

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

COMMITTEE ON ENERGY AND COMMERCE

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September 9, 2019

Ms. Carol Cave  
Director, Office of Enforcement and Import Operations  
Office of Regulatory Affairs  
Food and Drug Administration  
U.S. Department of Health and Human Services  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Ms. Cave:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, July 16, 2019, at the hearing entitled "Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Monday, September 23, 2019. As previously noted, this transmittal letter and your responses, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by e-mail in the Word document provided with this letter to Jourdan Lewis with the Committee staff ([jourdan.lewis@mail.house.gov](mailto:jourdan.lewis@mail.house.gov)). A paper copy of your responses is not required. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Ms. Carol Cave  
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Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Ms. Lewis at (202) 225-2927.

Sincerely,



Frank Pallone, Jr.  
Chairman

Attachment

cc: Hon. Greg Walden, Ranking Member  
Committee on Energy and Commerce

Hon. Diana DeGette, Chair  
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member  
Subcommittee on Oversight and Investigations

**Committee on Energy and Commerce  
Subcommittee on Oversight and Investigations**

**Hearing on  
“Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl”**

**July 16, 2019**

**Ms. Carol Cave, Director, Office of Enforcement and Import Operations, Office of  
Regulatory Affairs, Food and Drug Administration, U.S. Department of Health and  
Human Services**

**The Honorable Frank Pallone, Jr. (D-NJ)**

1. The inability of individuals to detect the presence of illicit fentanyl in counterfeit pills can result in the individuals unknowingly exposing themselves to fentanyl. As the agency tasked with addressing counterfeit drugs, how is the Food and Drug Administration preventing these pills from entering the marketplace, other than by prosecuting through DOJ?

**The Honorable Brett Guthrie (R-KY)**

1. Is the U.S. Food and Drug Administration (FDA) receiving intelligence from any other federal agencies on Chinese drug companies potentially involved with illicit fentanyl?
2. Is FDA sending and receiving intelligence among federal agencies related to combating illicit fentanyl trafficking?
3. Does FDA have a mechanism to receive or share intelligence related to illicit fentanyl trafficking?
4. What is the status of implementation of SUPPORT Act provisions related to advanced electronic data or debarment authorities related to illegal imports of drugs?
5. How has the SUPPORT Act changed the way in which you all operate on a day-to-day basis?
6. In April 2019, the FDA and U.S. Customs and Border Protection (CBP) signed an agreement to maximize inspection and detection capabilities in order to prevent illegal and harmful products such as fentanyl from the United States through the international mail facilities. What are some of the results from this agreement so far?
7. Over the last two years, how has FDA improved targeting of fentanyl entering the United States?

8. What is the role of the FDA's Office of Criminal Investigations (OCI) in combating the illicit fentanyl threat?
9. Over the last two years, how much has FDA increased staffing of OCI special agents working at points of entry?
10. What is the role of FDA's Forensic Chemistry Center in supporting FDA's efforts to combat illicit fentanyl?
11. Has FDA received additional resources to combat illicit fentanyl? If so, how much, and how are these additional resources being deployed?
12. FDA's testimony stated that it had applied its new section 801(u) authority to 4,017 drug products. Did any of these products contain fentanyl?
  - a. If so, about how many of the drug products contained fentanyl?
13. FDA's testimony stated that FDA and CBP have been actively working to expand the scientific presence at international mail facilities (IMF). What are some of the ideas being examined to expand the scientific presence?
14. How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?
15. Are labs at DEA, CBP, and FDA coordinating on fentanyl research and sharing fentanyl samples for each agency's specialized testing?
16. CBP's written testimony mentions pollen testing and analysis is being conducted by CBP's Laboratories and Scientific Services scientists to geolocate illicit opioid shipments. Are labs at other agencies working on testing techniques that could help geolocate illicit fentanyl shipments?
17. Could federal labs work to complement each other's effort to enhance geolocation of illicit fentanyl shipments?

**The Honorable Michael C. Burgess, M.D. (R-TX)**

1. In April, FDA and CBP signed an agreement regarding International Mail Facilities to prevent illegal fentanyl and other substances from entering our country through the mail. I toured the International Mail Facility at JFK International Airport last year with former

Commissioner Gottlieb. What specific actions has FDA taken to combat fentanyl in International Mail Facilities since the signing of this agreement?

2. How has CBP's work informed FDA's decision making and recent actions to combat fentanyl?
3. The SUPPORT for Patients and Communities Act included a provision to require advanced electronic data submission for all international mail shipments. How has the use of technology and data shaped FDA's response to the influx of fentanyl?