August 21, 2019

# Advisory to the Chemical Manufacturing Industry on Illicit Activity and Methods Related to the Manufacturing of Fentanyl and Synthetic Opioids

Drug Trafficking Organizations (DTOs) purchase illicit fentanyl, fentanyl analogues, and other synthetic opioids, primarily from Chinese fentanyl suppliers, and prepare these drugs for individual use and redistribution. DTOs may increasingly seek these drugs from other sources and/or expand their acquisition of the precursors and equipment needed for clandestine synthesis.

This advisory should be shared with Chief Executive Officers, Chief Operations Officers, Chief Risk Officers, Legal Departments, Chief Compliance Officers, the Chemical/Laboratory Equipment Industry, and the Pharmaceutical Industry.

#### Introduction

The opioid crisis is a serious epidemic that requires a multidisciplinary approach including aggressive investigation and prosecution, in addition to collaboration with private sector partners in the fields of technology, health care, prevention, treatment, and education. Federal, state, local, tribal, and territorial partners must work together with the private sector to leverage resources in the fight against this deadly threat. The private sector can play a key role in combatting the opioid epidemic by working with law enforcement to identify the ways in which criminals are exploiting legal platforms for illicit means and referring criminal activity to law enforcement.

This advisory¹ is intended to broaden the public and private sectors' awareness of unique manufacturing characteristics of synthetic opioids, so that all stakeholders can partner in combatting the scourge of fentanyl and other synthetic opioids entering the United States and minimize their impact on our nation. This advisory provides private sector partners information to identify the various stages of illicit fentanyl manufacturing and redistribution; refer this activity to law enforcement partners when identified; and end trafficker acquisition and transfer of the tools needed to prepare these drugs for individual use. This advisory is intended to enhance awareness so as to disrupt the devastating trade in fentanyl and illicit synthetic opioids.

<sup>&</sup>lt;sup>1</sup>This advisory is also part of a larger, United States government Fentanyl advisory covering the movement, manufacturing, marketing, and monetary aspects of the trafficking of fentanyl and other synthetic opioids. The comprehensive 21st Century Drug Trafficking: Advisories on Fentanyl and Other Synthetic Opioids can be found here <a href="https://www.whitehouse.gov/briefings-statements/white-house-announces-actions-crack-trafficking-fentanyl-synthetic-opioids-better-position-private-sector-protect-homeland/">https://www.whitehouse.gov/briefings-statements/white-house-announces-actions-crack-trafficking-fentanyl-synthetic-opioids-better-position-private-sector-protect-homeland/</a>

There are two, largely separate supply chains for fentanyl, fentanyl analogues,² and other synthetic opioids in the United States: the licit international and domestic supply chain, which has significant government oversight and safeguards, and the illicit supply chain. Available information suggests that most fentanyl and fentanyl-related substances abused in the United States are illicitly synthesized abroad and trafficked into the United States via international mail, express consignment, or across the Southwest Border. The extent to which fentanyl originating overseas is synthesized in clandestine laboratories versus synthesized off-hours in facilities that legally manufacture pharmaceuticals in their own countries is unknown. Diversion of pharmaceutical fentanyl in the United States occurs on a small scale, with the diverted fentanyl intended for personal use and low-level street sales.

Within the United States, traffickers typically acquire synthetic opioids and process them for street sales by cutting with diluents; mixing with other drugs such as cocaine, heroin, or methamphetamine; or pressing into pill form with binders and diluents. Pills containing synthetic opioids are often sold under the guise of prescription opioids.

# **Typologies**

The predominant source of illicit fentanyl in the United States is manufactured in international clandestine synthesis laboratories. To date, the vast majority of precursors and finished illicit fentanyl in the Western Hemisphere has originated from China. Sources of illicit fentanyl fueling the opioid epidemic include (i) International or domestic clandestine laboratory synthesis and (ii) on a very limited scale International and domestic diversion. The licit and illicit use of the equipment necessary to prepare these highly potent drugs for individual use presents additional law enforcement challenges; these challenges are discussed in section (iii), Redistribution: pill presses/tableting machines, encapsulating machines, and binding agents.

<sup>&</sup>lt;sup>2</sup>While fentanyl analogues have a similar chemical structure to fentanyl, small structural changes result in a seemingly endless number of variations of the drug with similar effects and of potentially unknown potency.

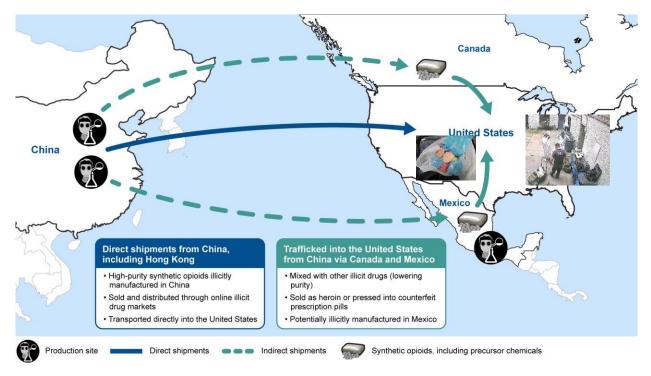


Figure 13,4

## **International or Domestic Clandestine Laboratory Synthesis**

Illicit fentanyl, fentanyl analogues, other synthetic opioids, and their immediate precursors are primarily produced overseas in countries with large pharmaceutical and chemical industries, particularly China. Manufacturers in other countries, such as India, the Netherlands, and Bangladesh, have the potential to become increasingly involved in supplying illicit synthetic opioids and their precursors. Synthetic opioids, in finished and raw form, are widely available for sale online through both domestic and international sellers on the Internet.<sup>5</sup> Illicit synthetic opioids are typically shipped through international mail or express consignment carriers directly to the United States or shipped to transnational criminal organizations (TCOs) in Mexico and Canada for later distribution.

<sup>&</sup>lt;sup>3</sup> See U.S. Government Accountability Office, Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess Their Efforts, March 10, 2018.

<sup>&</sup>lt;sup>4</sup> See Drug Enforcement Administration (DEA), Press Release: Black market pill manufacturing operation dismantled in Bronx apartment building; superintendent among three charged, <a href="https://www.dea.gov/press-releases/2018/10/09/black-market-pill-manufacturing-operation-dismantled-bronx-apartment">https://www.dea.gov/press-releases/2018/10/09/black-market-pill-manufacturing-operation-dismantled-bronx-apartment</a>, October 9, 2018.

<sup>&</sup>lt;sup>5</sup> The Internet is typically separated into three distinct parts: (i) the open Internet, also known as the Clearnet, which encompasses sites publicly accessible through search engines such as Google; (ii) the Deep Web, which consists of content not indexed and sites that cannot be found by normal search functions, such as paywall-protected pages; and (iii) the Darknet, which consists of many networks, and refer to areas of the Internet accessible only via specialized anonymizing software, such as the Tor network. (Sites only reachable through the Tor network are recognizable through their ".onion" URL domain suffix.) While Darknet content is varied, it is also home to hidden services such as criminal marketplaces that allow individuals to buy and sell illegal items, such as drugs, firearms, and other hazardous materials, with greater anonymity than is possible on the traditional Internet. Generally, these Darknet market websites use a variety of anonymizing and encryption technologies in an attempt to shield communications and transactions from interception and monitoring.

Synthesis of illicit fentanyl in countries bordering the United States or within the country may be increasingly attractive for DTOs. Instructions for manufacturing fentanyl and related substances are readily available on the Clearnet and Darknet, as is access to precursor chemicals and lab equipment. As authorities improve their ability to detect and interdict imported synthetic opioids and their precursors from unlawful sources, traffickers may look for opportunities to mitigate interdiction risk by synthesizing these substances closer to the U.S. market.

There have been relatively few takedowns of illicit fentanyl labs in Mexico and the United States in recent years, but DTOs of varying sizes and sophistication may increasingly try to produce their own fentanyl to increase profitability. As these illicit actors procure the necessary chemicals, and lab equipment, law enforcement would benefit from the reporting of suspicious activity that might indicate illicit fentanyl synthesis or suspicious distribution of precursor chemicals. Purchases of commonly used laboratory items that could be used for domestic synthesis—either alone or in combination with necessary precursors, chemicals, and redistribution tools—by unusual customers (e.g., individuals or businesses without an obvious connection to the pharmaceutical or chemical business) that are delivered to atypical locations like a residence, may indicate nefarious activity and should be reported to law enforcement.

The most common synthesis route for fentanyl uses two key precursor chemicals: 4-anilino-N-phenethyl-4-piperidine (ANPP) and N-phenethyl-4-piperidone (NPP). ANPP is a Schedule II controlled substance, and NPP is a List I precursor chemical. As common precursor chemicals come under tighter international scrutiny, illicit actors are exploring alternative methods of making fentanyl and buying chemicals to make their own precursors. These chemicals include propionic anhydride—a List I precursor chemical—piperidone, propionyl chloride, and aniline.

#### **International and Domestic Diversion**

The Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) regulate and oversee the legitimate pharmaceutical manufacture of fentanyl and other opioids for the United States market.<sup>6</sup> Accordingly, controlled substances containing fentanyl diverted from the legitimate prescription drug supply chain represents an insignificant part of the U.S. illicit fentanyl market.

The Controlled Substances Act (CSA) provides DEA numerous tools to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical,

<sup>&</sup>lt;sup>6</sup> For example, under U.S. federal law, fentanyl is a Schedule II controlled substance, which is lawfully produced and distributed in the United States by manufacturers of prescription drugs approved by FDA and is widely used in medicine.

commercial, and scientific needs. The CSA requires handlers of controlled substances to register with the DEA and imposes specific obligations to establish effective safeguards to prevent and detect diversion, maintain records, make periodic reports, and comply with DEA inspection requirements. Failure to comply with these requirements can result in administrative, civil, and/or criminal sanctions.

# Pill Presses/Tableting Machines, Encapsulating Machines, and Binding Agents

Clandestine production of fentanyl pills generally involves pressing previously manufactured fentanyl powder into tablets using tableting machines or pill presses. Traffickers also use encapsulating machines to make capsules containing fentanyl. Equipment that may indicate milling operations includes mixers, grinders, air purifiers, scales, packaging, and sealing equipment, and punches and dies (see Figure 3-7).

Federal law requires people who buy or sell pill presses or encapsulating machines to report these transactions to DEA. The notification of any domestic regulated transaction in a tableting machine or an encapsulating machine must be made orally to the Special Agent in Charge (SAC) of the DEA Divisional Office for the area in which the regulated person making the report is located when the order is placed with the seller. The regulated person must also file a report of the transaction to DEA via the DEA Form 452 through the DEA Diversion Control Division's secure network application within 15 calendar days after the order has been shipped by the seller.

<sup>&</sup>lt;sup>7</sup> *Pill press* is the commonly used name for tableting machines. A tableting machine is any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets. These machines come either as hand-held (manual), desktop, or floor model (manual or electric). The machines produce tablets at a rate of several tablets per hour with a manual hand held machine to the electronic floor model that can produce millions of dosages per hour.

<sup>&</sup>lt;sup>8</sup> Encapsulating machine is any manual, semi-automatic, or fully automatic equipment which may be used to fill shell or capsules with any powdered, granular solids, or semi-solid material, or liquid material.

<sup>&</sup>lt;sup>9</sup> For additional details on the marketing of pill presses and parts refer to the 21st Century Drug Trafficking: "Marketing Advisory" on Fentanyl and Other Synthetic Opioids (Tab B). A summary of the 21st Century Drug Trafficking: Advisories on Fentanyl and Other Synthetic Opioids, which includes links to each advisory, can be found here: <a href="https://www.whitehouse.gov/wp-content/uploads/2019/08/White-House-Fentanyl-Advisories-Summary.pdf">https://www.whitehouse.gov/wp-content/uploads/2019/08/White-House-Fentanyl-Advisories-Summary.pdf</a>





Figure 2<sup>10</sup> Figure 3<sup>11</sup>

Pill presses or encapsulating machines that are imported into the United States without the proper notification are subject to interception, seizure, and destruction by U.S. Customs and Border Protection (CBP). This equipment is also subject to forfeiture by the DEA.

The punches and dies used to produce counterfeit pharmaceutical pills are typically trademarked, and the use of these without permission from the trademark holder violates the law. It is also an offense under the CSA, subject to imprisonment up to four years, to possess, distribute, manufacture, import, or export any tableting or encapsulating machine, chemical, equipment, or material knowing, intending, or having reasonable cause to believe it will be used to manufacture a controlled substance or listed chemical in violation of the provisions of the CSA. 21 U.S.C. § 843(a)(6)–(7).





Figure 412

 $<sup>^{\</sup>rm 10}$  Images provided by the Drug Enforcement Administration on 11 April 2019.

<sup>&</sup>lt;sup>11</sup> See DOJ DEA's 2018 National Drug Threat Assessment (NDTA), https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20%5Bfinal%5D%20low%20resolution11-20.pdf, reviewed on 1 July 2019.

<sup>&</sup>lt;sup>12</sup>Image provided by the Drug Enforcement Administration on 11 April 2019.

<sup>&</sup>lt;sup>13</sup> Image provided by the Drug Enforcement Administration on 11 April 2019.



Figure 6 14



Figure 7 15

#### **Case Studies**

Example of International Fentanyl Traffickers Using Varying Routes to the United States

In October 2017, the Department of Justice (DOJ) announced the unsealing of indictments against Chinese nationals and their North American-based traffickers and distributors for separate conspiracies to distribute large quantities of illicit fentanyl and fentanyl analogues and other opiate substances in the United States. In one case, U.S.-based distributors received fentanyl and fentanyl analogues that were sent from China directly and via transshipment countries to the United States. The distribution of the fentanyl and fentanyl analogues in the United States resulted in the serious bodily injury or death of numerous victims.<sup>16</sup>

Example of a Chinese Fentanyl Global Drug Trafficking Organization

In August 2018, DOJ announced the indictment in the Northern District of Ohio (Cleveland) of leaders of the Zheng DTO, alleged to be led by a man known by the alias Gordon Jin and his father. These traffickers allegedly manufactured more than 250 types of synthetic drugs in China, including synthetic opioids and fentanyl analogues, which were distributed in more than 25 countries and 37 U.S. states. These individuals are the first manufacturers and distributors of illicit fentanyl and other opiate substances to be designated as Consolidated Priority Organization Targets, i.e. "command and control" elements of a prolific international drug trafficking and money laundering organization.<sup>17</sup>

<sup>&</sup>lt;sup>14</sup> Examples of tablet punches provided by the Drug Enforcement Administration on 11 April 2019.

<sup>15</sup> Examples of tablets made with different punches and dies provided by the Drug Enforcement Administration on 11 April 2019.

<sup>&</sup>lt;sup>16</sup> See DOJ Press Release: <u>Justice Department Announces First Ever Indictments Against Designated Chinese Manufacturers of Deadly Fentanyl and Other Opiate Substances</u>, October 17, 2017.

<sup>&</sup>lt;sup>17</sup> See DOJ Press Release: <u>Two Chinese Nationals Charged with Operating Global Opioid and Drug Manufacturing Conspiracy Resulting in Deaths</u>, August 22, 2018.

Examples of Domestic Counterfeit Fentanyl Pill Manufacturing Operations

In October 2018, the Bronx District Attorney announced the indictment and arrest of three individuals in connection with an alleged conspiracy to produce and distribute black market pills containing heroin, fentanyl, and methamphetamine. The search revealed a pill manufacturing operation, complete with a pill press machine, pill press imprints designed to create oxycodone markings, multiple surgical masks, and a vacuum sealer inside a bathroom.18

The FDA's Office of Criminal Investigations led an investigation in Northern California that dismantled 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 markings of FDA licit drugs.<sup>19</sup>

In March 2018, the FDA's Office of Criminal Investigations assisted DEA in its investigation of a massive overdose outbreak near Nashville, Tennessee. FDA's Forensic Chemistry Center was able to link counterfeit Percocet pills obtained from the victims to the point of manufacture in China by analyzing tablet dies and punch tips seized from the suspects.<sup>20</sup>

# **Red Flags**

Chemical companies should exercise caution when dealing with new customers or abnormal attempts to acquire the combination of chemicals used to synthesize fentanyl in a clandestine laboratory.



- 1. The 30 chemical reactants reported in literature for the several possible methods of fentanyl synthesis are:21
- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (fentanyl)
- N-phenyl-1-(2-phenylethyl)-4-piperidinamine
- N-[1-(2-phenylethyl)-4-piperidinylidene]-benzenamine
- 1-(2-phenylethyl)-4-piperidinone

<sup>&</sup>lt;sup>18</sup>See DEA Press Release: Black market pill manufacturing operation dismantled in Bronx apartment building; superintendent among three charged, October 9, 2019.

<sup>&</sup>lt;sup>19</sup>Burke, Daniel G., 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 Service, "Statement Before the Caucus on International Narcotics Control", United States Senate, October 2, 2018.

<sup>&</sup>lt;sup>20</sup>See Food and Drug Administration Office of Criminal Investigations, U.S. Department of Justice Press Release, "Massive Overdose Outbreak in Murfreesboro Left One Person Dead and More than 20 Hospitalized", March 27, 2018.

<sup>&</sup>lt;sup>21</sup> With the exception of the first chemical listed, fentanyl, one or more reactants listed above are necessary for fentanyl synthesis. Please refer any questions related to suspicious acquisition, delivery location, or combination of reactants ordered to DEA per reporting instructions below.

# 21st Century Drug Trafficking: "Manufacturing Advisory" on Fentanyl and Other Synthetic Opioids (Tab

- N-phenyl-N-[1-(phenylmethyl)-4-piperidinyl]-propanamide
- 1-(phenylmethyl)-4-piperidinone
- N-phenyl-1-(phenylmethyl)-4-piperidinamine
- N-phenyl-N-4-piperidinyl-propanamide
- N-phenyl-4-piperidinamine
- N-(1-cyano-4-piperidinyl)-N-phenyl-propanamide
- N-(1-methyl-4-piperidinyl)-N-phenyl-propanamide
- 1-methyl-N-phenyl-4-piperidinamine
- N-(3-methoxy-3-oxopropyl)-N-(2-phenylethyl)-β-alanine methyl ester
- N-(3-ethoxy-3-oxopropyl)-N-(2-phenylethyl)-β-alanine ethyl ester
- propanoyl chloride
- propanoyl bromide
- propionic anhydride
- propanoic acid
- benzeneethanol
- benzeneacetic acid
- (2-bromoethyl)-benzene
- (2-chloroethyl)-benzene
- benzeneacetaldehyde
- benzenamine
- 4-piperidinone
- 1-methyl-4-piperidinone
- 2-propenoic acid, methyl ester
- 2-propenoic acid, ethyl ester
- benzenemethanamine
- benzeneethanamine



2. Laboratory equipment distributors and online market places should be suspicious of non-traditional customers and locations ordering items that could be used to set up a large-scale clandestine fentanyl synthesis laboratory. The following equipment has been associated with larger-scale clandestine synthesis of synthetic opioids.

Equipment	Suspect size
Buchner funnel	≥ 12 cm diameter
Filter paper	≥ 12 cm diameter
Separatory funnel	≥ 2 liters
Erlenmeyer flask	≥ 2 liters
round bottom flask	≥ 2 liters
heating mantle	≥ 2 liters
(pilot plant) reactor	≥ 2 liters
Distillation column (any length)	Joint sizes 19/22;24/40;35/50; or ball point
condenser (any length)	Joint sizes 19/22;24/40;35/50; or ball point
organic glassware kit	Joint sizes 19/22;24/40;35/50; or ball point
(chromatography) column	≥ 6cm diameter; any length
rotary evaporator	Any
addition funnel	≥ 2 Liters
magnetic stirrer	Any
hotplate/w magnetic stirring	Any



- 2. The importation and domestic movement of pill presses, encapsulating machines, necessary binding agents, and dies can shed light on suspicious activity related to pill mill operations. Some red flags are:
  - Non-DEA registrants ordering the precursor chemicals used to manufacture illicit fentanyl.
  - The ordering of punches and dies for legitimate pharmaceutical products via the Internet by individuals.
  - Imports, exports, and domestic movement of machines not being reported to DEA via the DEA Form 452.
  - Importation of large quantities of binding agents such as microcrystalline cellulose and magnesium stearate.



4. Domestic suppliers should be on the watch for suspicious counterparties. The CSA generally prohibits importing Schedule I and II controlled substances (except for research and certain other legitimate purposes). Likewise, domestic suppliers cannot conduct business involving controlled substances with individuals or business entities who are unable to provide documentation verifying their DEA registration or other identification as applicable.

## **Reminder of Regulatory Obligations**

Requirements for the importation, exportation, or distribution of tableting and encapsulating machines can be found in the Code of Federal Regulations at:

- 21 CFR 1300.02(b) defines an encapsulating machine as "Any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material."
- 21 CFR 1300.02(b) defines a tableting machine as "any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets."
- 21 CFR 1310.03(a) states that "each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by 21 CFR 1310.04 and file reports as specified by 21 CFR 1310.05."
- 21 CFR 1310.04(a) states that "every record required to be kept subject to 21 CFR 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for 2 years after the date of transaction."
- 21 CFR 1310.05 describes the reporting requirements for listed chemicals, tableting machines, and encapsulating machines.
- 21 CFR 1310.06 describes the content requirements for records and reports regarding listed chemicals, tableting machines, and encapsulating machines.
- 21 CFR 1310.07 describes the proof of identity that regulated persons must obtain from the other party when engaging in a regulated transaction.

The United States Federal Food, Drug, and Cosmetic Act (FDCA) prohibits doing or causing the following acts:

- The introduction into interstate commerce of any drug that is "misbranded." See 21 U.S.C. § 331(a).
  - A drug may be deemed "misbranded" for numerous reasons, including if its labeling is false or misleading or if it is an imitation of another drug. See 21 U.S.C. § 352(a), (i)(2).
- The receipt in interstate commerce of any drug that is misbranded and the delivery or proffered delivery of such drug for pay or otherwise. See 21 U.S.C. § 331(c).
- The introduction into interstate commerce of a new drug that has not been approved by the FDA. See 21 U.S.C. § 331(d).

• The doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. See 21 U.S.C. § 331(i)(3).

Title 18 of the United States Code also provides:

- 18 U.S.C. § 545 makes it illegal to fraudulently or knowingly import or bring into the United States any article "contrary to law."
- 18 U.S.C. §§ 1956 and 1957 prohibit the laundering of money derived from specified unlawful activities, including smuggling and violations of the CSA.

The CSA and its implementing regulations establish the following obligations on the lawful handling of controlled substances.

- Registration.
  - o 21 U.S.C. §§ 822, 823, 957, and 958
  - o 21 CFR parts 1301 and 1312
- Security.
  - o 21 U.S.C. §§ 821, 823, and 871(b)
  - o 21 CFR 1301.71-1301.93
- Labeling and packaging.
  - o 21 U.S.C. § 825
  - o 21 CFR part 1302
- Inventory.
  - o 21 U.S.C. § 827
  - o 21 CFR 1304.03, 1304.04, and 1304.11
- Records.

- o 21 U.S.C. § 827
- o 21 CFR parts 1304, 1312, and 1317
- Reports.
  - o 21 U.S.C. § 827
  - o 21 CFR parts 1304 and 1312
- Order Forms.
  - o 21 U.S.C. § 828
  - o 21 CFR part 1305
- Importation and Exportation.
  - o 21 U.S.C. §§ 952, 953, 957, and 958
  - o 21 CFR part 1312
- Quotas.
  - 21 U.S.C. §§ 826 and 842(b)
  - 21 CFR part 1303
- *Liability.* Any person who violates the CSA may be subject to administrative, civil, and/or criminal sanctions.
- 21 U.S.C. § 841 generally makes it illegal to knowingly and intentionally distribute a controlled substance in a manner not authorized by the CSA.
- 21 U.S.C. § 843 includes several crimes, including activities with chemicals, equipment, and materials with requisite criminal intent with respect to illegal drug or chemical production.
- 21 U.S.C. § 952 makes it illegal to import a controlled substance into the United States except under the circumstances provided therein.

# **Reporting Instructions**

If you suspect counterfeit or diverted prescription pills are being trafficked, report suspected criminal activity to:

<u>Drug Enforcement Administration:</u> Please refer relevant information to the nearest DEA field office or through the DEA tip line at <a href="https://www.dea.gov/submit-tip">https://www.dea.gov/submit-tip</a>.

FDA's Office of Criminal Investigations (FDA-OCI): Please call 1-800-551-3989 or visit www.fda.gov/oci.

<u>Drug Notification of Illegitimate Product to FDA (Form FDA 3911)</u> for finished drugs. Under section 582 of the FDCA, 21 U.S.C. § 360eee-1, manufacturers, re-packagers, wholesale distributors, and dispensers are required to notify FDA and all immediate trading partners within 24 hours of determining a product is illegitimate. <u>FDA drug notifications page:</u> <a href="https://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm">https://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm</a>.

If you suspect the importation or domestic distribution of a tableting or encapsulating machine(s) that have not been reported to the DEA, or suspect that they are being used or sold for illicit purposes, report this suspicious activity to DEA. Additionally, if you suspect that dies and binding agents are being purchased or used for illicit synthesis of a controlled substance or listed chemical(precursor purchases, lab equipment sent to suspicious locations, binding agents, etc.), report this to DEA.

# Federal Bureau of Investigation:

The FBI encourages referrals of activity related to illicit fentanyl manufacturing, processing, or trafficking to the nearest FBI field office (<a href="https://www.fbi.gov/contact-us/field-offices">https://www.fbi.gov/contact-us/field-offices</a>) or embassy representative (<a href="https://www.fbi.gov/contact-us/legal-attache-offices">https://www.fbi.gov/contact-us/legal-attache-offices</a>) nearest you, 24 hours a day, seven days a week, or report suspected crimes through the FBI tip line at: <a href="https://www.fbi.gov/tips">https://www.fbi.gov/tips</a>.

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