U.S. FOOD & DRUG ADMINISTRATION

JAN 23 2020

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
Washington, D.C. 20515-6115

Dear Chairman Pallone:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the July 16, 2019, hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, entitled "Oversight of Federal Efforts to Combat the Spread of Illicit Fentanyl." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

Karas Gross
Associate Commissioner for
Legislative Affairs

cc: The Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce

The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations

The Honorable Brett Guthrie, Ranking Member, Subcommittee on Oversight and Investigations

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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?**

   FDA refers any drug product that is determined to contain fentanyl to CBP as the lead interdicting authority for controlled substances generally. FDA currently uses a rapid screening tool to screen products of interest to identify suspected counterfeit pills coming through the International Mail Facilities (IMF) that have been referred to the FDA by CBP. These articles are then evaluated by FDA's Forensic Chemistry Center to confirm authenticity against the established library of drugs. Finally, if the article is determined to be a non-controlled drug and is counterfeit, FDA will destroy the drug using our administrative destruction authority.

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?**

   FDA's Office of Criminal Investigation routinely shares intelligence with DEA, CBP and ICE related to illicit fentanyl trafficking through agents assigned to work at International Mail Facilities, CBP's National Targeting Center and DEA's Special Operations Division as well as through routine criminal investigations such as Operation CyberPharma which targets online sellers of counterfeit opioids.

2. **Is FDA sending and receiving intelligence among federal agencies related to combating illicit fentanyl trafficking?**

   See previous answer.

3. **Does FDA have a mechanism to receive or share intelligence related to illicit fentanyl trafficking?**

   FDA's Office of Criminal Investigations has access to information-sharing databases as part of our work at International Mail Facilities, CBP's National Targeting Center and DEA's Special Operations Division. In addition, FDA continues to work with United Stated Postal Service (USPS) and CBP on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening.

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?**

FDA continues to work with United Stated Postal Service (USPS) and U.S. Customs and Border Protection (CBP) on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening. Meetings have begun between CBP, USPS and the partner government agencies (PGAs) regarding the ability to receive advanced electronic data through the Automated Commercial Environment (ACE) and/or other electronic data systems. In addition, FDA is actively implementing the new debarment authority added by section 3022 of the SUPPORT Act and is currently seeking the debarment of several individuals related to the illegal importation of drugs or controlled substances. In one of the cases, an individual was served with an FDA Notice of Debarment in July 2019 and we are currently processing that debarment order.

5. **How has the SUPPORT Act changed the way in which you all operate on a day-to-day basis?**

The SUPPORT Act allows investigators in the IMFs to more efficiently and effectively determine that a product is an illicit drug and focus their resources on documenting the violation and refusing the product. This allows FDA staff to review more parcels and process more violative drugs for destruction, thereby preventing the entry of illicit articles containing identified active pharmaceutical ingredients (APIs) into U.S. commerce. Largely as a result of the implementation of section 801(u) of the Federal Food, Drug, and Cosmetic (FD&C) Act, as added by the SUPPORT Act, the destruction rate for illicit drugs entering the U.S. through the IMFs has increased eightfold compared to the same time period in FY2018 (through August 2018, our destruction rate was 5.42%, for the same time period through August 2019, it is 44.27%). FDA continues to identify additional APIs amenable to this new authority.

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?**

FDA is working with CBP to establish and staff satellite laboratory facilities within the five higher volume IMFs located in Jamaica, Secaucus, Miami, Long Beach and Chicago. These facilities will be shared by FDA and CBP scientists using a toolkit of technologies selected for identifying counterfeit pharmaceuticals and determining the presence of fentanyl or other adulterants. FDA and CBP laid the foundation to pilot this effort at the Chicago IMF using a mobile laboratory unit, which has been prepared by the US Army Futures Command, and delivered to the IMF in November. That unit will be staffed by scientists trained by FDA's Forensic Chemistry Center specialists, along with CBP's Laboratories and Scientific Services scientists.

In support of the Letter of Intent, FDA and CBP have held multiple discussions regarding operational areas for agreement, and a draft MOU based on those discussions, shared with both CBP and USPIS, is currently being vetted within those agencies.

7. Over the last two years, how has FDA improved targeting of fentanyl entering the United States?

CBP is generally the lead interdicting authority for controlled substances, including fentanyl and other opioids. Operationally, CBP is the agency with first review of products and will handle fentanyl and other opioids following their processes. If FDA encounters products containing fentanyl, FDA will refer these products back to CBP for processing.

8. What is the role of the FDA's Office of Criminal Investigations (OCI) in combating the illicit fentanyl threat?

OCI continues to leverage FDA's enforcement authorities to combat a wide range of criminal conduct involving opioids, including combatting illicit fentanyl. Online, OCI's Cybercrime Investigation Unit is targeting darknet marketplaces and vendors manufacturing and selling counterfeit opioids, including fentanyl-tainted counterfeits, through arrest and the seizure of assets. Thus far, Operation CyberPharma has led to the arrest of 7 darknet vendors and aided in the takedown of a major darknet marketplace as well as the seizure of drug counterfeiting tools and tens of thousands of dollars in virtual currencies and other assets. Additional arrests and seizures are anticipated with this on-going operation.

OCI's Import Operations Program also plays an important role combating the illicit fentanyl threat at our International Mail Facilities. While CBP handles the majority of opioid-related interdictions, FDA also encounters these products. OCI agents work to identify the source and destination of these drugs and collaborate with other federal agencies such as ICE, DEA and the Postal Inspection Service.

9. Over the last two years, how much has FDA increased staffing of OCI special agents working at points of entry?

In FY 19 the number of criminal investigators assigned to the OCI Import Operations Program (IOP) increased from 17 in fiscal year 2018 to 21 agents currently.

10. What is the role of FDA's Forensic Chemistry Center in supporting FDA's efforts to combat illicit fentanyl?

FDA's Forensic Chemistry Center (FCC) developed proposals to assist in increasing the number of packages screened at the IMFs, putting advanced tools in the hands of FDA investigators and agents and providing training. FCC also developed a toolkit for use by scientists at the IMFs including associated training courses and materials, as well as, developed safety protocols for handling fentanyl and fentanyl analogs.

11. Has FDA received additional resources to combat illicit fentanyl? If so, how much, and how are these additional resources being deployed?

The Office of Regulatory Affairs (ORA) was allocated 125 FTEs and approximately $86M to support the increased workload associated with combating the Opioid crisis. As of Sept

2019, 75 of 125 positions are onboarded and approximately $76M has been obligated to support field work, laboratory sciences, and criminal investigations. Some highlights of expenditures are $41.7M for Forensic Chemistry Center (FCC) expansion, approximately $8M in payroll, $1.2M IMF build out, $15M for IT enhancements, and $5M for equipment for Office of Regulatory Science (ORS) and Office of Criminal Investigations (OCI).

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?

To use our FD&C Act section 801(u) authority, FDA must identify specific active pharmaceutical ingredients (API) which meet the criteria indicated in this provision. When FDA implemented this new authority, we targeted the highest volume APIs we see entering the U.S. via international mail. Fentanyl citrate is not among the APIs with the highest volume, thus we have not applied the new authority to drug products containing this API at this time.

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?

FDA is working with CBP to establish and staff satellite laboratory facilities within the five higher volume IMFs located in Jamaica, Secaucus, Miami, Long Beach and Chicago. These facilities will be shared by FDA and CBP scientists using a toolkit of technologies selected for identifying counterfeit pharmaceuticals and determining the presence of fentanyl or other adulterants. FDA and CBP laid the foundation to pilot this effort at the Chicago IMF using a mobile laboratory unit, which has been prepared by the US Army Futures Command, and was delivered to the IMF in November. That unit will be staffed by scientists trained by FDA's Forensic Chemistry Center specialists, along with CBP's Laboratories and Scientific Services Scientists in the use of the toolkit.

In addition, FDA plans to deploy additional rapid screening tools to the IMF facilities to help identify counterfeit products and products containing undeclared and/or non-permitted drug ingredients.

14. How can data collection be improved to bolster your agency's intelligence and ability to interdict packages or seize narcotics, such as fentanyl?

With access to automated postal data, FDA would be able to automate targeting of incoming mail parcels based on historical results from parcel and product reviews, which benefits FDA through better parcel screening for FDA-regulated product issues. Using our experience with our PREDICT screening tool for screening and targeting non-IMF import entries, we would envision creating similar risk-based targeting for IMF parcels.

FDA would also gain operational benefits from having advanced electronic data for international mail parcels. First, it would streamline the main time expenditure in FDA's processing of international mail parcels – data entry. Currently all mail parcel information is manually entered by FDA staff into FDA's entry processing system. With access to advanced electronic data, FDA can automate data collection, greatly reducing processing time, further expanding our coverage, and getting more quickly to the process of determining admissibility of the parcel contents.

Second, we envision an operational benefit not only for FDA but also for USPS and CBP from automated data and processing by removing steps from the current process, which require routing of parcels by USPS to CBP, for CBP to then screen and determine which should be forwarded on to FDA. FDA can take greater ownership of this part of the process, freeing up the other two agencies to focus on areas more germane to their day-to-day operations.

15. Are labs at DEA, CBP, and FDA coordinating on fentanyl research and sharing fentanyl samples for each agency's specialized testing?

FDA and CBP have been communicating and sharing information on the opioid problem, focusing on improving screening at the IMFs in keeping with an agreement in the form of a Letter of Intent between the two agencies. We do not maintain the same level of communications and information sharing with DEA, as CBP is generally the lead interdicting authority for fentanyl and other controlled substances. FDA has participated in meetings with the Joint Project Manager for Nuclear, Biological, and Chemical Contamination Avoidance (JPM NBC CA) and the TICO (Technology Innovation to Combat the Opioid epidemic) Workgroup, where information on opioid testing capabilities is exchanged.

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?

FDA's FCC is exchanging information with CBP's LSS, has the ability to detect the presence of pollen in submissions, and can leverage CBP's expertise. FCC also has the ability to establish chemical profiles or a chemical fingerprint of materials used in the production of opioid containing products. This information assists in connecting products with raw materials and material suppliers.

17. Could federal labs work to complement each other's effort to enhance geolocation of illicit fentanyl shipments?

Yes. See response to 15 and 16 above.

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?**

   The FDA and CBP signed a Letter of Intent on April 4, 2019, to establish an outline of strategies for advanced collaboration between the agencies that will be carried out through a series of separate written agreements. These agreements are expected to include procedures to enhance information sharing and operations, including the establishment of a list of controlled substances that are imported via international mail and which agency will retain primary interdiction responsibility. Three FDA/CBP work groups to implement the Letter of Intent have been established in the following areas: (1) Collaboration at Ports of Entry; (2) On-Site Laboratory and Scientific Services; and (3) Shared Facilities and Space at the IMFs.

   In support of the Letter of Intent, FDA and CBP have held multiple discussions regarding operational areas for agreement, and a draft MOU based on those discussions was shared with both CBP and USPIS and is currently being vetted within those agencies.

   Additionally, FDA is working with CBP to establish and staff satellite laboratory facilities within the five higher volume IMFs located in NY, Secaucus, Miami, Long Beach and Chicago. These facilities would be shared by FDA and CBP scientists using a toolkit of technologies selected for identifying counterfeit pharmaceuticals and determining the presence of fentanyl or other adulterants.

2. **How has CBP's work informed FDA's decision making and recent actions to combat fentanyl?**

   CBP has provided information identifying International Mail Facilities as points of entry, among others, for counterfeit and unapproved drugs including fentanyl and fentanyl analogs.

   FDA continues to collaborate with CBP on the implementation of section 3022 of the SUPPORT Act. FDA and CBP leaders have met to discuss the development of a list of controlled substances that, under section 3022(a)(1) of the SUPPORT Act, FDA will transfer to CBP when such substances are offered for import via international mail and appear to violate the Controlled Substances Act (21 U.S.C. 801 et seq.) (CSA), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or any other applicable law. The Letter

of Intent and the pursuant MOU will enhance the coordination activities between agencies at the mail facilities.

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?**

FDA continues to work with United Stated Postal Service (USPS) and U.S. Customs and Border Protection (CBP) on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening. Meetings have begun between CBP, USPS and the partner government agencies (PGAs) regarding the ability to receive advanced electronic data through the Automated Commercial Environment (ACE) and/or other electronic data systems. Receiving accurate and complete electronic data in advance of shipment arrival would allow for better targeting and resource allocation within the international mail facilities (IMFs).