



The Honorable Charles E. Grassley
Chairman
Caucus on International Narcotics Control
Washington, DC 20510

DEC 14 2018

Dear Chairman Grassley:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the October 8, 2018, hearing before the Senate Caucus on International Narcotics Control, entitled "Stopping the Poison Pills: Combatting the Trafficking of Illegal Fentanyl from China." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John Martin
Principal Associate Commissioner
for Legislative Affairs

Your questions are restated below, in bold, followed by FDA's responses.

Sen. Charles E. Grassley

- 1. Fentanyl trafficking occurs out in the open as much as it does through cryptocurrency and the Dark Web. My staff has pressed private companies and major internet search platforms on the role they play – willfully or negligently – in providing internet consumers with access to illicit e-pharmacies. You mentioned that FDA tries to address online pharmacies or marketplaces selling illicit substances.**

a. How does FDA identify and track such sites?

Over the years, FDA has developed expertise investigating illegal online pharmacies using open source tools, court orders, and contract support where appropriate. Generally, once a website is targeted for investigation, we work to identify the entire scope of the operation. This analysis often includes affiliated sites, payment processing services, supply chain identification, and shipping methods.

b. Does the FDA work with governments like China to identify these sites?

FDA's China Office maintains a close working relationship with the China Food and Drug Administration in performance of FDA's regulatory duties in China.

c. What, specifically, does FDA do to help shut these sites down?

FDA has a multi-faceted and coordinated approach to address illegal online pharmacies. FDA issues public Warning Letters that identify sites selling fentanyl and other illicit substances. These Warning Letters are supplied to various parts of the internet ecosystem such as search engines, registrars and registries, social media platforms, and marketplaces. In addition, FDA regularly submits abuse complaints to domain name registrars of websites found to offer illicit substances for sale to U.S. consumers. In some instances, these companies then take voluntary action to terminate their business relationship with these sites. In some cases, FDA's Office of Criminal Investigations will initiate criminal investigations in conjunction with a U.S. Attorney's Office, which may result in enforcement actions such as arrests, indictments, and court orders to seize domain names, assets, or financial accounts.

- 2. What do your investigations tell you about the identity of those operating these websites?**

Generally speaking, who are the operators, how many are out there, where are they operating, and how much illicit narcotics are they able to sell over these networks. Although each case is different, our criminal investigations generally show that the operators of these sites can be located anywhere in the world. We have arrested website operators from the Republic of Georgia, India, Turkey, Thailand, Israel, Pakistan, Canada, Greece, and China. Larger networks easily reap profits in the millions of dollars annually. Further, with the growth and stabilization

of cryptocurrencies, laundering these funds has become relatively simple. The raw materials or finished drugs that reach the U.S. are generally manufactured in China, India and Pakistan, but counterfeiting operations have also been uncovered in the United States.

3. Senator Feinstein and I wrote a number of letters to internet companies with search engine platforms asking about illicit online sales. We were easily able to find illicit sites willing to sell illegal narcotics through simple online searches. For example, we were able to search for, and find, sites offering illicit forms of fentanyl, oxycodone, or Vicodin for sale.

a. What is the FDA doing to address this issue, specifically with respect to search engines?

FDA continues to engage various parts of the internet ecosystem to first seek voluntary action to remove sites that illegally sell narcotics and other dangerous drugs. An example is our June 2018 Online Opioid Summit discussed in Mr. Burke's testimony. FDA also uses our regulatory, civil, and criminal tools when appropriate. For example, a 2011 investigation by FDA's Office of Criminal Investigations of Google's AdWare program resulted in a non-prosecution agreement with Google and the forfeiture of \$500 million generated by online ads and prescription drug sales by illegal online pharmacies. In that case, Google provided advertisement assistance to internet pharmacies that targeted U.S. consumers and illegally imported controlled and non-controlled prescription drugs into the United States.

b. How can Congress and Executive agencies – such as the FDA – continue working with private sector stakeholders in addressing the concerns that have been raised on this issue?

We must continue to educate private sector stakeholders about their specific role in the online sale of narcotics and other dangerous drugs online. FDA finds that many companies advocate for specific provisions in law that enable action and release of liability for removing sites selling illicit drugs.

Sen. Dianne Feinstein

1. International Cooperation

The opioid epidemic is the most severe drug crisis our country has ever faced. I firmly believe that the United States must do more to address the demand for fentanyl and other illicit drugs, and I hope that the bi-partisan, bi-cameral opioid package that the House and Senate recently passed will help to do so.

However, the opioid crisis – and fentanyl in particular – is a global issue. As such, we must continue to engage our international partners.

- a. Can you please speak to your agency's working relationship with the Chinese government and identify any gaps that may exist, both at the national and provincial levels?**

FDA's China Office maintains a close working relationship with the China Food and Drug Administration in performance of FDA's regulatory duties in China. Further, earlier this year, FDA hosted a meeting with a delegation from the Chinese Ministry of Public Security and a direct line of communication with the MPS-Police Liaison Officer is maintained by FDA's Office of Criminal Investigations.

- b. Are there additional steps Congress can take to encourage China to more proactively confront synthetic drug traffickers?**

FDA appreciates Congress's continued support and engagement with China on this issue. Engaging with Chinese officials in-country is important as we continue to identify and work with China on eliminating sources of supply.

2. Online Sale of Fentanyl

In February of this year I, along with Chairman Grassley and several of my other colleagues, sent a letter to a number of search engine providers and online marketplaces regarding the online sale of illicit narcotics and prescription drugs without a valid prescription.

Several of these providers and marketplaces have since taken some steps to address this issue, including the immediate removal of sites identified by the Food and Drug Administration as being illegal. However, I remain concerned that they continue to take a reactive, rather than proactive approach to addressing this problem.

- a. How is your agency engaging the various internet service providers and online marketplaces to address the online sale of illicit drugs?**

FDA continues to engage various parts of the internet ecosystem to first seek voluntary action to remove sites that illegally sell narcotics and other dangerous drugs. An example is our June 2018 Online Opioid Summit discussed in Mr. Burke's testimony. FDA also uses our regulatory and criminal tools when appropriate. For example, a 2011 investigation by FDA's Office of Criminal Investigations of Google's AdWare program resulted in a non-prosecution agreement with Google and the forfeiture of \$500 million generated by online ads and prescription drug sales by illegal online pharmacies. In that case, Google provided advertisement assistance to internet pharmacies that targeted U.S. consumers and illegally imported controlled and non-controlled prescription drugs into the United States.

- b. Current law does not require internet service providers or online marketplaces to proactively remove links that facilitate the online sale of illicit drugs. What challenges does this present in terms of disrupting the flow of fentanyl, fentanyl analogues, and other illicit substances?**

We must continue to educate private sector stakeholders about their specific role in the online sale of sell narcotics and other dangerous drugs online. FDA finds that many companies advocate for specific provisions in law that enable action and release of liability for removing sites selling illicit drugs.

3. Dark Web

The dark web provides anonymity to its users and allows websites to operate without being easily detected. This environment lends itself to criminals, and the advent of digital currency makes the dark web rife with opportunities for transnational criminal groups and even independent drug traffickers to use it for illicit activities.

a. To what extent are transnational criminal groups versus discrete individuals are using the dark web to conduct drug crimes?

It is clear that dark web marketplaces allow discrete individuals to create and be part of transnational criminal groups without ever having to meet or physically engage with coconspirators. The cases highlighted in Mr. Burke's testimony demonstrate how individuals can conspire with one another across the world and without ever having to meet in person. In today's world, transnational criminal groups can easily form in "online pharmacy" chat rooms or discussion boards.

b. To what extent are transnational organizations in China using the dark web to facilitate the sale of illicit fentanyl and other new psychoactive substances to customers in the United States?

Illicit fentanyl and other new psychoactive substances are widely available on dark web sites and marketplaces. Evidence from packages being imported into the United States through international mail facilities, along with the criminal investigations highlighted in Mr. Burke's testimony, indicate that China is a major manufacturing source of illicit drugs. The distribution of illicit substances is not limited to the dark web. In fact, a broader customer base is reached on the surface web simply because it is more easily accessible.

c. How is the U.S. working with its Chinese counterparts to stop these operations?

FDA's China Office maintains a close working relationship with the China Food and Drug Administration in performance of FDA's regulatory duties in China. Further, earlier this year, FDA hosted a meeting with a delegation from the Chinese Ministry of Public Security and a direct line of communication with the MPS-Police Liaison Officer is maintained by FDA's Office of Criminal Investigations.

d. Would any additional authorities be helpful to your efforts to counter the use of the dark web to facilitate these crimes?

FDA's Office of Criminal Investigations plays a narrow but important role in combatting the illegal online sale of opioids, in cooperation with our fellow law enforcement agencies. We

are proud of the work we have done, and will continue to do, on this front, and we welcome the continued assistance of Congress in this effort.