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ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
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July 10, 2012

Dr. Toby Merlin
Director
Division of Preparedness and Emerging Infections
Centers for Disease Control and Prevention
395 E Street, S.W.
Washington, D.C. 20024

Dear Dr. Merlin:

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.

To facilitate the printing of the hearing record, please respond to these questions 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 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

Attachment

Attachment—Additional Questions for the Record

The Honorable Tim Murphy

1. Do you agree that expanding BioWatch with Gen-3 would increase the financial strain of state and local health departments?
 - a. Do you agree that an additional financial strain could negatively impact the capability of these state and local departments to respond to an actual bioterrorism event?
2. Given the reductions in the capacity of the state and local health departments to respond, do you think the country is worse off in this regard than we were five years ago in preparing against bioterrorism?
3. Do you know what the sensitivity is for the current BioWatch technology?
4. Do you agree with the Department of Homeland Security's Assistant Secretary Alexander Garza that BioWatch has never had a false positive result?
5. When BioWatch has a BioWatch Actionable Result (BAR) and that BAR is not a detection of the threat agent but a detection of a near-neighbor bacteria that exists naturally in the environment, is the adjudication of a BAR a drain or burden on federal, state, and local authorities?
6. Isn't it true that there were some problems with the APDS (autonomous pathogen detection system) deployment regarding environment cross reactivity?
 - a. What were some of the problems with the "previous experience with environmental cross reactivity and the problematic APDS [Gen-2.5] deployment?"
7. 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?
 - a. And when a BAR is caused because the tests have detected near-neighbors or background organisms, rather than the targeted bioterrorism agent, in your professional judgment, is that a false-positive?
8. If BioWatch had been in place in 2001, would BioWatch have detected the anthrax letter attacks?
9. How important is it to have a complete assay validation before deployment of Gen-3?

- a. Is there a completely validated Gen-2 assay?
10. What are some of the perceived limitations of the current Gen-2 system?
 - a. What would be some improvements?
11. With respect to the Gen-3 autonomous “robot” system, do you believe that the public health labs will have confidence to take action on one test result from a Department of Homeland Security robot that does not use LRN assays?
12. What is the difference between the Public Safety Actionable Assay (PSAA) standard and the Public Health Actionable Assay (PHAA) testing standard?
 - a. Which testing standard would you support?
 - b. Why is the testing standard important?
13. Why is it important to detect these agents as early as possible before citizens begin to develop symptoms?
 - a. Is it true that PHAA would give public health officials more information to base decisions for proscribing clinical remedies (e.g. vaccinations) in the event there was an attack?
14. In the event of a BAR, what additional information will the Centers for Disease Control and Prevention look for before taking public health actions with the distribution and dispensing of medical counter-measures?