

ONE HUNDRED THIRTEENTH 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

January 31, 2013

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20221

Dear Secretary Sebelius:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce continues its investigation of 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. This letter hereby reauthorizes the request sent to the Centers for Disease Control and Prevention (CDC) on November 13, 2012.

It is our understanding that the CDC document production in response to the November 13, 2012, document request letter is still under review at the Department of Health and Human Services (HHS). There has been no production of any documents from HHS, although the Department of Homeland Security (DHS) has made substantial document production to the Committee in response to our BioWatch-related document request made on November 13, 2012. Prompt production of these documents from HHS is needed to help the Committee proceed with this inquiry with the benefit of the CDC's expertise and knowledge in this area.

We note that a December 22, 2012, article in the *Los Angeles Times* continued to raise concerns about BioWatch, especially the question of how best to protect public health. For example, the *Los Angeles Times* reported that Dr. Arthur L. Kellerman, a physician and public health researcher at Rand Corporation, who studied BioWatch as a member of a National Academy of Sciences committee, said it "has generated nothing but false alarms." Dr. Kellerman and other specialists, according to the *Los Angeles Times*, said the money spent on BioWatch could have paid for training and equipment to help medical professionals more quickly diagnose a patient exposed to an attack. These experts are concerned that the many false alarms invite complacency.

Because of the CDC's role in BioWatch and the important public health protection issues raised, we urge you to expedite this document production so we can work with you and your Department more effectively on improving protection against the threat of bioterrorism.

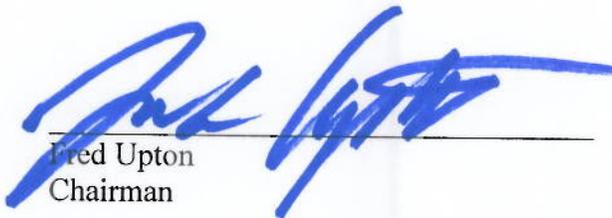
To assist the Committee in its examination of the issues raised in the November 13, 2012, letter, please provide the following by February 14, 2013:

1. All documents relating to the tests conducted by the 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.

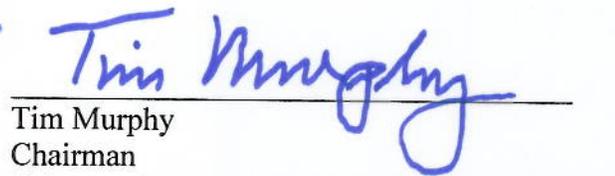
If the Department cannot provide complete document production by the requested deadline, we request that the Department provide evidence of cooperation with this request before February 14, 2013. Such evidence of cooperation must include a significant partial production, detailed information on how the production is being managed (number of FTEs handling, number of hours devoted to processing the request, number of pages being processed, internal emails substantiating the date CDC provided the documents to HHS), and a timetable of production.

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



Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations

cc: Thomas Frieden, M.D., Director, CDC

The Honorable Jim Esquee, Assistant Secretary for Legislation, HHS

The Honorable Henry A. Waxman, Ranking Member

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

Attachment

## RESPONDING TO COMMITTEE DOCUMENT REQUESTS

*In responding to the document request, please apply the instructions and definitions set forth below:*

### INSTRUCTIONS

1. In complying with this request, you should produce all responsive documents that are in your possession, custody, or control or otherwise available to you, regardless of whether the documents are possessed directly by you.
2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee.
3. In the event that any entity, organization, or individual named in the request has been, or is currently, known by any other name, the request should be read also to include such other names under that alternative identification.
4. Each document should be produced in a form that may be copied by standard copying machines.
5. When you produce documents, you should identify the paragraph(s) and/or clause(s) in the Committee's request to which the document responds.
6. Documents produced pursuant to this request should be produced in the order in which they appear in your files and should not be rearranged. Any documents that are stapled, clipped, or otherwise fastened together should not be separated. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. Indicate the office or division and person from whose files each document was produced.
7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph(s) and/or clause(s) of the request to which the documents are responsive, should be provided in an accompanying index.
8. Responsive documents must be produced regardless of whether any other person or entity possesses non-identical or identical copies of the same document.
9. The Committee requests electronic documents in addition to paper productions. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, back up tape, or removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), you should immediately consult with Committee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above.

10. If any document responsive to this request was, but no longer is, in your possession, custody, or control, or has been placed into the possession, custody, or control of any third party and cannot be provided in response to this request, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control, or was placed in the possession, custody, or control of a third party.
11. If any document responsive to this request was, but no longer is, in your possession, custody or control, state:
  - a. how the document was disposed of;
  - b. the name, current address, and telephone number of the person who currently has possession, custody or control over the document;
  - c. the date of disposition;
  - d. the name, current address, and telephone number of each person who authorized said disposition or who had or has knowledge of said disposition.
12. If any document responsive to this request cannot be located, describe with particularity the efforts made to locate the document and the specific reason for its disappearance, destruction or unavailability.
13. If a date or other descriptive detail set forth in this request referring to a document, communication, meeting, or other event is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.
14. The request is continuing in nature and applies to any newly discovered document, regardless of the date of its creation. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.
15. All documents should be bates-stamped sequentially and produced sequentially. In a cover letter to accompany your response, you should include a total page count for the entire production, including both hard copy and electronic documents.
16. Documents should be delivered to the Committee majority staff in Room 316 of the Ford House Office Building. You should consult with Committee majority staff regarding the method of delivery prior to sending any materials.
17. In the event that a responsive document is withheld on any basis, including a claim of privilege, you should provide the following information concerning any such document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; (e) the relationship of the author and addressee to each other; and (f) any other description necessary to identify the document and to explain the basis

for not producing the document. If a claimed privilege applies to only a portion of any document, that portion only should be withheld and the remainder of the document should be produced. As used herein, "claim of privilege" includes, but is not limited to, any claim that a document either may or must be withheld from production pursuant to any statute, rule, or regulation.

18. If the request cannot be complied with in full, it should be complied with to the extent possible, which should include an explanation of why full compliance is not possible.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; (2) documents responsive to the request have not been destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee since the date of receiving the Committee's request or in anticipation of receiving the Committee's request, and (3) all documents identified during the search that are responsive have been produced to the Committee, identified in a privilege log provided to the Committee, as described in (17) above, or identified as provided in (10), (11) or (12) above.

#### DEFINITIONS

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail ("e-mail"), instant messages, calendars, contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, power point presentations, spreadsheets, and work sheets. The term "document" includes all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments to the foregoing, as well as any attachments or appendices thereto. The term "document" also means any graphic or oral records or representations of any kind (including, without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotapes, recordings, and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, back up tape, memory sticks, recordings, and removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, electronic format, disk, videotape or otherwise. A document bearing any notation not part of the original text is considered to be a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "documents in your possession, custody or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that have been placed in the possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure, transmission, or exchange of information, in the form of facts, ideas, opinions, inquiries, or otherwise, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, e-mail, instant message, discussion, release, personal delivery, or otherwise.

4. The terms "and" and "or" should be construed broadly and either conjunctively or disjunctively as necessary to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes the plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, limited liability corporations and companies, limited liability partnerships, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, other legal, business or government entities, or any other organization or group of persons, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, mean anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.

7. The terms "you" or "your" mean and refers to

For government recipients:

"You" or "your" means and refers to you as a natural person and the United States and any of its agencies, offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on your behalf or under your control or direction; and includes any other person(s) defined in the document request letter.