GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH 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

July 12, 2018

Rear Admiral Denise Hinton
Chief Scientist
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Admiral Hinton:

Thank you for appearing before the Subcommittee on Oversight and Investigations on June 15, 2018, to testify at the hearing entitled "The State of U.S. Public Health Biopreparedness: Responding to Biological Attacks, Pandemics, and Emerging Disease Outbreaks."

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. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, July 26, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

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

Sincerely,

Gregg Harper

Gregg Harper
Chairman
Subcommittee on Oversight and Investigations

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

Attachment

Attachment—Additional Questions for the Record

The Honorable Gregg Harper

1. Medical countermeasure (MCM) development can be a costly, time-consuming venture for the private sector. It is often one of the reasons why companies are reluctant to enter the MCM product space. How could the FDA provide better guidance and get involved earlier in the development process to help reduce this burden?

The Honorable Michael C. Burgess

1. Pharmaceutical companies face economic barriers to discovering and developing urgently needed new antibiotics to address drug resistant infections. I was encouraged by Commissioner Gottlieb's announcement earlier this week that FDA is working with CMS and other agencies to develop new payment models that would incentivize antibiotic research and development and the appropriate use of new antibiotics. Can you describe how these new models may work? Does Congress need to provide additional authorities or resources?

The Honorable Frank Pallone, Jr.

1. When a crisis does occur, what can FDA do to fast-track approval of countermeasures like vaccines and therapeutics?

2. How have GAIN and ADAPT helped FDA to incentivize antibiotic development in the private sector?