(U) Fentanyl: A Complex and Expanding Threat in the United States

(U) Event

(U//DSEN) Fentanyl is a Schedule II synthetic opioid originally developed to serve as both an analgesic (painkiller) and an anesthetic; however, its strong opioid properties have made it an attractive drug of abuse in the United States. Fentanyl, in its licit form, is diverted from the market on a small scale for personal use or sale. Illicitly manufactured and trafficked fentanyl is responsible for the current domestic crisis. Fentanyl, fentanyl-related compounds, and the precursor chemicals needed to produce these substances originate in China and transit Mexico or Canada enroute to U.S. markets. It is believed that illicit fentanyl manufacturing is occurring in Mexico. Moreover, small-scale production facilities have been discovered in the United States and Canada.

(U) Significance

(U//DSEN) Fentanyl will remain an extremely dangerous public safety threat while trafficking of non-pharmaceutical fentanyl continues in the United States. Fentanyl poses not only a threat to users, but also to law enforcement personnel and postal service employees because minute amounts of the drug are lethal and can be inadvertently inhaled or absorbed through the skin. Although many drug users avoid fentanyl, others actively seek it because it provides a strong and intense high. In 2015, traffickers expanded the reach of fentanyl beyond traditional white powder heroin markets as evidenced by the increased presence of fentanyl detected in counterfeit prescription pills and the drug has also been manipulated to appear as black tar heroin. In the near term, the fentanyl market will continue to expand as it is introduced to witting and unwitting users.
(U) Details

(U//DSEN) The map below depicts the number of fentanyl exhibits reported by state during calendar year 2015, according to National Forensic Laboratory Information System (NFLIS).\(^1\) The state with the most fentanyl exhibits was Ohio, with 3,861 exhibits. The data reveal that every state had at least one fentanyl exhibit during 2015; however, the largest concentrations are in the same areas with long-standing white powder heroin markets.

(U) Figure 1. Fentanyl Exhibits in NFLIS 2015.

Source: National Forensic Laboratory Information System

\(^1\) (U//FOUO) The NFLIS is a Drug Enforcement Administration (DEA) program that systematically collects drug chemistry analysis results, as well as other related information, from cases analyzed by state, local, and federal forensic laboratories. These laboratories analyze substances secured in law enforcement operations across the country. NFLIS offers a valuable resource for monitoring illegal drug abuse and trafficking, including the diversion of legally manufactured pharmaceutical drugs into illegal markets. NFLIS data are used to support drug regulatory and scheduling efforts as well as to inform drug policy and drug enforcement initiatives both nationally and in local communities. Data in the NFLIS database are based on case- and item/exhibit-level information analyzed by forensic laboratories. It should be noted that NFLIS data are not “real time,” as participating laboratories report to NFLIS on different schedules and delays in evidence analysis can create backlogs on occasion. Moreover, during exhibit analysis, laboratories may identify several distinct drug reports within an exhibit; therefore, a single exhibit reported to NFLIS may include several individual drug reports. All identified distinct drug reports are stored in the NFLIS database. Finally, drug evidence that is seized by law enforcement but not analyzed by participating laboratories is not included in the NFLIS system.
According to NFLIS data, Figure 2 depicts the amount of fentanyl in grams seized in each state from January 2015 to June 2016. California had the highest total with 172 kilograms seized, followed by Georgia (42 kilograms), New Jersey (40.5 kilograms), Massachusetts (30.8 kilograms), and Ohio (19 kilograms). The elevated seizure amounts in New Jersey, Massachusetts, and Ohio are expected because of the mature heroin markets in these states. The large seizure levels in California and Georgia are the result of smuggling routes, largely associated with the Southwest Border, that transit these states en route to Eastern and Midwestern markets. As a result, large seizures of wholesale (multi-kilogram) amounts of fentanyl have occurred in these states. This is further depicted with the shading in the states of Texas, Oklahoma, Missouri, and Illinois—as illicit manufactured fentanyl enters Texas across the Southwest Border and is smuggled into Midwestern markets.

(U//LES) Figure 2. Fentanyl Seizure Quantities by State in NFLIS: January 2015 – June 2016.

Source: National Forensic Laboratory Information System

(U//LES) Note: The seizure amounts provided in Figure 2 should not be considered “all-inclusive,” as some participating laboratories submitted drug exhibit reports without providing the amount of drug seized. For the states with no color shading (Oregon, Wyoming, South Dakota, Nebraska, and Arkansas), fentanyl was identified in exhibits submitted from these states, but the reporting laboratories did not provide the seizure amount, thus the "presence detected, weight not provided" notation in the map legend.
According to NFLIS and National Seizure System (NSS) data, seizures of fentanyl, fentanyl-related compounds, and fentanyl precursor chemicals have continued to increase in the United States during the last two fiscal years (FYs):

- **FY 2015**: 167.7 kilograms fentanyl/51 kilograms precursor chemicals
- **FY 2016**: 362.9 kilograms fentanyl/79.1 kilograms precursor chemicals  
  (1\textsuperscript{st}-3\textsuperscript{rd} quarters)

During 2016, there have been several large seizures of wholesale quantities of fentanyl in the United States:

- **March 2016** – DEA New Jersey Field Division seized 20 kilograms of fentanyl powder, a pill press machine, and dye powder in Clifton, New Jersey.
- **March 2016** – Bartow County, Georgia, law enforcement officers seized 40 kilograms of fentanyl powder hidden in various compartments of a pickup truck during a traffic stop.
- **June 2016** – A DEA New York Field Division investigation resulted in the seizure of 24 kilograms of fentanyl powder in Burlington, New Jersey.
- **September 2016** – U.S. Border Patrol agents at the Pine Valley, California, checkpoint seized 8 kilograms of fentanyl secreted in a hidden vehicular compartment.
- **September 2016** – The Tennessee Highway Patrol seized 29 kilograms of a heroin/fentanyl mixture hidden in a semi-trailer during a highway traffic stop.

Analysis of NFLIS fentanyl exhibit data by the DEA Diversion Control Division, Drug and Chemical Evaluation Section (DRE), from 2012 through 2015 revealed the overall source: Bartow County Police Department.
number of fentanyl exhibits increased significantly during this timeframe, as did the amount of exhibits containing a mixture of fentanyl and heroin. Additional exhibits containing fentanyl with cocaine and heroin/cocaine also increased between 2014 and 2015; but, at much lower rates than exhibits containing just fentanyl or a combination of fentanyl and heroin.

(U) Figure 4. Total Number of Fentanyl Seizures by Type and Year, 2012 – 2015.

![Graph showing total number of fentanyl seizures by type and year from 2012 to 2015.](source)


(U//DSEN) As of early October 2016, the DEA Special Testing and Research Laboratory (SFL1) has analyzed more than 170 fentanyl or fentanyl-related compound exhibits (162 powders, 9 tablets, and 1 blotter paper) from 92 different seizures. The average purity of bulk fentanyl hydrochloride (HCl) seized at the Southwest Border is approximately 7 percent. The most common diluents or adulterants are lactose, mannitol, and dipyrone. Fentanyl profiling methodologies developed by SFL1 have also revealed the fentanyl precursor chemical 4-ANPP is being clandestinely manufactured, as well as being purchased from commercial vendors.

(U//DSEN) In addition, SFL1 analysis revealed that at least one fentanyl trafficking organization has gained access to film-coating technology to produce film-coated counterfeit M-30 tablets containing fentanyl. M-30 is the logo for Mallinckrodt’s generic 30-milligram oxycodone tablet. The compressed tablets with a single score mark and box logo were well-made and are a counterfeit of the commercial product (see Figure 5). Film-coating technology is a sophisticated commercial process requiring...
dedicated equipment and a moderate degree of manufacturing technology and methodology experience. Film-coated counterfeit tablets are rarely seen in the controlled substance street market. SFL1 has only seen two or three samples of film-coated counterfeit tablets containing a controlled substance in the last three decades. However, film-coating has become very popular in the legitimate pharmaceutical industry; therefore, used machinery and personnel with knowledge to operate it have become readily available.

(U) Figure 6. Confirmed and Unconfirmed Cases of Carfentanil – 2016.

*Cases of carfentanil are confirmed when the drug is positively identified in a forensic laboratory using analytical reference standards.

Source: DEA

(U) Carfentanil

(U) Carfentanil is a synthetic opioid controlled federally as a Schedule II substance under the U.S. Controlled Substances Act and is a fentanyl derivative not approved for use in humans. Carfentanil is used as a tranquilizing agent by veterinarians in zoos and large wildlife environments for use on elephants and other large mammals. The lethal dose range for carfentanil in humans is unknown; however, carfentanil is approximately 100 times more potent than fentanyl, which is lethal at the 2 milligram range or less. The arrival of carfentanil in U.S. illicit drug markets has the potential to critically exacerbate the fentanyl and larger opioid crisis in the United States. If carfentanil is further trafficked in illicit U.S. drug markets, overdoses and overdose deaths will increase significantly due to dosing issues.
(U//DSEN) As of early October 2016, SFL1 has been notified of 413 confirmed identifications of carfentanil in drug samples tested by laboratories in the following U.S. states—Florida, Illinois, Kentucky, Michigan, Ohio, Rhode Island, Georgia, Indiana, and Washington (in 2014). In addition, SFL1 has been notified of suspected carfentanil samples in Pennsylvania and New York, but is not aware of a confirmed identification. The most commonly encountered form is powder, but carfentanil has also been seen in capsule-form, tablets and liquid samples. In addition, carfentanil has been identified in blood samples from several overdose deaths in West Virginia. Carfentanil is most commonly identified either as the only active component or in a mixture with heroin. Carfentanil has been encountered in a number of different mixtures, to include those with fentanyl; furanyl fentanyl; heroin and fentanyl; and heroin and furanyl fentanyl.

(U) According to the DEA Diversion Control Division’s Regulatory Section (DRG), there is no indication the carfentanil in U.S. illicit drug markets is being diverted from DEA registrants, lawful domestic manufacturing, or lawful imports. The carfentanil that has been seized in multiple U.S. states is believed to be arriving from foreign sources via illicit networks and dark web purchases.

(U) Any carfentanil that is imported into the United States is strictly controlled by the DEA Diversion Control Division and the DEA Registrant Program. According to DRG reporting, the one DEA-registered importer of carfentanil that was bringing a Food and Drug Administration (FDA)-approved carfentanil product into the United States has stopped importing the product this year and is transitioning to another FDA-approved product for its legitimate veterinary needs. There are approximately 20 firms (manufacturers, distributors, importers, and exporters) that maintain a registration with DEA that include the drug code for carfentanil. Only 10 import permits have been issued in 2016; however, according to DEA records, no carfentanil has been imported in 2016.