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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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April 4, 2016

Dr. Luciana Borio
Assistant Commissioner for 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 Oversight and Investigations on Wednesday, March 2, 2016, to testify at the hearing entitled "Examining the U.S. Public Health Response to the Zika Virus."

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.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, April 18, 2016. Your responses should be mailed to Giulia Giannangeli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Giulia.Giannangeli@mail.house.gov.

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

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Attachment —Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

1. On March 2, 2016, FDA warned two Texas hospitals, Texas Children's and Houston Methodist that their lab-developed tests to detect the Zika virus were being offered without premarket clearance, approval, or Emergency Use Authorization. What factors led FDA to take this step? What specific legal authority does FDA have to regulate laboratory-developed tests offered within a laboratory?

The Honorable Frank Pallone, Jr.

The FDA is responsible for the review and approval of the medical products needed to diagnose, treat, and combat the spread of Zika. Access to diagnostic tests will be critical to helping to identify patients with Zika virus infections. Recently, FDA issued an Emergency Use Authorization for the use of a diagnostic test developed by CDC to detect Zika virus antibodies in individuals; however, a commercial diagnostic test is still not available.

1. How is FDA working with the public and private sectors to encourage and support diagnostic development as a part of the Zika response?

2. The President's emergency funding request for Zika includes $10 million for FDA to support diagnostic development and review, as well as post-market surveillance. How will the agency use this funding to support diagnostics?

Developing a vaccine is only part of the equation. We have to make sure that we have pharmaceutical companies interested in manufacturing and distributing the vaccine.

1. What preclinical and clinical data will be necessary to approve a vaccine, and in particular, what preclinical and clinical data will be necessary for a Zika vaccine to be used in pregnant women?

Vector control is one effective way to helping reduce the transmission of Zika. This may include insecticides or repellents, among other techniques. Genetically engineered mosquitoes have emerged as a new tool that may hold some promise in reducing the population of mosquitoes that carry Zika or dengue for example.

The World Health Organization has recommended that further field trials and risk assessments should be used to evaluate how GE mosquitoes may help to reduce disease transmission. FDA is the responsible agency in the United States in determining whether a field trial of GE mosquitoes could proceed.

1. What role does FDA see the GE mosquito playing in protecting the public health from further spread of Zika?

There has been much discussion around the use of genetically engineered mosquitoes as one potential tool in combatting the spread of Zika. Genetically engineered animals are regulated

under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act and the applicable new animal drug regulations issued by the agency. In the context of Zika, this would mean GE mosquitoes would be subject to the new animal drug provisions and regulations.

1. Why are GE animals regulated under the new animal drug provisions? How will the regulation of new animal drugs differ from the regulation of drugs and devices?

2. There has been interest in testing the use of GE mosquitoes as a way to prevent the spread of Zika. The company that has developed the GE mosquito, Oxitec, has publicly stated that they have been in conversations with FDA about field tests and have submitted an Investigational New Animal Drug file to FDA. Can you provide the Committee with a general update regarding the status of the company's file?