

Congress of the United States  
Washington, DC 20515

January 8, 2015

Dr. Luciana Borio  
Assistant Commissioner  
Counterterrorism Policy  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Borio:

Thank you for appearing before the Subcommittee on Health on Wednesday, November 19, 2014, to testify at the hearing entitled "Examining Medical Product Development in the Wake of the Ebola Epidemic."

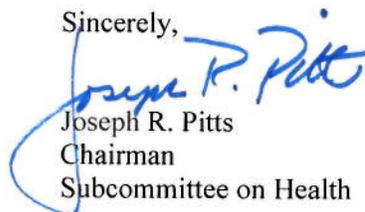
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose 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 with a transmittal letter by the close of business on Thursday, January 22, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to [Adrianna.Simonelli@mail.house.gov](mailto:Adrianna.Simonelli@mail.house.gov).

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

Sincerely,



Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

## Attachment 1—Additional Questions for the Record

### The Honorable Joseph R. Pitts

1. Given the long timeline required to develop new vaccines and therapeutics and then demonstrate clinical safety, what initiatives are underway at the Department of Health and Human Services (HHS) to improve care for patients who are infected with Ebola today?
2. Given many of the well-reported supply challenges with mass-producing and manufacturing Ebola drug treatments, such as ZMapp and others, in the near-term pipeline of Ebola experimental and investigational treatments, do you see potential paths forward that could have the drug supply available to actually treat thousands of Ebola patients in West Africa?
3. What is the role and pathway to join the global coalition of clinical trials for finding effective new experimental therapies in patients with Ebola Virus Disease in West Africa?
4. How would a treatment that focused on surviving the deadly complications of Ebola rather than the virus itself be tested in the coalition forming for clinical trials in West Africa?
5. For experimental treatments that are available today, what funds are being made available to rapidly test them to improve outcomes in patients in West Africa for patients with Ebola?

### The Honorable Marsha Blackburn

1. How many companies have requested the ability to export investigational new drugs pursuant to the U.S. Food and Drug Administration's ("FDA") investigational new drug emergency export provisions (21 C.F.R. § 312.110(b)(5))?
2. When were those requests received by the Department of Health and Human Services ("DHHS")?
3. When were those same requests forwarded to the FDA for advice and consultation?
4. If any of those requests have been supported by DHHS to date, when was the respective company notified?
5. Please explain the nature of DHHS's consultations with FDA. Which divisions of DHHS and FDA have primary authority in such consultations?
6. If DHHS or FDA needs more information in order to complete their consultation, will they consult with the respective company?
7. Have any countries made requests import investigations new drugs pursuant to FDA's investigations new drug emergency export provisions? If so, have they been notified of the timeline for consideration of their request?

### The Honorable Michael C. Burgess

1. As the FDA fails to consider all options when it comes to vaccine, diagnostic, and drug development, how will you assess studies performed outside of the United States *not* under FDA's guidance if they prove to be safe and efficacious?

2. How are you evaluating the risk profile of therapeutics given the high mortality rate from Ebola?
3. How are you ensuring that you are prioritizing the right, and the most promising, vaccines, therapeutics, and diagnostics?
4. Currently, there are six rapid diagnostics that have been approved for Emergency Use Authorization. What is the plan for providing a pathway to approval for these diagnostics when the Ebola crisis winds down?
5. False negatives are a real concern in testing for Ebola. In the case of the physician from Maryland who was treating patients in Sierra Leone, treatment was delayed because of a false negative on his initial Ebola test. How are you combatting confounding false negatives?
6. How is the efficacy of the tests receiving Emergency Use Authorization being tested?

**The Honorable Eliot L. Engel**

1. I have frequently said that the U. S. cannot meet the challenge that Ebola presents alone. Ebola is a global challenge requiring a global response. Can you discuss how the FDA is working with our international partners to facilitate collaboration and the exchange of important information on investigational products for Ebola?

## **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 are provided below.*

### **The Honorable Marsha Blackburn**

1. Please submit in writing a timeline, an orderly process timeline that will give us an idea of how quickly you anticipate these products are going to be able to be available for emergency export. This will be a timeline for drugs, vaccines, and devices that will be made available to those in West Africa.