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ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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November 9, 2017

The Honorable Scott Gottlieb, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Gottlieb:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, October 24, 2017, to testify at the hearing entitled "Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season."

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 Tuesday, November 28, 2017. 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](mailto:Ali.Fulling@mail.house.gov).

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

Sincerely,



Greg Walden  
Chairman

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

Attachment

**Attachment—Additional Questions for the Record**

**The Honorable Greg Walden**

1. Approximately how many of the pharmaceutical and medical device manufacturing facilities in Puerto Rico are still operating on generator power?
  - a. How much longer can the facilities using generator power continue to rely on generator power?
  - b. Has the Food and Drug Administration (FDA) identified any preservation concerns or access issues associated with temperature-controlled pharmaceuticals, and if so, what is it doing to address them?
  - c. How many pharmaceutical and medical device manufacturing facilities in Puerto Rico are fully functional?
  - d. As the crisis in Puerto Rico has evolved, have any new challenges arisen for pharmaceutical and medical device manufacturing facilities in Puerto Rico? If so, what steps is FDA taking to help address these issues?

**The Honorable Gus Bilirakis**

1. What challenges still exist for Florida and what are your post-storm recommendations?
2. What resources are available to communities like mine impacted by Irma?

**The Honorable Frank Pallone, Jr.**

1. The widespread devastation in Puerto Rico caused by Hurricane Maria had a direct effect on pharmaceuticals and medical device manufacturing facilities located on the Island. Has FDA partnered with the suppliers of life-saving medicines to treat Puerto Rico's residents? What has the agency done to ensure facilities are well-equipped to ensure consistent production for residents in Puerto Rico and the rest of the nation?
2. During your testimony before this Committee on October 24, you stated that Puerto Rican pharmaceutical plants manufacture 30 products that are considered "critical medicines," and that of these 30, 14 are sole-source products, meaning that there are no alternative drug products available.
  - a. Are all plants which manufacture the 30 critically-important products operating at full capacity today?
  - b. Has FDA evaluated how long each such plant can continue to operate under current conditions?

- c. What contingency plans has the FDA considered in the event that power and other capabilities are not restored by the first quarter of next year?
3. On October 20, you released a statement that Puerto Rican manufacturers produce 50 types of medical devices that are critically important to patient care because they are life-sustaining and/or because they are produced by the only manufacturer of that device type. According to your statement, blood-related medical devices are of particular concern.
  - a. Are all plants which manufacture the 50 types of medical devices operating at full capacity today?
  - b. Has FDA evaluated how long each such plant can continue to operate under current conditions?
  - c. What contingency plans has the FDA considered in the event that power and other capabilities are not restored by the first quarter of next year
4. What is the status of delivery of essential medical products to geographically remote areas such as Vieques, Culebra, St. Croix, and St. Thomas?

**The Honorable Jan Schakowsky**

1. Following up, in the aftermath of disasters like these devastating Hurricanes, government should provide relief and recovery workers with required health and safety protections and Personal Protective Equipment (PPEs) to ensure workers' health is not compromised during current and ongoing clean-up and future rebuilding. Unfortunately, we have heard that this is causing problems in Puerto Rico.

We know Puerto Ricans in both the private and public sector want to do the work needed to help rebuild their lives, homes, communities, and their Commonwealth. Government workers are willing and eager to help address short-term needs –even when working as assigned by the Puerto Rico government is outside their long-standing employee responsibilities and expertise. Nonetheless, workers simultaneously want to protect their own health and safety and avoid unnecessary health problems. The long-term medical problems flowing from the tragic events on September 11, 2001 and the resulting cleanup efforts at Ground Zero and on the Pile taught us the vital importance of providing appropriate health and safety equipment and training to workers in conditions that are dangerous or uncertain.

- a. What is HHS, CDC, and other federal agencies doing to ensure local Puerto Rico government employees have the necessary health and safety equipment to protect themselves during their ongoing relief and recovery work?
  - b. Have these issues been addressed in Puerto Rico?
  - c. Which federal government agencies are responsible for providing needed PPEs to recovery workers?

**The Honorable Pete Olson**

1. After tackling 3 Hurricanes in a short period of time, what strains have you seen on your current resources. Also, what additional resources do you need to provide these communities the help that they need?