



STATEMENT OF

DANIEL G. BURKE

SENIOR OPERATIONS MANAGER

CYBERCRIME INVESTIGATIONS UNIT

OFFICE OF CRIMINAL INVESTIGATIONS

OFFICE OF REGULATORY AFFAIRS

U.S. FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

CAUCUS ON INTERNATIONAL NARCOTICS CONTROL

UNITED STATES SENATE

**“STOPPING THE POISON PILLS:
COMBATTING THE TRAFFICKING OF ILLEGAL FENTANYL FROM
CHINA”**

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RELEASE ONLY UPON DELIVERY

Introduction

Chairman Grassley, Co-Chair Feinstein, and other distinguished members of the Caucus:

Thank you for the opportunity to appear before you today to discuss how illegal online pharmacies, and other areas of the online ecosystem, facilitate trade in illegal pharmaceuticals, including illicit fentanyl and other harmful substances, as well as the efforts of the U.S. Food and Drug Administration (FDA or the Agency) to disrupt and dismantle these operations.

As FDA's criminal law enforcement arm, the Office of Criminal Investigations (OCI) protects the public health of Americans by conducting criminal investigations of illegal activities involving FDA-regulated products, arresting those responsible, and working with the Department of Justice for prosecution. Since our inception in 1993, FDA-OCI has investigated thousands of criminal schemes involving a broad range of illegal conduct affecting public health. These schemes include the illegal manufacture and trafficking of counterfeit, unapproved, or misbranded drugs and medical products; theft and diversion of prescription drugs; fraudulent schemes involving bogus cures for Alzheimer's disease, cancer, and AIDS; product tampering and substitution; clinical investigator fraud, and fraud involving FDA-regulated drugs and medical devices.

As a Senior Operation Manager, I direct the investigative activities of the Special Agents within the Cybercrime Investigations Unit (CcIU). CcIU was launched in 2013 specifically to address the sale of counterfeit drugs, tainted dietary supplements, and other potentially dangerous FDA-regulated products on the Internet. Our agents aggressively pursue these transnational organized crime networks directly to the source of supply, often working in conjunction with foreign law enforcement and the FDA overseas offices as well as the Drug Enforcement Administration (DEA), and U.S. Immigration and Customs Enforcement's Homeland Security Investigations (ICE-HSI). CcIU also targets the online infrastructure that supports the illegal distribution of pharmaceuticals on the internet. We focus on investigating businesses that knowingly profit from, but deliberately ignore, their part in these schemes. We have successfully sought prosecution of search engine providers, payment processors, shipping companies, pay-per-click advertisers and online marketplaces. Furthermore, as described below, the Agency is currently engaging in outreach with other parts of the online ecosystem, such as domain name registries and registrars, in an effort to highlight their supporting role in the illegal sale of opioids in particular.

In FY 2017, FDA-OCI's Internet-related cases resulted in 44 arrests; 31 convictions; fines and restitution totaling \$5.8 million; and the seizure of assets valued at over \$33 million. Our agents have also seized a total of 4,229 domain names via court order.

Investigations of Online Sales of Fentanyl and other Opioids

To ensure we do not duplicate the efforts of DEA, ICE-HSI, and our other law enforcement partners, FDA-OCI's efforts to combat the online sale of illicit fentanyl and other opioids is strategic. In the course of our investigations, we often come across websites offering suspected counterfeit controlled substances. We focus our efforts involving controlled substances specifically to drug counterfeiting operations. Many of these investigations involve raw materials or tooling originally manufactured in China and mailed to the United States. For example:

- A recent FDA-OCI-led investigation in Northern California led to the dismantling of a criminal conspiracy to manufacture and distribute counterfeit Xanax and Percocet pills. As part of this conspiracy, the suspects purchased and imported from China a pill press, punches, and dies, and other manufacturing equipment necessary to form pills that bore the markings of controlled substances approved in the United States by FDA. Members of the organization also ordered through the Internet the active and inactive ingredients and colored dyes necessary to make the counterfeit pills.
- On September 1, 2016, a young woman who resided in Wellington, Florida, died after overdosing on counterfeit oxycodone pills. The pills contained a fentanyl analog, furanyl fentanyl, as the active ingredient. Furanyl fentanyl is an extremely powerful synthetic opioid, many times more powerful than street level heroin or oxycodone. An extensive investigation by a Federal task force including DEA, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), ICE-HSI, FDA-OCI, and local law enforcement identified 52-year-old Dr. Johnny Benjamin, an orthopedic surgeon practicing in Vero Beach, Florida, as the source of the counterfeit oxycodone pills that caused the young woman's death. The suspected source of the raw materials used in this operation was China. On July 6, 2018, Dr. Benjamin was sentenced to life in prison after having been convicted at trial of participating in a conspiracy to possess with intent to distribute furanyl fentanyl, hydrocodone, and oxycodone which resulted in death and other related crimes.
- On May 30, 2018, a joint investigation involving DEA, the Internal Revenue Service (IRS), Customs and Border Protection (CBP) and FDA-OCI resulted in charging two suburban Chicago residents with illegally selling fentanyl or fentanyl precursors obtained from China over the Internet. The defendants offered various controlled and non-controlled drugs for sale on their websites including the opioids fentanyl, oxycodone, and hydrocodone.
- FDA-OCI also recently assisted DEA in their investigation of a massive overdose outbreak in the Nashville, Tennessee area. To link counterfeit Percocet pills containing fentanyl obtained from China to the point of manufacture, FDA's Forensic Chemistry

Center (FCC) conducted an analysis of the tablet dies and punch tips seized from the suspects and compared them with counterfeit Percocet tablets obtained from the victims. The FDA-FCC used 3D image analysis to determine that the tablet debossing profiles and overall surface morphology of the counterfeit Percocet tablets were consistent with the seized tablet punch tips. This toolmark evidence was used in the successful prosecution of eight defendants linked to the manufacture and distribution of the counterfeit Percocet pills containing fentanyl that caused at least seven hospitalizations and one death.

- In November 2017 an FDA-OCI-led investigation in conjunction with the Postal Inspection Service and DEA uncovered a drug counterfeiting operation in Champaign, Illinois. In this case, a single defendant admitted to producing over 80,000 capsules of the synthetic opioid Tramadol with powders, gelatin capsules, and an encapsulating machine he purchased on the Internet from China. Beginning in 2013, the defendant operated an online pharmacy marketing and selling Tramadol capsules and other drug substances to customers throughout the United States.
- Just last month, an FDA-OCI led investigation resulted in the arrest and indictment of a San Diego resident known as “The Drug Llama” on a Dark Net marketplace. The suspect in this case is alleged to be responsible for shipping over 50,000 counterfeit oxycodone tablets containing fentanyl throughout the United States via the Dark Net marketplace Dream Market.
- Finally, to target the infrastructure supporting the illegal online sales of drugs, a series of recent FDA-OCI investigations has focused on credit card processors involved in a scheme known as “transaction laundering” or “factoring.” Transaction laundering occurs when legitimate merchant accounts are used to process transactions for another business. In June 2018, FDA-OCI’s investigation led to an indictment in the Western District of Pennsylvania charging a complex conspiracy in which the defendant opened credit card accounts in the names of shell companies and fake websites and used them to process payments for pharmaceutical drugs.

Outreach to Internet Stakeholders:

Online, at this moment, there are tens of thousands of websites offering illegal pharmaceutical drugs to Americans sourced from clandestine supply chains. FDA-OCI simply does not have the resources to investigate all the reports we receive regarding illegal online pharmacies.

Accordingly, we often send complaints about illegal activities to domain name registries and registrars. Many of the domain names linked to online pharmacies clearly indicate the function and purpose of the website; for example: buyhydrocodoneonline.com or buyklonopin.com, two domain name registrations we recently seized. We also see a host of frauds and non-delivery

schemes associated with the online sale of drugs. Although some registries and registrars are very responsive to our concerns, others have been much less so.

Accordingly, this past June, FDA convened Internet stakeholders, government entities, academic researchers, and advocacy groups at a one-day Online Opioid Summit ¹ to discuss ways to collaboratively take stronger action in combatting the opioid crisis by reducing the availability of illicit opioids online. The discussion during the summit was candid and, overall, there was a shared desire to prevent the illicit sale of opioids online. Stakeholders provided information about the unique nature of their platforms. Some described existing surveillance and security protocols they have implemented. We discussed challenges that stakeholders viewed as potential barriers to take further steps such as legal, policy, and regulatory concerns. The dialogue is ongoing and we are hopeful that raising the issue in this high-level forum caused many of these companies to think about their policies with regard to the use of their platforms to sell drugs.

Working with Foreign Partners:

FDA-OCI is a world leader in public-health law enforcement. Our experienced Special Agents act nimbly to pursue criminals who know no borders and callously disregard the rule of law and the public's health. We continue to expand our international outreach, with Special Agents permanently assigned to both Europol and at Interpol's Global Complex for Innovation, located in Singapore. Our agents also work closely with foreign counterparts through the Permanent Forum on International Pharmaceutical Crime.

Our agents often share our knowledge, expertise, and experience with other countries in areas such as cybercrime, transnational pharmaceutical trafficking, tampering, and clinical trial fraud. In 2018, FDA-OCI provided training to prosecutors, customs, police, and regulatory counterparts from over 13 countries and we anticipate additional training opportunities for a host of West African countries and countries in Southeast Asia later this year.

Each year, FDA participates in Operation Pangea, a global cooperative effort led by Interpol, to combat the unlawful sale and distribution of illegal and potentially counterfeit or substandard medical products on the internet. During Operation Pangea X, FDA sent 13 warning letters to the operators of 401 websites selling opioids. In addition, nearly 100 website domain names were seized during this operation. FDA import staff, in collaboration with other federal agencies, screened packages suspected of containing illegal drug products at international mail facilities in Chicago, Miami, and New York. These screenings resulted in nearly 500 parcels being detained.

Earlier this year, FDA hosted a meeting with a delegation from the Chinese Ministry of Public Security, specifically to learn about each country's approach to combatting counterfeit food, drugs, tobacco, and medical devices. The dialogue included mechanisms for sharing information

¹ <https://www.fda.gov/Drugs/NewsEvents/ucm608633.htm>.

and conducting coordinated investigations. In my experience, Chinese authorities are generally receptive to working with FDA-OCI and we have shared actionable intelligence regarding drug counterfeiting operations in China. The result of this information sharing, however, is not always clear.

Challenges

Conducting online investigations is not easy, and FDA has a narrow, but important role in combatting the online sale of opioids. For good or bad, much of the Internet ecosystem, including dark nets, have adapted and changed to build in anonymity. Public information about the owner of a domain name, known as “whois” data, is now often impossible to access with the implementation of the European General Data Protection Regulation (GDPR); servers can hide their location through third parties and cloud computing configurations; email can be encrypted and stored overseas; and cryptocurrencies hide the financial trail. Seizing domain names is not practical on a large scale. Once seized, the government has to pay a domain name registrar to hold the domain name indefinitely, otherwise it can be re-registered. Unlike FDA, manufacturers of illicit drugs do not need to consider legal treaties, jurisdictions, or conflicting legal frameworks. To help overcome such obstacles, we need to rely on cooperation, not only with our international partners such as China, but also with internet stakeholders, to find workable solutions to effectively combat illegal internet operations dealing drugs.

Conclusion

Thank you again for the opportunity to appear before you today and for your continued support of FDA’s critical law enforcement and regulatory mission. I am very proud to represent and work alongside some amazing public servants who are truly committed and passionate about protecting public health.

I appreciate your interest in combatting the trafficking of illegal fentanyl from China and its impact on our communities. I look forward to any questions.