

ONE HUNDRED TWELFTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

November 13, 2012

Dr. Thomas Frieden  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30333

Dear Dr. Frieden:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is investigating the BioWatch program, the nation's first early detection and warning capability for biological attacks, and its impact on the nation's public health system.

On July 19, 2012, we wrote to you requesting information and documents to determine how the BioWatch program is performing and whether it is meeting public protection goals. We expressed particular interest in a news report indicating that officials at the Centers for Disease Control and Prevention (CDC) told White House aides at a meeting on November 21, 2011, that they would not rush medications to the site of an attack detected by BioWatch unless a BioWatch warning was confirmed by follow-up sampling and analysis. To date, CDC has provided insufficient responses to our July 19, 2012, inquiry. Moreover, in the intervening time additional details have come to light regarding program failures.

The Los Angeles Times reported on October 23, 2012, that the BioWatch system operated with defective components that left it unable to detect deadly pathogens for a two-year period, according to scientists with direct knowledge on the matter. The article raises further questions about the BioWatch program, in addition to the ones raised in our July 19, 2012, letter.

To assist the Committee in its examination of these additional issues, please provide the following by November 26, 2012:

1. All documents relating to the tests conducted by CDC that found multiplex assays unsuitable for BioWatch.
2. All documents dated since January 1, 2009, in the possession of Dr. Toby Merlin and/or Dr. Stephen Morse relating to BioWatch.

In addition to the above requested information, we seek your cooperation in responding to the July 19, 2012, request letter. The response from CDC to date has been inadequate, highlighting, at minimum, a lack of coordination and communication among agencies, and making clear that CDC or Department of Health and Human Services (HHS) is withholding responsive documents.

In the more than three months since our initial request, CDC has produced only two pages of test results. CDC staff advised Committee staff that documents have been submitted to the Department of Health and Human Services for clearance. However, HHS told Committee staff there are no documents from CDC in clearance, and that CDC advised them there are no responsive documents. CDC persisted in telling Committee staff that there are documents in clearance even after being advised that HHS denied that was the case. CDC has also claimed for weeks that a letter response is also in the clearance process at HHS.

On October 11, 2012, CDC provided a phone briefing for Committee staff with Dr. Toby Merlin. Dr. Merlin spent considerable time briefing Committee staff in cooperation with our efforts. In the course of that briefing, Dr. Merlin provided information demonstrating that CDC is in possession of responsive documents that have not been provided to the Committee. For example, Dr. Merlin acknowledged problems with the BioWatch assays cross-reacting with benign organisms in the environment, so-called near neighbors to the pathogen of concern, especially in the context of the *Francisella tularensis* test results. In response to a question from Committee staff, Dr. Merlin said he would call such a test result detecting a near neighbor a "false positive." This statement was responsive to request number 4 from the July 19, 2012, letter, one of several questions to which CDC has not provided an adequate written response. We urge CDC to resolve its internal difficulties with the Department and cooperate with the Committee's investigation as CDC has done on other occasions.

An attachment to this letter provides additional information about how to respond to the Committee's request. If you have any questions regarding this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927.

Sincerely,



Fred Upton  
Chairman



Cliff Stearns  
Chairman  
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member  
Subcommittee on Oversight and Investigations

Attachment