

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Review of CDC Anthrax Lab Incident

July 16, 2014

Centers for Disease Control and Prevention (CDC) Responses to Questions for the Record

The Honorable Billy Long

Are there any research programs at the CDC that require mandatory vaccination? If so, which are they and why are those vaccinations mandatory while the anthrax vaccination is voluntary?

Although CDC has a longstanding practice of strongly recommending vaccinations for employees at all CDC laboratories that work with agents for which there are Food and Drug Administration (FDA)-licensed vaccines, vaccination has not been mandatory. However, as part of the broad review of lab safety at CDC, CDC is reviewing issues related to vaccination of employees that work in laboratories with agents that cause vaccine-preventable diseases.

The Honorable Phil Gingrey

What is the impact and cost estimate with regard to the BRRAT laboratories being shut down throughout this moratorium period?

Closure of CDC's Bioterrorism Rapid Response and Advanced Technology (BRRAT) laboratory impacts numerous U.S. and state government activities, because the BRRAT laboratory is critical to the operation of the Laboratory Response Network (LRN). The LRN is a nationwide network of approximately 150 laboratories that uses highly sophisticated tests to examine clinical and environmental samples for the presence of biological threat agents. The BRRAT laboratory develops tests and assures the performance of testing materials that are routinely used in the LRN. The BRRAT laboratory also provides technical and public health support to the U.S. jurisdictions participating in the Department of Homeland Security's BioWatch Program, which utilizes LRN assays for verification of positive tests, and provides 24/7 technical support to the LRN laboratories and Federal Agencies that are engaged in analyzing potential threat materials.

As long as the closure of the BRRAT laboratory is short-term, it will not degrade the Nation's ability to respond to a bioterrorism event. Although the physical laboratory space is closed, the BRRAT laboratory scientific staff continues to monitor and respond to technical questions related to potential bioterrorism activities around the clock, and the LRN is still able to detect and respond to potential threats. In the next three to six months, the laboratory will be needed for the production, development, quality assurance, and distribution of assays and reagents for the LRN to use for testing and analysis. Actions are underway to enable reopening of the BRRAT laboratory.

We expect that the moratorium's impact on the BRRAT laboratory will be budget neutral. A majority of the laboratory's costs are fixed (*e.g.*, personnel, equipment, equipment maintenance agreements, facilities). While activities conducted in the sections of the BRRAT laboratory that were impacted by the moratorium are on hold, a majority of these activities will be completed in the future on a more accelerated timeline.

The Honorable Gregg Harper

In the September 2012 letter that you sent to the committee responding to concerns about CDC lab safety, you stated that a senior official was designated to report directly to you about safety issues. Who was that senior official?

CDC designated Mr. Joe Henderson to provide reports directly to the CDC director regarding concerns and complaints related to safety at CDC's laboratories. Assigning Mr. Henderson this role was one of the key steps that CDC implemented in 2012 to address biosafety and biosecurity concerns raised by an incident in our Emerging Infectious Diseases Laboratory at Roybal Campus earlier that year. Mr. Henderson was also responsible for coordinating CDC's internal investigation of incidents at certain high-containment laboratories in Building 18 that were of particular concern at the time.

It should be noted that Mr. Henderson is the Director of CDC's Office of Safety, Security, and Asset Management (OSSAM) and reports to CDC's Chief Operating Officer. OSSAM consolidates multiple business services offices that are involved with CDC's laboratory safety improvement efforts. OSSAM's services include several thematic areas that are directly relevant to these efforts: protection and safety of the CDC population, physical and personal security of CDC staff and contractors, operations and maintenance of CDC owned and leased property, health and wellness within the CDC community, transportation, and commitment to continuous quality improvement and sustainability.

Mr. Henderson also serves as Vice Chair of CDC's internal Laboratory Safety Improvement Workgroup (LSIW), newly formed as part of the more robust changes being made now to heighten lab safety and security. He and Dr. Michael Bell, Chair of LSIW and Interim Director of Laboratory Safety, both have leadership roles in LSIW to ensure that their distinct work areas (business operations and science) in addressing laboratory safety are well-coordinated. In addition, their reporting structure, in which Dr. Bell reports to the CDC Director and Mr. Henderson reports to the Chief Operating Officer on all matters (including lab safety), allows for checks and balances in CDC's laboratory safety improvement oversight.

What were the results of that action?

In this role, Mr. Henderson completed a comprehensive review of the incidents and adequacy of corrective measures taken to address them. He and laboratory program leadership also took additional steps to improve laboratory safety overall, including consolidating sources of safety and other information for laboratory staff.

The Honorable Bill Johnson

Do you use the National Science Advisory Board for Biosecurity for any sort of consultation?

The National Science Advisory Board for Biosecurity (NSABB) provides advice, guidance, and leadership regarding biosecurity oversight of dual use research of concern to all Federal Departments and Agencies with an interest in life sciences research. CDC, along with other Government Agencies, has an ex officio, non-voting member on the NSABB. To effectively respond to biosecurity concerns within the Agency, CDC formed an internal Institutional Biosecurity Board, which—as one of its primary functions—interfaces with NSABB and also ensures our Agency implements NSABB guidance.

The Honorable Billy Long

How many CDC laboratory workers received the FDA licensed anthrax vaccine prior to the anthrax incident last month as recommended by the CDC, its Advisory Committee on Immunization Practices for lab workers since 2002?

It is important to note that the FDA-licensed anthrax vaccine requires an annual booster to maintain immunity; therefore, going back 12 months prior to the date of discovery of the recent anthrax event gives a snapshot of the current anthrax vaccination status of CDC staff. Going back further than 12 months would not yield accurate numbers about the present, because staff who previously received the vaccine, but skipped the annual booster, would not be considered current.

For the 12-month period prior to the date of the recent anthrax event, 22 CDC staff were immunized against anthrax and are considered current, 4 staff had received at least three doses (after the third dose, immunity is considered adequate but not durable), and two staff are in the process of receiving anthrax immunizations.