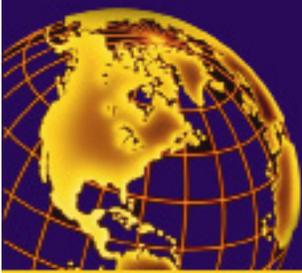


Counterfeit Prescription Pills Containing Fentanyls: A Global Threat



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BRIEF

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This product was prepared by the DEA Strategic Intelligence Section. Comments and questions may be addressed to the Chief, Analysis and Production Section at dea.onsi@usdoj.gov.

Executive Summary

Hundreds of thousands of counterfeit prescription pills, some containing deadly amounts of fentanyl^a have been introduced into U.S. drug markets, exacerbating the fentanyl and opioid crisis. The sudden arrival of wholesale amounts of counterfeit prescription drugs containing fentanyl will result in an increase in overdoses, deaths, and opiate-dependent individuals. Motivated by enormous profit potential, traffickers exploit high consumer demand for prescription medications by producing inexpensive, fraudulent prescription pills containing fentanyl. The equipment and materials necessary to produce these counterfeit drugs are widely available online for a small initial investment, greatly reducing the barrier of entry into production for small-scale drug trafficking organizations (DTOs) and individual players. In addition, small-scale fentanyl production laboratories have been identified in the United States and Canada, and fentanyl production and milling laboratories are believed to be operating in Mexico, indicating a vast expansion of the traditional illicit fentanyl market.

Details

Fentanyl in the United States

The United States is in the midst of a fentanyl crisis, with law enforcement reporting and public health data indicating higher availability of fentanyl, increased seizures of fentanyl, and more known overdose deaths from fentanyl than at any other time since the drugs were first created in 1959. From August 2013 through the end of 2015, U.S. law enforcement agencies seized at least 239 kilograms of illicitly produced fentanyl. Although the total quantity of fentanyl seized may appear small relative to other illicit drugs, fentanyl is more lethal to potential users than other illicit drugs due to its extremely small lethal dose (approximately 2 milligrams). Between late 2013 and late 2014 alone, there were over 700 deaths related to fentanyl in the United States, and this figure is largely believed to be underestimated due to variations in state reporting techniques and deaths being attributed to heroin. In addition to being deadly to users, fentanyl poses a grave threat to law enforcement officials and first responders, as a lethal dose of fentanyl can be accidentally inhaled or absorbed through the skin.

Fentanyl is traditionally mixed into or sold as heroin, oftentimes without the customer's knowledge. Since 2014, U.S. law enforcement agencies have been seizing a new form of fentanyl—counterfeit prescription opioid pills containing fentanyl. The counterfeit pills often closely resemble the authentic medications they were designed to mimic, and the presence of fentanyl is only detected upon laboratory analysis.

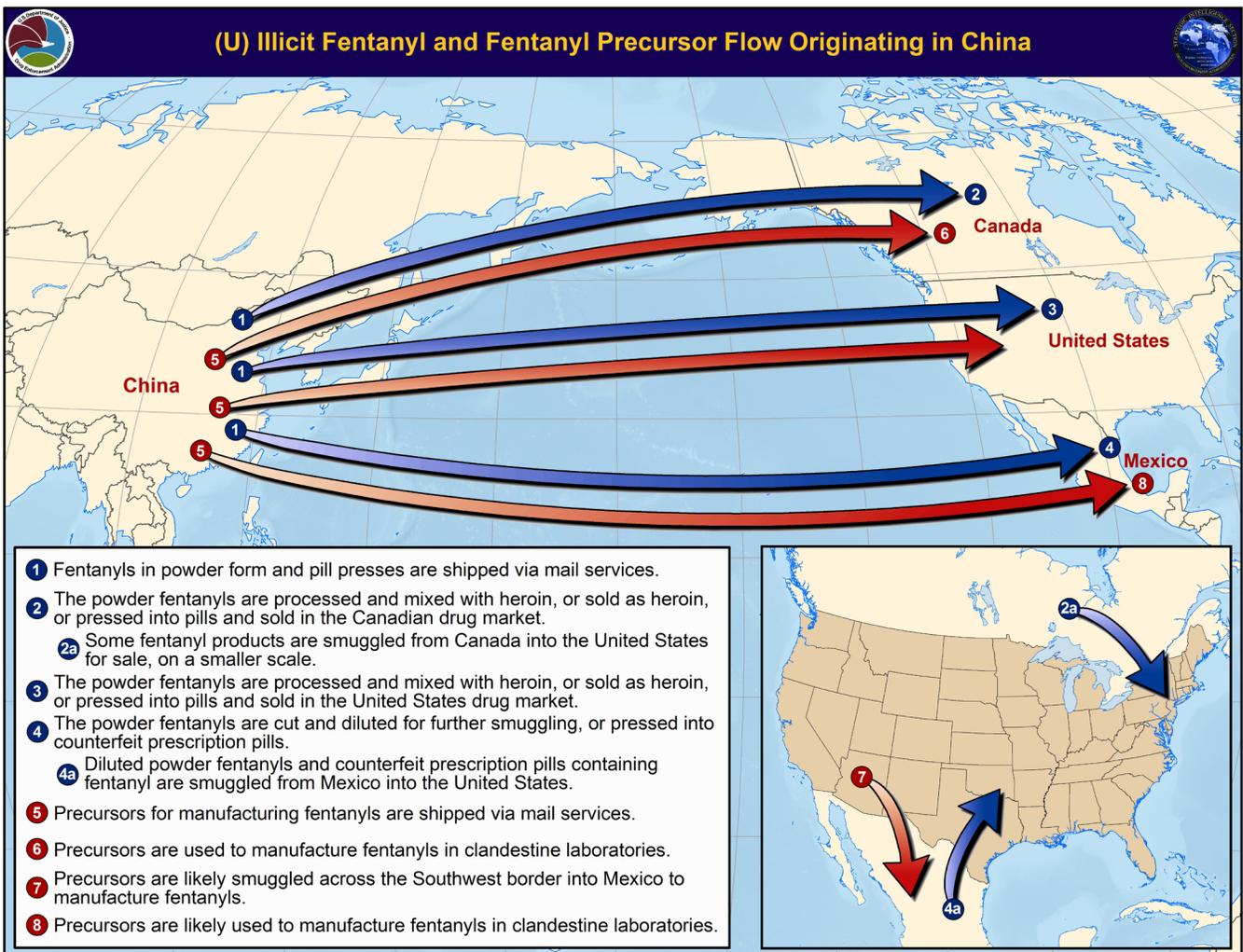
The current fentanyl crisis is multi-faceted and involves a global supply of fentanyl and related materials. Counterfeit pills containing fentanyl are smuggled into the United States from Mexico and Canada (see Figure 1). Clandestine pill press operations also occur in the United States. Traffickers usually purchase powdered fentanyl and pill presses from China to create counterfeit pills to supply illicit U.S. drug markets. Under U.S. law, the Drug Enforcement Administration (DEA) must be notified of the importation of a pill press. However, foreign pill press vendors often mislabel the equipment or send it disassembled to avoid law enforcement detection.

- March 2016 - The DEA Los Angeles Field Division (FD) executed a federal search warrant at a residential location and seized a counterfeit prescription pill operation using fentanyl and other synthetic opiates. Three pill presses, powder mixing equipment, ventilation equipment, and numerous buckets filled with powder were discovered (see Figure 2).

^a When used in this publication, the term “fentanyl” includes fentanyl and related variants such as acetyl fentanyl, butyrfentanyl, and furanylfentanyl. Due to variations in the legal and scientific definitions of analogs, it may be inaccurate to call all fentanyl varieties a fentanyl analog.

- January 2016 - The DEA New Jersey FD arrested a counterfeit prescription pill producer after making undercover purchases of approximately 6,000 pills. The pills were manufactured to look like 30 milligram oxycodone pills, but contained either fentanyl citrate or acetyl fentanyl and were produced domestically in the trafficker’s New York residence.
- From early 2014 through late 2015 the DEA New England Field Division seized approximately 7,000 counterfeit 30 milligrams oxycodone pills from a DTO. Laboratory analysis indicated that the pills did not contain oxycodone, but rather fentanyl or combinations of fentanyl or heroin.
- May 2015 - The Tennessee Bureau of Investigation issued a public warning concerning the presence of counterfeit fentanyl pills on the market. A law enforcement officer seized several pills that appeared to be 30 milligram oxycodone tablets; however, laboratory analysis indicated that the pills instead contained fentanyl (see Figure 3).

Figure 1: Illicit Fentanyl and Fentanyl Precursor Flow Originating in China



Source: DEA

*Arrows do not represent specific transportation routes.

Figure 2: Pill Presses Used to Manufacture Counterfeit Prescription Pills in Los Angeles.



Source: DEA

Figure 3: Counterfeit 30 Milligram Oxycodone Pills Containing Fentanyl.



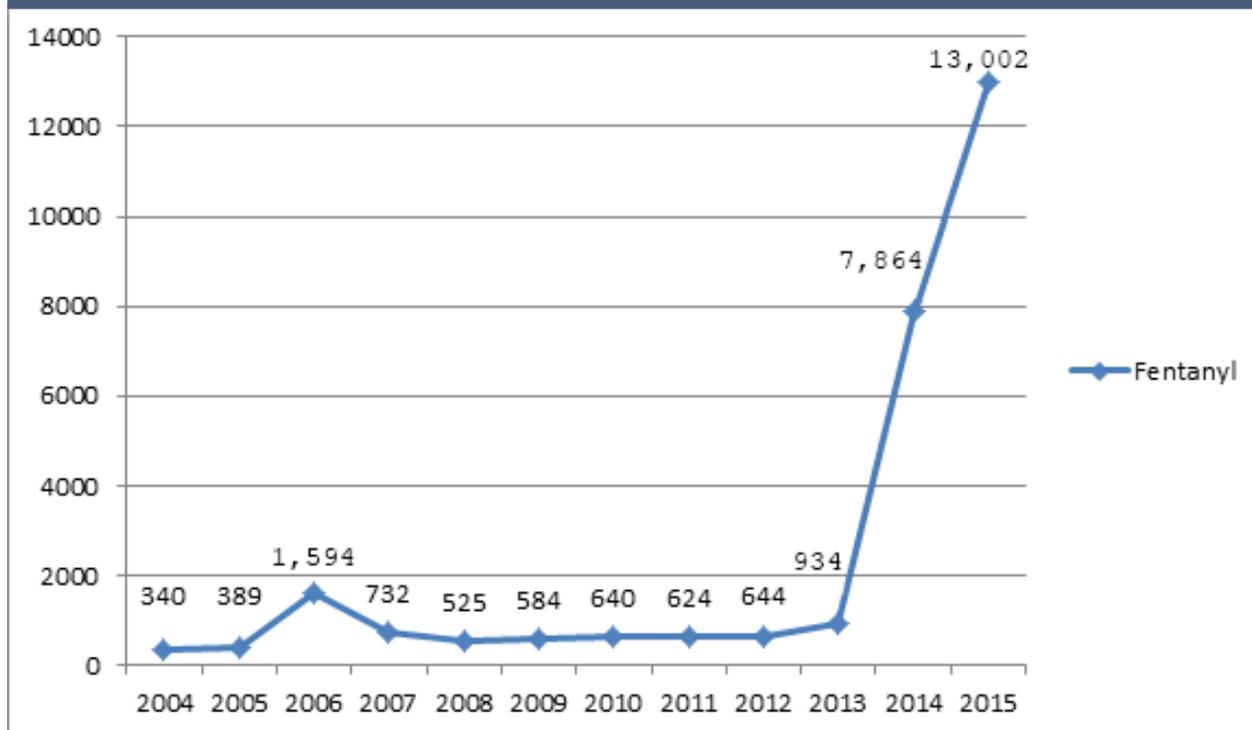
Source: Tennessee Bureau of Investigation

The 2006 fentanyl crisis in the United States was the result of fentanyl being mixed into heroin and distributed to unsuspecting heroin users. During the current fentanyl crisis (2013-present), traffickers have not only used similar historical production and distribution techniques, but have also expanded the fentanyl market by producing wholesale quantities of counterfeit prescription medications containing various fentanyls. Fentanyls are no longer only mixed into the heroin supply, but take on new shapes in order to be desirable for a different subset of opioid users. Another distinction between the 2006 outbreak and the current fentanyl crisis is the complex global reach. The 2006 fentanyl crisis was fueled by a single clandestine laboratory in Toluca, Mexico, and once the laboratory was seized, the seizures of fentanyl and overdose deaths in the United States suddenly tapered off. The current fentanyl crisis is fueled by China-sourced fentanyls and fentanyl precursor chemicals that are being sold to various individuals and organizations responsible for fentanyl processing and distribution operations; this scenario includes individuals linked to Mexican cartels and other criminal organizations that are not affiliated with Mexican cartels. The seizures of fentanyl-laced pills and clandestine pill press operations all across North America indicate that this is becoming a trend, not a series of isolated incidents.

Fentanyl traffickers have been successful at expanding the fentanyl market and introducing new fentanyl-laced drug products to the U.S. drug market. The DEA National Forensic Laboratory Information System (NFLIS)^b reported that there were 13,002 fentanyl exhibits tested by forensic laboratories across the country in 2015 (the latest year for which data is available), which is a 65 percent increase from the 7,864 fentanyl exhibits in 2014 (see Figure 4). There were approximately eight times as many fentanyl exhibits in 2015 as there were during the 2006 fentanyl crisis, clearly demonstrating the unprecedented threat and expansion of the fentanyl market.

^b The NFLIS is a DEA program that systematically collects results from drug chemistry analyses conducted by state, local, and federal forensic laboratories across the country. During analyses of the exhibits, laboratories may identify several distinct drug reports within an exhibit; therefore, an exhibit reported to NFLIS may include up to three drug reports. Drug evidence that is secured by law enforcement officials but not analyzed by participating laboratories is not included in the NFLIS system.

Figure 4: Number of Fentanyl Exhibits in NFLIS, 2004-2015



Source: DEA

The 2014 National Survey on Drug Use and Health estimated that there were 4.3 million nonmedical users of pain relievers in the United States in 2014; a population second only in size to marijuana users. High demand for authentic prescription drugs strongly incentivizes traffickers to produce counterfeit pills containing fentanyls to increase their revenues and meet market demand for these products.

The rise of counterfeit pills that contain fentanyls in the illicit drug market will likely result in more opioid-dependent individuals, overdoses, and deaths. There were over 700 fentanyl-related deaths reported in the United States between late 2013 and 2014. During 2013-2014, the Centers for Disease Control and Prevention (CDC) reported that deaths from synthetic opioids increased 79 percent, from 3,097 to 5,544. Although the synthetic opioid category does contain other opioids, this sharp increase coincides with a sharp increase in fentanyl availability, and the CDC reports that a substantial portion of the increase appears to be related to illicit fentanyls.

Expansion of the counterfeit pill market, to include pills containing fentanyls, threatens to circumvent efforts by law enforcement and public health officials to reduce the abuse of opioid medications. Efforts to reduce the amount of opioid pills available on the market for abuse include DEA's National Take-Back Initiative, and education for doctors on the dangers of opioid medications. The arrival of large amounts of counterfeit prescription drugs containing fentanyls on the market threatens to devalue such initiatives and replaces opioid medications taken off of the street. Although not all controlled prescription drug users eventually switch to heroin, fentanyl-laced pills give DTOs broader access to the large controlled prescription drug user population, which is reliant upon diversion of legitimate pills. This could undermine positive results from the state Prescription Drug Monitoring Programs, as well as from legislative and law enforcement programs.

The success traffickers have experienced with secreting fentanyls in counterfeit opioid medications will likely result in the emergence of fentanyls in a variety of other counterfeit prescription drugs. Between January and March 2016, nine people died from counterfeit Xanax® pills containing fentanyl in Pinellas County, Florida. In March and April 2016, 52 overdoses and 10 deaths occurred in Sacramento, California from counterfeit Norco® pills containing fentanyl. University of California Davis laboratory analysis indicated that the pills contained a variety of fentanyl doses; one sample of pills contained between 0.6 and 6.9 milligrams of fentanyl per pill (2 milligrams of fentanyl is a lethal dose for non-opioid users). Such wide disparity in dosing reveals that the producers were likely new to incorporating fentanyl in pill production, as the fentanyl was not thoroughly mixed with the other powders before binding and pressing into pills. Although Norco® is an opioid like fentanyl, Xanax® is a benzodiazepine.^c This demonstrates that though traffickers are interested in expanding the fentanyl market to other counterfeit opioid medications, they are also willing to utilize fentanyls in other non-opiate drugs with exploitable user populations.

Research Chemical U-47700 in Counterfeit Oxycodone Pills

In March 2016, law enforcement officers in Lorain County, Ohio, seized 500 pills that visually appeared to be oxycodone. The pills were blue and had “A 215” markings, consistent with 30 milligram oxycodone pills (see Figure 5). Laboratory analysis indicated that the pills did not contain oxycodone, but were instead the research chemical U-47700.¹⁹ U-47700 is an unscheduled synthetic opioid not studied for human use that has caused at least 17 overdoses and several deaths in the United States. Although counterfeit opioid pill traffickers currently use fentanyls, it is likely that other synthetic opioids will be utilized if fentanyls become inaccessible, or if market preferences shift to other substances.

Figure 5: Counterfeit Oxycodone Pills Containing U-47700.



Source: Lorain County, Ohio, Sheriff's Office

^c Opioids target completely different receptors than benzodiazepines. Opioids are primarily used to treat pain, whereas benzodiazepines are used to treat anxiety.

Fentanyls in Canada

Canada has seen a sharp increase in overdoses and deaths resulting from the use of fentanyls since 2012, when the Government of Canada removed the prescription opioid OxyContin® from the legitimate market. Between 2009 and 2014, there were at least 1,019 fentanyl-related drug poisoning deaths in Canada, with more than half occurring during 2013 and 2014. Canadian officials advise that this is likely an underestimate.

In Canada, fentanyls are mixed with or disguised as heroin and pressed into counterfeit prescription pills. Traffickers import fentanyls into Canada directly from China; however, Canadian officials have also seized fully functional fentanyl synthesis and pill-producing clandestine laboratories. While pill presses and tableting machines are not currently regulated by Canada's federal government, the Province of Alberta recently passed legislation, which will implement regulation of these devices effective January 1, 2017. In addition, efforts are underway to draft similar legislation for at least one more Canadian province.

Fentanyls in Mexico

Mexico often serves as a transshipment point for fentanyls shipped from China. Mexican traffickers prepare the fentanyls to be mixed with heroin destined for the United States, or press the fentanyls into counterfeit prescription pills before the drugs are smuggled into the United States. In addition to purchasing fentanyls directly from China, it is likely there are also clandestine fentanyl synthesis laboratories in Mexico. The immediate precursor to fentanyl, N-phenyl-1-(2-phenylethyl) piperidin-4-amine (ANPP), has been seized at the U.S.–Mexico border, indicating that traffickers are producing fentanyl or attempting to stockpile precursors in advance of a future shortage in Chinese supply.

Fentanyls in China

China is the primary source of supply for fentanyls and fentanyl precursors destined for the United States, Canada, and Mexico. According to the Chinese Anti-Smuggling Bureau, China does not have a fentanyl consumption problem; therefore, fentanyls illicitly produced in China are most likely intended for export to the Americas. Customers can purchase fentanyl products from Chinese laboratories online, by travelling to China and purchasing in person, or through a chemical broker. DEA reporting indicates that many Chinese laboratories illicitly manufacturing synthetic drugs, such as fentanyls and their precursors, also manufacture legitimate chemicals for purchase by U.S. companies. This means that laboratories responsible for supplying the fentanyls in counterfeit pills can also run legitimate businesses. Although Chinese clandestine laboratories may be contributing to the fentanyl supply, legitimate laboratories may also be sources of supply.

Chinese Scheduling of Popular Fentanyls

In October 2015, China introduced new controls on 116 drugs or chemical compounds, to include several different fentanyls. This scheduling action may reduce the availability of those fentanyls; however, in December 2015, one China-based chemicals supplier offered a Florida-based fentanyl purchaser a new version of the drug to circumvent the scheduling. China controls 19 fentanyl compounds, including fentanyl.

In addition to supplying fentanyls and fentanyl precursor chemicals, Chinese laboratory companies also provide industrial pill presses used in tableting fentanyls intended for American, Canadian, and Mexican purchasers. There are no laws in China regulating the production or sale of pill presses, making them easily accessible to drug traffickers.

Traffickers often use freight forwarders to mail fentanyls from China. Several DEA investigations have revealed that the original supplier will provide the package to a freight forwarding company or individual, who transfers it to another freight forwarder, who then takes custody and presents the package to

customs for export.³⁵ The combination of a chain of freight forwarders and multiple transfers of custody makes it difficult for law enforcement to track these packages. Often, the package will intentionally have missing, incomplete, and inaccurate information.

- May 2015 - Chinese Customs officials seized 46 kilograms of fentanyl and 26 kilograms of acetyl fentanyl hidden in a cargo container destined for Mexico. Six customs officials became ill and one fell into a coma as a result of handling the fentanyls. The fentanyls had been transferred through five different freight forwarders before arriving at customs.
- March 2016 - Over the course of several months, DEA and Homeland Security Investigations offices in the southeastern United States seized multiple shipments from China containing mislabeled pill presses, fentanyl, acetylfentanyl, and butyrylfentanyl.

Fentanyl Profits

The profitability of fentanyls provides a strong motive for traffickers to produce counterfeit prescription pills to expand the current user base. Traffickers can typically purchase a kilogram of fentanyl powder for a few thousand dollars from a Chinese supplier, transform it into hundreds of thousands of pills, and sell the counterfeit pills for millions of dollars in profit. If a particular batch has 1.5 milligrams of fentanyl per pill, approximately 666,666 counterfeit pills can be manufactured from 1 kilogram of pure fentanyl.

According to DEA reporting, counterfeit pills containing fentanyls retail at prices between \$10 and \$20 USC per pill in U.S. illicit drug markets. In February 2016, a DEA source in the Miami FD reported that counterfeit Roxycodone pills containing fentanyl were sold at \$20 USC each. In December 2015, a DEA source in the New Jersey FD reported that counterfeit prescription pills containing fentanyl can be bought in bulk quantities at \$6.50 USC per pill and sold for \$10 USC per pill in the New York City club scene. At these prices, a kilogram of fentanyl used to manufacture counterfeit pills could generate between \$5 and \$20 million in retail sales, depending on the purity of the fentanyl and the dosage (see Figure 13).

- In 2014 and 2015, a China-based chemical distributor sold fentanyl to purchasers in the United States for \$3,500 USC per kilogram.
- In 2016, DEA Miami Field Division reporting indicated a kilogram of acetyl fentanyl could be purchased in Florida for \$1700, sourced from China.

Figure 11: Synthetic Drug Factory in China.



Figure 12: Synthetic Drug Factory in China.



Source: DEA

Figure 13. Potential Revenue Generated from Fentanyl Pill Sales Using 1 Kilogram of Fentanyl (in USC)

Amount of Fentanyl Per Pill	Price Per Pill	Price Per Pill	Price Per Pill
	\$10	\$15	\$20
1.5 milligrams (666,666 pills)	\$6.6 million	\$9.9 million	\$13.3 million
1 milligram (1 million pills)	\$10 million	\$15 million	\$20 million

Source: DEA

There is not an industry standard as to how much fentanyl is in the counterfeit pills, and the dosage varies between vendors and batches. One 2016 seizure of counterfeit prescription pills had approximately 1.8 milligrams of fentanyl in each pill. Such a large amount of fentanyl in each pill is alarming considering that approximately 2 milligrams is a lethal dose for most non-opioid-dependent individuals. Drug users have discussed only consuming partial amounts of a counterfeit pill containing fentanyl in online forums, and one user stated he began vomiting after taking one-quarter of a pill.

Fentanyls and the Internet

The tools needed to manufacture counterfeit pills containing fentanyls are available online and are relatively inexpensive compared to other forms of drug production, contributing to its unique level of threat. Such access paves the way for non-cartel-affiliated individuals to undertake fentanyl trafficking. Fentanyls are available for purchase online from anonymous darknet markets^d and even overtly-operated websites. Industrial pill press machines are also widely available on the open Internet. An April 2016 online search of auction websites by DEA revealed a wide variety of pill presses for sale. One pill press capable of producing 5,000 pills per hour was priced at \$995, and die molds for oxycodone and Xanax[®] pills were for sale at \$115 and \$130, respectively.

Outlook

The availability of counterfeit prescription drugs containing fentanyls will continue to grow in the near term. The relative ease and low cost associated with obtaining the drugs and equipment needed to manufacture counterfeit pills containing fentanyls will encourage individuals, as well as large and small DTOs, to move in this direction. Additionally, non-cartel-affiliated individuals may undertake production of counterfeit pills. Fentanyls will continue to appear in counterfeit opioid medications and will likely appear in a variety of non-opiate drugs as traffickers seek to expand the market in search of higher profits. Overdoses and deaths from counterfeit drugs containing fentanyls will increase as users continue to inaccurately dose themselves with imitation medications.

^d A darknet market is a website hidden on the dark web, accessible only through special browsers such as The Onion Router (TOR). Darknet markets function primarily as black markets, selling drugs, counterfeit currency, and other illicit goods.