



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

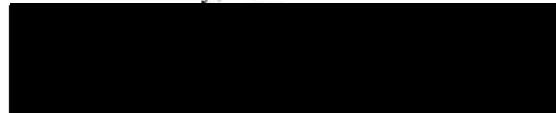
MAR 31 2015

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the October 16, 2014, hearing before the Subcommittee on Oversight and Investigations, entitled "Examining the U.S. Public Health Response to the Ebola Outbreak." This is the response for the record to questions posed by two Committee Members, in a letter we received on November 10, 2014.

Please let us know if you have any further questions.

Sincerely,



Thomas A. Kraus
Associate Commissioner for Legislation

cc: The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

We have restated your questions below in bold, followed by our responses.

The Honorable Ben Ray Luján

- 1. The appearance of a handful of Ebola cases in the United States demonstrates the importance of robust investments in our nation’s public health infrastructure. Unfortunately, the National Institutes of Health’s budget has been largely flat for years. In addition, we’ve seen cuts to the Center for Disease Control and the Department of Health and Human Services’ Hospital Preparedness program. Can each of you discuss if budget cuts have had any impact on our response to the Ebola outbreak in West Africa or impacted the handling of the cases here in the United States?**

FDA has not sustained funding cuts related to the programs listed here or to programs to prepare for and respond to the types of public health emergencies that include the current Ebola epidemic.

The Honorable Paul Tonko

- 1. By all accounts, the FDA has worked at an unprecedented speed to aid in bringing an Ebola vaccine to market. Instead of lengthy reviews taking months or years, the potential treatments have cleared FDA hurdles in days. Given the urgency of this need, is there anything else that Congress can do to support this critical mission?**

As it has done in the past, with other urgent public health situations such as SARS and the 2009 H1N1 influenza pandemic, FDA has responded to the current Ebola outbreak with a sense of urgency appropriate to the nature of the events. In 2010, Congress provided additional resources to FDA to launch its Medical Countermeasures Initiative. These resources have allowed FDA to increase its capacity to prepare for and respond to public health emergencies such as the Ebola epidemic. In responding to public health emergencies, FDA operates within current resources and uses a variety of regulatory tools to expedite review of candidate products. However, maintaining due attention to multiple priorities simultaneously can stress the available resources. The recent appropriation of \$25 million in one-time emergency supplemental funds for increased work at FDA related to the ongoing Ebola epidemic, and for increased medical countermeasures activities, will help FDA continue response and preparedness activities while maintaining our ongoing regulatory oversight of products that are important to public health.