

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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July 10, 2012

Dr. Michael Walter  
BioWatch Program Manager  
Office of Health Affairs  
U.S. Department of Homeland Security  
245 Murray Lane, S.W.  
Washington, D.C. 20528

Dear Dr. Walter:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, June 18, 2013, to testify at the hearing entitled "Continuing Concerns Over BioWatch and the Surveillance of Bioterrorism."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on July 24, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at [brittany.havens@mail.house.gov](mailto:brittany.havens@mail.house.gov) and mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

## Attachment 1—Additional Questions for the Record

### The Honorable Tim Murphy

1. The Department of Homeland Security has asked the National Academies of Science to organize workshops to develop locally-owned jurisdictional response plans for response to BioWatch Actionable Results. Is that an indication that local authorities do not have sufficient guidance for handling a BAR?
  - a. Why has DHS allowed this lack of guidance to occur for so many years?
2. Is there any discussion inside the Department of Homeland Security to redefine what constitutes a BAR?
3. The National Academies of Science, in its 2011 report on BioWatch, wrote: “From the wider perspective of public health authorities responsible for determining whether a confirmed positive laboratory test (a BAR) represents a plausible indication of a bioterrorist attack meriting initiation of mass dispensing of prophylaxis, the committee concluded that all BARs to date have been ‘BAR false positives,’ meaning they have signaled the potential occurrence of a terrorist attack when none has occurred.” Do you agree with this statement?
4. Even though Dr. Garza said there had never been a false positive, does BioWatch really want to detect near-neighbors or background organisms?
  - a. Even if the BioWatch detection of near-neighbors are true-positives, aren't the Department of Homeland Security and the Centers for Disease Control and Prevention working to minimize the number of BARs for near-neighbors?
5. What was the total cost of Generation-2.5?
6. How much money has been spent on testing and evaluation of the Gen-3 system to date?
  - a. How much money has been spent on R&D by both the Department of Homeland Security's Science and Technology Directorate and the Office of Health Affairs on the testing and evaluation of Gen-3?
  - b. Is the Department of Homeland Security still spending money on Gen-3? If so, how much?
  - c. How much will it cost for workshops and the study to be conducted by the National Academies of Science on Gen-3?

7. Before making a certification on the science of Gen-3, will the Secretary of DHS rely on information from the study and report by the National Academies of Science that is to be conducted over the next year?
8. How can an Analysis of Alternatives be done by this fall that includes a cost-benefit comparison between Generation 2 and Generation 3, when the Department of Homeland Security will not have Generation 2 data from Dugway Proving Ground until fall of this year?
9. Under the current plan for Gen-3, what is the concept of operations for confirming that a sample is actually a bio-threat once there is a BAR?
10. Does the Department of Homeland Security recommend the Public Safety Actionable Assay (PSSA) for Gen-3?
  - a. During his interview with Committee staff, a prior BioWatch program manager, Dr. Jeffrey Stiefel, said that he unequivocally supported the PHAA standard for Gen-3. He took the same position publicly when he was BioWatch program manager in 2005 in a lecture before the NIH. Why don't you agree with Dr. Steifel?
  - b. Why won't the Department of Homeland Security accept the Public Health Actionable Assay (PHAA) for Gen-3?
  - c. If the National Academies study recommends the PHAA standard, would that standard be too rigorous for Gen-3 to meet the requirements for certification by the Secretary?
  - d. Which testing standard would give the public health community and the public the most confidence in Gen-3?
  - e. Do you believe that with a PSAA standard, you would need to have confirmatory testing?
11. What are the drawbacks for having a largely outdoor detection system?
  - a. What are the drawbacks for having a largely indoor detections system?
  - b. What are the advantages for an indoor detection system?
  - c. Are you aware that Dr. Stiefel favors only deploying Gen-3 indoors? Do you agree with this?

## **Attachment 2—Member Requests for the Record**

*During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information based on the relevant excerpts from the hearing transcript regarding these requests are provided below.*

### **The Honorable Tim Murphy**

1. Has DHS produced a strategic implementation plan in response to the President's directive last July when he released the National Strategy for Biosurveillance?
  - a. If so, what are the projected costs of this plan?

### **The Honorable Steve Scalise**

1. How much money has been spent on BioWatch?

### **The Honorable Gus Bilirakis**

1. Once the analysis of alternatives report comes out, please give us an update on any efforts to measure the cost-effectiveness of the BioWatch program.