposure to anthrax concluded that rapid distribution of antibiotics following detection of the event is a critical element in reducing fatalities, and could represent a potential bottleneck in the response.<sup>56</sup>

Another concern is the burden on a public health workforce asked to support a new program when faced with naturally occurring challenges, such as West Nile virus and Severe Acute Respiratory Syndrome (SARS). At a July 2003 hearing on biodefense readiness, CDC Director Julie Gerberding noted,

... in the middle of our smallpox program, we did have to take the very same people and work on a SARS outbreak, and then a monkey-pox outbreak, and now a West Nile outbreak, and we have a number of very high priorities throughout CDC and the public health system that compete for the same personnel. ... we have been in crisis mode for two years now.<sup>57</sup>

State public health laboratory workers have voiced concern about meeting their public health duties due to the increase in responsibility for certain federal programs.<sup>58</sup> Similar concerns were voiced about impacts on the public health infrastructure with respect to smallpox vaccination and terrorism preparedness.<sup>59</sup> Since the day-to-day operation of the BioWatch program was transferred to state and local public health laboratories, the Department of Homeland Security attempted to mitigate these impacts by providing for hiring of laboratory personnel dedicated to supporting the BioWatch program.<sup>60</sup> Additionally, direct costs of the program, including consumables such as biological reagents, are provided for by DHS.

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<sup>55</sup>Centers for Disease Control and Prevention, *The Public Health Response to Biological and Chemical Terrorism: Interim Planning Guidance for State Public Health Officials*, July 2001, available online at [<http://www.bt.cdc.gov/Documents/Planning/PlanningGuidance.PDF>].

<sup>56</sup>Lawrence M. Wein, David L. Craft, and Edward H. Kaplan, *op cit*.

<sup>57</sup>Testimony of Julie L. Gerberding, CDC Director, before the Senate Committee on Health, Education, Labor, and Pensions Hearing on Federal Biodefense Readiness on July 24, 2003.

<sup>58</sup>Association of Public Health Laboratories, Executive Director's Note, *The APHL Minute*, March-April 2003, available online at [<http://www.aphl.org/docs/newsletter/ACF4BA8.pdf>].

<sup>59</sup>See, for example, Stephen Smith, "Anthrax vs. The Flu," *The Boston Globe*, July 29, 2003.

<sup>60</sup>Michael Lasalandra, *op cit*.

## Future Directions of the BioWatch Program

Several aspects of the BioWatch Program are undergoing further development. As stated above, the initial implementation of the system expanded to a reported 31 cities,<sup>61</sup> with potentially more areas under surveillance in FY2004.<sup>62</sup> This expansion may lead to efficiencies, and the alleviation of some current concerns, as experience is gained and problems are solved.

The Department of Homeland Security, through the Science and Technology Directorate, is also requesting proposals for next-generation detection systems for biological countermeasures. The Homeland Security Advanced Research Projects Agency issued Research Announcement 03-01 which requests submissions for systems able to continuously monitor urban areas for biological agents as well as new indoor monitoring systems.<sup>63</sup>

Additional work is being performed at Department of Energy National Laboratories to complete commercialization of an automated pathogen detection and analysis capability. This project, called the Autonomous Pathogen Detection System, would result in a completely automated system.<sup>64</sup> The developers expect to have the ability to measure up to 100 different agents and controls per sample, with low false positive and false negative rates and a relatively low cost per assay.<sup>65</sup>

Research and development efforts on other detection systems continue. For example, the Department of Defense Chemical and Biological Defense Program continues to develop and deploy technologies for instantaneous detection of biological and chemical weapons.<sup>66</sup> Other prospective technologies include the SensorNet program, which reportedly is developing a capability to detect chemical, biological, and radiological dispersion,<sup>67</sup> the Urban Atmospheric Observatory,<sup>68</sup>

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<sup>61</sup>David B. Caruso, *op cit*.

<sup>62</sup>Comments made in "Meeting Minutes," Centers for Disease Control and Prevention Information Council, February 27, 2003, found online at [<http://www.cdc.gov/cic/minutes/CIC%20minutes%202-27-03.pdf>].

<sup>63</sup>Homeland Security Advanced Research Projects Agency, *Detection Systems for Biological and Chemical Countermeasures; (RA 03-01)*, Department of Homeland Security, September 23, 2003.

<sup>64</sup>For more information on the Autonomous Pathogen Detection System, see online at [<http://www-pat.llnl.gov/Organization/MDivision/Research/apds.html>].

<sup>65</sup>As reported by the company providing the fluidics engine for the Autonomous Pathogen Detection System, Global FIA, located online at [<http://www.globalfia.com/whatsnew/apds.html>].

<sup>66</sup>For an overview of the range of equipment being developed and deployed by the Department of Defense Chemical and Biological Defense Program, see the Department of Defense Chemical and Biological Defense Program, *Volume 1: Annual Report to Congress*, Annex A, 2003.

<sup>67</sup>Allyson Vaughan, "Making Sense Of Homeland Security," *Wireless Week*, July 8, 2002.

which aims to determine the atmospheric patterns in an urban environment, and DCNet, a program to map wind currents in the Washington, DC area.<sup>69</sup> Such research may eventually develop the next generation of biological detection equipment and could provide valuable raw data for analysis of results arising from the current BioWatch monitors. A better understanding of urban air flow may provide for a more exact determination of areas affected by an aerosol release.<sup>70</sup>

## Policy Concerns

Many aspects of the BioWatch Program raise policy questions Congress may consider in the coming months. One question addressed may be whether this program is an appropriate federal response to the threat of bioterrorism, both in scale and scope. If it is deemed to be, Congress may be interested in how detection systems, such as BioWatch and other prototype systems, are being used by the Department of Homeland Security to increase national security. The BioWatch Program was deployed rapidly, with little publicity, but lessons learned during this process may be applicable to other detection systems that the federal government develops. Congress may also wish to consider how the performance of this system is measured and determine whether the funding level that the BioWatch Program receives is appropriate for its performance or effectiveness. Future development of more advanced monitoring systems and further refinement of the BioWatch monitors may also be areas of Congressional interest. Another issue is how results from the BioWatch monitors are integrated into state and federal response plans, especially since BioWatch is a locally operated, federally funded program.

## Significant Role of Detection Systems in DHS Strategy

Distributed detection networks appear to play a significant role in the Department of Homeland Security's strategy for protecting the United States. The Department of Homeland Security's Directorate of Science and Technology is establishing a Biological Warning and Incident Characterization (BWIC) system. BWIC consists in part of environmental monitoring networks in selected cities with direct agent detection and a nationwide biosurveillance system looking for indicators of biological agent exposure in people, animals and plants. The DHS Under

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<sup>67</sup>(...continued)

For more information, see Oak Ridge National Laboratory, "CBRN Detection & Defense—SensorNet Fact Sheet," located online at [<http://www.ornl.gov/~webworks/security/SensorNet.pdf>].

<sup>68</sup>Brian Kates, "Tough Job to Sniff Out Terror," *New York Daily News*, July 6, 2003, p. 16. More information on the Urban Atmospheric Observatory is found online at [<http://www.uao.bnl.gov/>].

<sup>69</sup>See also Written Testimony of Bruce B. Hicks, Director, Air Resources Laboratory, National Oceanic and Atmospheric Administration, Department of Commerce, before the Subcommittee on National Security, Emerging Threat, and International Relations, Committee on Government Reform, U.S. House of Representatives, June 2, 2003.

<sup>70</sup>Spencer S. Hsu, "Sensors May Track Terror's Fallout," *The Washington Post*, June 2, 2003, p. A1.

Secretary for Science and Technology McQueary testified that the BWIC system will be available as a pilot in FY2004.<sup>71</sup> The DHS also received FY2004 funds for programs to develop and demonstrate advanced technologies, including sensors, to detect radiation using systems distributed over a geographic area.

In the further development of such national-level detection systems, what features might potentially be addressed, and the priorities assigned to them, is open to debate. One priority setting decision might be the extent to which the BioWatch system is further deployed. This decision may prompt additional policy questions. Will further installation of these systems occur only in metropolitan areas, or will smaller urban, suburban, and/or rural areas also be eventually included under BioWatch coverage? Should more monitors be installed in cities currently under BioWatch, so as to increase the likelihood of detecting a small release? Should monitors be installed inside buildings or public transportation, where people may be concentrated? Some experts have criticized the BioWatch program for being primarily designed to detect large releases while not detecting the potentially more likely small releases.<sup>72</sup> Others point out that during the Salt Lake City Olympics BASIS was successfully installed in sporting venues and transport hubs where small releases might be detected.<sup>73</sup> On the other hand, deploying multiple sensor units within a particular area may lead to significant overlap between sensors, providing diminishing returns per monitor. A complicating factor is the cost of expanding the BioWatch Program and the increased likelihood of false positives. Since biological terrorism is often considered to be a low probability/high consequence event, the risk of an event occurring is balanced against the costs of maintaining the detection infrastructure necessary to detect the event. Unlike previous investments in public health preparedness, the BioWatch Program may not have dual-use application, being predominantly applicable only as an anti-bioterrorism program. Congress may choose to fund other programs which have greater dual-use application to gain benefit from such funds if no bioterror event occurs.

Another area of potential interest to Congress may be the method DHS used to prioritize development and deployment of national monitoring systems. Other federal agencies have programs to develop biodetectors and monitoring systems. These systems use a variety of techniques to detect aerosolized pathogens, but have often contained undesirably high false positive rates or low sensitivity. For example, the Department of Defense is developing a “stand-off” detection system for some uses rather than a point detection system, as is employed by DHS in the BioWatch Program.<sup>74</sup> In military settings, the ability to determine whether a threat is posed by

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<sup>71</sup>Statement of Under Secretary Charles McQueary, Department of Homeland Security, before the U.S. Senate Committee on Appropriations, Homeland Security Subcommittee, April 10, 2003.

<sup>72</sup>David B. Caruso, *op cit*.

<sup>73</sup>“BioWatch Program Aims For Nationwide Detection of Airborne Pathogens,” *CIDRAP News*, February 26, 2003, revised March 10, 2003.

<sup>74</sup>One example of stand-off detection equipment being developed by the Department of Defense is the Joint Biological Standoff Detection System (JBSDS). For an overview of the  
(continued...)

an aerosol cloud at a distance, allows combat troops to don appropriate gear and equipment. Also, the Department of Defense focuses on detection systems with real-time detection,<sup>75</sup> attempting to develop a “detect-to-warn” rather than a “detect-to-treat” capability. These systems provide higher false positive rates than that reported for BASIS. Because of the ready availability of protective equipment, including masks and suits, and the high training provided to troops regarding this equipment’s use, false positives requiring the donning of protective gear are more acceptable than in a civilian setting. Further research into such technologies and assessment of the potential performance of these military detector systems when placed in a civilian environment may be areas for future study. Congress may also wish to consider how DHS plans to assess the effectiveness and performance of the BioWatch Program. Since evaluations for homeland security are still being developed, judging the success of the BioWatch system may prove challenging in the short term.

## Deployment of Other DHS Programs

Another issue is whether the deployment of the BioWatch program, using federal government technologies, government contractors, and providing little official information with regards to capabilities and locations, is an appropriate approach to homeland security vulnerabilities. While the deployment of BioWatch as a federal program may have increased the speed of implementation and thus enhanced homeland security, a question remains as to whether a more effective, efficient, or inexpensive system might be developed or deployed if greater public and commercial input were involved. Other homeland security projects, such as radiation detectors, were developed and commercialized by engaging competitive market forces through requests for proposals.<sup>76</sup>

## Evaluating Effectiveness

Frequently expressed concerns about the BioWatch Program are its lack of ability to detect smaller outdoor releases, its potential for false positives, and its capabilities in an urban environment. One way to address these concerns is by disseminating information about performance characteristics of the BioWatch Program. This type of information is available for other military systems, especially chemical detectors. For example, the Department of Defense released the detection

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<sup>74</sup>(...continued)

Department of Defense chemical and biological detection capability, see Department of Defense Chemical and Biological Defense Program, *Volume 1: Annual Report to Congress*, 2003.

<sup>75</sup>For more information about such detection systems, see National Research Council, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response*, (Washington DC; National Academy Press) 1999.

<sup>76</sup>For example, the Technical Support Working Group holds Broad Agency Announcements to develop technologies important to members. For more information on the Technical Support Working Group, see [<http://www.tswg.gov/>].

levels for some chemical detection equipment,<sup>77</sup> and some performance characteristics, such as false positive rates, are provided for BASIS.<sup>78</sup> Even if these metrics were not publicly disseminated, providing concrete information at the state and local level might enhance the BioWatch effectiveness. Advantages from early detection depend on a timely response to a biological release. If state and local officials lack confidence in the monitor performance, consequence management may be delayed, leading to greater casualties.<sup>79</sup> Alternatively if officials overestimate the monitor capability, consequence management activities may be engaged even when there is no need, consuming valuable resources and generating unnecessary public anxiety. In the case of the BioWatch detection of airborne tularemia in Houston, the distribution of countermeasures was not begun, pending the collection of additional information. One option would be to further refine the decision-making process invoked upon a positive finding to more optimally achieve the goals of rapid response to a bioterror event.

Determining the effectiveness of the BioWatch Program in achieving its public health goal, to minimize casualties by detecting exposures more rapidly than would otherwise have occurred, will be difficult in any circumstances. Assessments of public health effectiveness are typically considered in the context of opportunity cost; are allocations of funds and person-hours worthwhile, or might they be better used elsewhere? BioWatch, designed to detect low-probability/high-consequence events, is unlike public health surveillance programs, which track conditions expected to occur in the population. CDC publishes an evaluation protocol for surveillance systems, “to promote the best use of public health resources through the development of efficient and effective public health surveillance systems.”<sup>80</sup> Information about a number of the performance characteristics typically described for surveillance systems – including flexibility, data quality, and representativeness – is not available to the public for the BioWatch Program. A senior CDC official stated that BioWatch is in the “proof of concept” phase, a relatively early stage of technology development, and notes that CDC is, “trying to build systems to assure that once we have true positives, we can mobilize a response rapidly, but also develop a system for false positives which we feel could be a potential problem in the future.”<sup>81</sup> Efforts to

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<sup>77</sup>See, for example, Chemical Casualty Care Division, U.S. Army Medical Research Institute of Chemical Defense, *Medical Management of Chemical Casualties Handbook*, 3<sup>rd</sup> Edition, July 2000, or National Research Council, *Strategies to Protect the Health of Deployed U.S. Forces; Detecting, Characterizing, and Documenting Exposures*, (Washington, DC: National Academy Press) 2000.

<sup>78</sup>Vin LoPresti, *op cit*.

<sup>79</sup>Lawrence Wein, a mathematician at Stanford University, reportedly stated that for every day’s delay before responding to a 1 kg anthrax release 10,000 additional people would die. Amanda Onion, “Calculating the Unthinkable,” *ABCNews.com*, March 18, 2003.

<sup>80</sup>Centers for Disease Control and Prevention, “Updated Guidelines for Evaluating Public Health Surveillance Systems,” *Morbidity and Mortality Weekly Report*, Vol. 50 (RR13), July 27, 2001.

<sup>81</sup>Testimony of Joseph Henderson, Associate Director for Terrorism Preparedness and Response, CDC, before the House Select Committee on Homeland Security, Emergency (continued...)

explain the system to those needing to know, and to coordinate the activities of multiple agencies at the federal, state and local levels, are ongoing.<sup>82</sup>

The BioWatch Program draws upon the expertise of three federal agencies, the Department of Homeland Security, the Department of Health and Human Services (through the CDC), and the Environmental Protection Agency. Which agency is best suited to provide oversight and evaluation of the BioWatch program is an unresolved question. DHS funds and currently oversees the program, but some may argue that the BioWatch Program is inherently a public health program. In this case, the Department of Health and Human Services, potentially through the CDC, would be best equipped to assess the effectiveness of the program. The CDC has experience in federal/state relations regarding public health and in the evaluation of public health surveillance systems. Also, the CDC may be best qualified to judge the validity of response and consequence management plans following a BioWatch positive. Advocates for such a view might point to the retention of bioterrorism-related civilian countermeasure research and development by HHS, in the Homeland Security Act (P.L. 107-296), as indicative of the expertise retained within that Department. Others may assert that the BioWatch Program is a homeland security program, in which case DHS is the logical choice for sole oversight and assessment of this program. Since the technologies involved during BioWatch development originated with elements of DHS, that agency may be uniquely qualified to assess the state of development and deployment of the system.

Because this program cuts across the expertise of different federal agencies, oversight and evaluation of the BioWatch Program will likely include the federal agencies involved. The precedent set in the Homeland Security Act (P.L. 107-296), where a collaborative approach between the Secretary of Health and Human Services and the Secretary of Homeland Security is required with respect to civilian human health-related research and development activities relating to countermeasures for chemical, biological, radiological, and nuclear and other emerging terrorist threats,<sup>83</sup> may be a model for assessment of the BioWatch Program. Determining the relative authorities of the participating agencies may be an area of Congressional interest.

The Homeland Security Act (P.L. 107-296) also established a Homeland Security Institute. The Act allows this institute, following a determination by the Secretary of Homeland Security, to take on the duties of “evaluation of the effectiveness of measures deployed to enhance the security of institutions, facilities, and infrastructure that may be terrorist targets,” “assistance for Federal agencies and departments in establishing testbeds to evaluate the effectiveness of technologies under development and to assess the appropriateness of such technologies for deployment,” and “design of metrics and use of those metrics to evaluate the

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<sup>81</sup>(...continued)

Preparedness and Response Subcommittee, on September 24, 2003.

<sup>82</sup>Center for Infectious Disease Research and Policy, “CIDRAP Completes Planning Meetings for BioWatch Program,” undated, available online at [<http://www.cidrap.umn.edu/cidrap/center/mission/articles/bwatch.html>].

<sup>83</sup>“Homeland Security Act of 2002,” P.L. 107-296, Sec. 304(a).

effectiveness of homeland security programs throughout the Federal Government, including all national laboratories.”<sup>84</sup> Some may advocate that such an institute would provide the necessary mixture of federal, private, and public opinions to fully evaluate the different components of the BioWatch Program.

## Funding for the BioWatch Program

The degree to which DHS should focus its spending on such a program is an area of potential Congressional interest. The DHS reportedly spent approximately \$40 million in FY2003 on the BioWatch program.<sup>85</sup> FY2003 funding for the BioWatch Program was reprogrammed from part of the \$420 million transferred from the Department of Defense to DHS with the National Bio-Weapons Defense Analysis Center.<sup>86</sup> The \$40 million for the BioWatch Program represented 12% of the \$340 million dedicated to Biological Countermeasures in FY2003. For FY2004, the request for the Biological Countermeasures program was \$364 million. Congress provided \$199 million, in addition to \$68 million in unexpended FY2003 funds, for a total of \$267 million, and increased the amount dedicated to BioWatch. The conference report accompanying Appropriations for the Department of Homeland Security (P.L. 108-90), in the section on Biological Countermeasures, states “an additional \$15,000,000 is provided for the urban monitoring program.”<sup>87</sup> According to the White House, a total of \$38 million, or 14% of the Biological Countermeasures budget, will be spent on the BioWatch Program.<sup>88</sup> Whether this focus should continue, the funding levels for the BioWatch Program, and how high a priority this specific detection system should be for DHS are areas where Congress may exercise its oversight role.

## Future BioWatch Development Priorities

Several of the technological aspects of the BioWatch Program are areas where gains may be achieved. Areas where successful upgrades of technology might have significant benefits include reducing the cost of each BioWatch monitor, both in initial capital outlay and in daily operational cost, further development of detection methods for more pathogens, or for genetically modified pathogens, and increasing the automation of the BioWatch technologies. Improving the current technology might allow coverage of more people and/or detection of more pathogens for the current cost. Additionally, research into alternate sensor technologies, such as

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<sup>84</sup>“Homeland Security Act of 2002,” P.L. 107-296, Sec. 312 (c) (3), “Homeland Security Act of 2002,” P.L. 107-296, Sec. 312 (c) (5), and “Homeland Security Act of 2002,” P.L. 107-296, Sec. 312 (c) (6) respectively.

<sup>85</sup>Dina Cappiello, “‘BioWatch’ to Sound Alarm; Monitors Screen Air Quality for Bacteria Attack,” *Houston Chronicle*, July 29, 2003, p. A11.

<sup>86</sup>Personal Communication, Dr. Parney Albright, Assistant Secretary, Plans, Programs and Budgets, Department of Homeland Security, September 16, 2003.

<sup>87</sup>Conference Report 108-280, p. 56.

<sup>88</sup>Executive Office of the President, The White House, “FY2004 Budget Fact Sheet,” October 1, 2003, found online at [http://www.whitehouse.gov/news/releases/2003/10/20031001-7.html].

biological assays, laser fluorescence, and other more novel techniques, and topics such as more efficient collection and analysis tools are currently funded by the federal government. Inclusion of such advances into BioWatch or other detectors may be worth consideration.

## Coordinating Bioterrorism Testing

The BioWatch Program and the Laboratory Response Network (LRN) share common goals in providing laboratory support for detecting a bioterrorism event, and both are deployed in state and local public health laboratories, but important differences may hamper their effective coordination. The BioWatch Program was developed by the Department of Energy and EPA and was delivered to state and local public health laboratories in a near-final state in early 2003.<sup>89</sup> It is managed and funded at the federal level by the Department of Homeland Security, with state and local public health agencies responsible for on-the-ground management of laboratory activities and response to positive findings. The LRN, in contrast, was developed by the CDC, FBI, and state and local health agencies, with the first set of test methods developed prior to the anthrax mailings of 2001. The LRN is managed and funded at the federal level by the Department of Health and Human Services through CDC, and, in a fashion similar to the BioWatch Program, state and local public health agencies are responsible for on-the-ground management of network assets and response to positive findings.<sup>90</sup> The LRN has the benefit of a longer history as a civilian public health program, during which time policies, procedures and protocols have matured.

The BioWatch program shares some operational similarities with the LRN, but there may be areas in which simultaneous operation of the two systems might prove difficult. Both systems would likely be in significant use during a bioterrorism event, and handling large influxes of both BioWatch and environmental samples might cause competition for limited resources. Conflict might arise in areas including prioritizing samples for testing (triage), referral testing and data management.<sup>91</sup> On the other hand, close involvement of BioWatch operation and testing with the public health community may prove to be of benefit in the case of an actual attack. In a fact

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<sup>89</sup> Judith Miller, "U.S. Deploying Monitor System For Germ Peril," *The New York Times*, January 22, 2003, p. A1.

<sup>90</sup>For an example of a state's use of established LRN assets for its own detection and response activities, see Leslie Tengelson, *et al.*, "Coordinated Response to Reports of Possible Anthrax Contamination, Idaho, 2001," *Emerging Infectious Diseases*, Vol. 8, No. 10, October 2002. See also Julie L. Gerberding, Director, CDC testimony before the House Appropriations Committee, Subcommittee on Labor, Health and Human Services, and Education, April 9, 2003, for a recent discussion of CDC's role in maintaining the Network and its assets.

<sup>91</sup>See James A. Higgins, *et al.*, "A Field Investigation of *Bacillus anthracis* Contamination of U.S. Department of Agriculture and Other Washington, D.C. Buildings During the Anthrax Attack of October 2001," *Applied and Environmental Microbiology*, Vol. 69, No. 1, January 2003. During the anthrax mailings of 2001, the testing backlog from the limited resources of the LRN forced laboratory workers from the Department of Agriculture to extend their testing work beyond USDA-owned buildings.

sheet released at the signing of the FY2004 Homeland Security appropriations bill (P.L. 108-90), the White House noted that the BioWatch program and the LRN are both early-detection programs for bioterrorism, and that federal partners, “are working with state and local officials to implement an effective consequence management plan that incorporates the BioWatch system.”<sup>92</sup>

## Clarifying Roles and Responsibilities

The BioWatch Program is a federal program, while first responders and some immediate decision makers are state and local officials. Since the results are generated from federal equipment operated by federally funded workers in a state or local public health laboratory, which entity bears ultimate responsibility for the functioning of the system? What is the chain of authority for BioWatch results? While it has been reported that states are developing response plans in the case of BioWatch positives,<sup>93</sup> the degree of coordination between federal and state officials, and the mechanisms of federal assistance to states in such an event, appear unclear at this point. The response plans developed on a state and local level may have significant differences in approach, depending on the particular resources available, leading to inconsistent responses to BioWatch positives. Coordination between adjacent states, and especially coordination with federal authorities in a potential multi-state event, is crucial to limiting the public health impact. A variety of considerations, including means to provide security clearances to essential state and local personnel so they are fully involved in planning and response activities, remain to be clarified.<sup>94</sup> The Department of Homeland Security is developing an updated national response plan which will define the roles the various federal agencies will play in a national emergency.<sup>95</sup> Areas of potential Congressional interest include the specificity of federal guidance to states with respect to results from the BioWatch program, the coordination and cooperation between federal and state resources following a BioWatch positive, and the incorporation of BioWatch results into this national response plan’s implementation.

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<sup>92</sup>Executive Office of the President, The White House, “FY2004 Budget Fact Sheet,” October 1, 2003, found online at [<http://www.whitehouse.gov/news/releases/2003/10/20031001-7.html>].

<sup>93</sup>“BioWatch Program Aims For Nationwide Detection of Airborne Pathogens,” *CIDRAP News*, February 26, 2003, revised March 10, 2003.

<sup>94</sup>Michael Janofsky, “Intelligence to Be Shared, Ridge Tells Governors,” *New York Times*, August 9, 2003, p. A19.

<sup>95</sup>This responsibility was conferred onto the Department of Homeland Security by the Homeland Security Act of 2002 (P.L. 107-296) in Title V, Section 502.

## Conclusion

With early detection and treatment of those exposed to biological weapons, illness and subsequent fatalities may be minimized, and the presence of BioWatch in urban areas may serve as an effective deterrent to potential bioterrorists. Some have questioned the effectiveness of such a system. With a limited number of monitors within a metropolitan area, these critics question whether potentially more likely smaller-scale events are detected. Others question whether such a system will provide dependable results upon which sound decisions are made.

Since much information on BioWatch has not been released to the public, it is difficult to evaluate criticisms of the system. Many of the technical issues raised may have been or are being addressed by the Department of Homeland Security. Agreements on coordination between state and federal authorities may be developed but not released. Congress, in overseeing the use of limited homeland security resources, may wish to further assess and oversee the impacts of BioWatch and its further development.

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