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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

June 8, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is examining the FDA's Office of Criminal Investigations (OCI), specifically OCI's role in the FDA's comprehensive approach to combatting the opioid crisis.

We share a common goal in combatting the opioid epidemic. You have testified before our Committee and made public statements that the opioid crisis is a top priority for you and the FDA. In your speech at the FDA OCI meeting on November 14, 2017, you stated that combatting the opioid crisis should "be one of [OCI's] highest priorities as well." You added, "there's more we can, and must, be doing to penalize and deter the criminal misconduct that contributes to and worsens this crisis." You also stated that it is crucial that FDA build upon its capacity to detect and disrupt the flood of illegal opioids, kratom, and other products that are being imported through the international mail facilities, and directed FDA to take action. Specifically, you noted that the FDA devised an Enforcement Operations Work Plan focused on preventing the import of unapproved drugs, and would double the number of port of entry special agents that OCI maintains from 6 to 12 FTEs. FDA has received $94 million for Fiscal Year 2018 for work in international mail facilities.

However, we have concerns about whether FDA is appropriately devoting its resources to prioritize these efforts to protect against unapproved opioids and other potentially harmful products at ports of entry.

Your leadership in ensuring the integrity of these products at the nation's ports of entry is appreciated and we support your efforts. We write today to request information about the implementation of your priorities at OCI. Committee staff initially requested statistical

information about OCI's port of entry cases. At the behest of FDA staff, we are formalizing those requests in today's letter.

To assist our oversight in this area, please provide the following by June 22, 2018:

1. OCI's Investigative Priority List for FY 2017 and FY 2018, respectively.

2. The total number of OCI's port of entry (POE) cases for FY 2017, and the total thus far for FY 2018. Out of the total numbers of POE cases for FY 2017 and FY 2018, please provide the number of POE cases related to (1) foreign unapproved medical and tobacco products, (2) cosmetic products, and (3) opioids/fentanyl/kratom, by OCI field office.

3. Data regarding POE cases related to (1) foreign unapproved medical product and tobacco products, (2) cosmetic products, and (3) opioids/fentanyl/kratom, including for each case category: the number of FDA OCI cases opened, the number of FDA referrals to state law enforcement, the number of seizures, the number of asset forfeitures, the number of arrests, the number of prosecutions, the number of guilty pleas or convictions (including the number related to FDA violations), and the number of convictions vacated or overturned.

4. The number of port of entry special agents currently employed by OCI. Has the number doubled in accordance with FDA's Enforcement Operations Work Plan? If not, why not? If yes, please provide a description of the anticipated priorities for the new agents.

5. FDA OCI has memoranda of agreement with the Drug Enforcement Administration and U.S. Customs and Border Protection, but FDA staff reported that the FDA is not aware of a memorandum of agreement with U.S. Immigration and Customs Enforcement - Homeland Security Investigations (HSI). Does FDA OCI plan to enter into a memorandum of agreement with HSI? If not, why not? Is FDA OCI working with HSI, DEA or FBI on any opioid-related dark web cases?

6. FDA OCI has not had a permanent director since January 2017. What is the expected timeline to install a permanent director at FDA OCI?

If you have any questions regarding information in this letter or about this request, please contact Alan Slobodin with the Majority Committee staff at (202) 225-2927 or Kevin McAloon with the Minority Committee staff at (202) 225-3641.

Sincerely,

Greg Walden
Chairman

Frank Pallone
Ranking Member

Gregg Harper
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

Gene Green
Ranking Member
Subcommittee on Health

Marsha Blackburn
Member of Congress

Kathy Castor
Member of Congress

Attachment