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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225–2927
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June 28, 2019

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Comptroller General Dodaro:

In June 2018, the Food and Drug Administration (FDA) announced the voluntary recall of certain generic medications used to treat high blood pressure and heart failure. According to FDA, these medications were recalled because their active ingredient contained probable human carcinogens. The manufacturers of the active ingredient in these affected products are located in China and India. The Committee has long held an interest in FDA's ability to oversee medical products manufactured overseas and in the foreign offices FDA set up to improve its oversight of these and other products. It is our understanding that, due in part to the U.S. Government Accountability Office's (GAO) previous work on these topics for the Committee, GAO added FDA's oversight of medical products to its High-Risk Series in 2009.

GAO last reported on FDA's foreign drug inspection program and its foreign offices in December 2016 and found that FDA had increased its foreign drug inspections and enhanced its ability to prioritize drug establishments for inspection.[1] However, GAO also found that FDA had not yet assessed its foreign offices' contributions to drug safety and that the offices faced persistently high vacancy rates. More recently, a Bloomberg investigation that analyzed FDA data found a decline in foreign surveillance inspections at drug manufacturing establishments in 2017 and 2018.[2] Bloomberg's review of FDA data and documents also suggested that FDA field

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[1] GAO, *Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices* (Dec. 2016) (GAO-17-143).

[2] *How a Tainted Heart Drug Made in China Slipped Past the FDA*, Bloomberg (Jan. 29, 2019). We note that while FDA drug inspections increased 18 percent in India in fiscal year 2018, FDA's inspections declined 11 percent in China. *America's Love Affair with Cheap Drugs Has a Hidden Cost,* Bloomberg (January 29, 2019).

inspection staff and managers at FDA's Center for Drug Evaluation and Research (CDER) may differ on key concerns when violations are discovered during foreign drug inspections.

Therefore, we request that GAO conduct a review of FDA's drug inspection program, including examining the following:

1. To what extent are FDA's efforts adequate to oversee the drug product supply chain, including active pharmaceutical ingredient manufacturing? Such analysis should include:

    a. The number of inspections of foreign and domestic drug manufacturing establishments FDA conducted since GAO's last report;

    b. The number of foreign facilities subject to FDA inspection in each country, the frequency by which FDA conducts inspections of these facilities, and whether FDA has adequate resources to meet its inspection goals;

    c. Implementation of FDA's risk-based selection process, including the criteria used in the selection process, adherence to such criteria, and consistency with which such criteria is applied to foreign and domestic drug manufacturing establishments;

    d. Trends in FDA staff resources dedicated to conducting inspections, including the number of inspections conducted by foreign office staff, the number of inspections performed by only one FDA inspector, and the number of inspections performed without an FDA translator; and

    e. Implementation of the Mutual Reliance Initiative and the role foreign inspectional collaborations play in FDA's efforts to oversee the drug product supply chain.

2. To what extent are FDA's efforts adequate to assess its foreign and domestic inspection program? Such analysis should include:

    a. How FDA is prioritizing high-risk inspections, and whether FDA has analyzed its risk-based selection process;

    b. The quality of the data FDA relies on to select establishments for inspection;

    c. FDA's current efforts and future plans for hiring and retaining its inspection staff; and

    d. FDA's efforts to assess its foreign offices' contributions to drug safety.

We appreciate your attention to this matter. If you have any questions, please contact Kevin McAloon of the Majority Committee staff at (202) 225-2927 or Alan Slobodin of the Minority Committee staff at (202) 225-3641.

Sincerely,

Frank Pallone, Jr.
Chairman

Greg Walden
Ranking Member

Diana DeGette
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Subcommittee on Oversight
and Investigations

Brett Guthrie
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