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Fentanyl: China's Deadly Export to the United States

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Table of Contents

Executive Summary.....	3
A Dangerous and Increasingly Abundant Drug	3
U.S. Drug Policy: Regulations and Enforcement	4
Fentanyl Flows from China	5
China’s Chemical and Pharmaceutical Production	7
Chinese Exporters Circumvent U.S. Chemical Regulations	8
Conclusions	11
Appendix	12

Executive Summary

Chemical flows from China have helped fuel a fentanyl crisis in the United States, with significant increases in U.S. opioid overdoses, deaths, and addiction rates occurring over the last several years. Unlike previous opioid epidemics, including a temporary spike in U.S. fentanyl use in 2006 that was traced to a single clandestine lab in Mexico, fentanyl sold in the United States is now being produced by individual distributors across the country. The diffused nature of fentanyl distribution and the drug's high potency have complicated U.S. counternarcotic efforts and necessitated new policies aimed at reducing flows of fentanyl and other synthetic opiates to the United States. The U.S. Drug Enforcement Administration (DEA) is the federal government's primary counternarcotic authority, working with state and local law enforcement to regulate and enforce controls on illicit drugs and chemicals.

According to U.S. law enforcement and drug investigators, China is the primary source of fentanyl in the United States. Along with shipments sent directly to the United States, fentanyl is shipped from China to Mexico and, to a lesser degree, Canada, before being trafficked across the U.S. border. In response, the U.S. and Chinese governments have taken steps to increase counternarcotic cooperation and strengthen regulations governing chemical flows. However, these efforts have not adequately adapted to drug exporters' increasingly sophisticated production and distribution methods.

China is a global source of fentanyl and other illicit substances because the country's vast chemical and pharmaceutical industries are weakly regulated and poorly monitored. Chinese law enforcement officials have struggled to adequately regulate the thousands of chemical and pharmaceutical facilities operating legally and illegally in the country, leading to increased production and export of illicit chemicals and drugs. Chinese chemical exporters utilize various methods to covertly ship drugs to the Western hemisphere, including sending illicit materials through a chain of forwarding systems, mislabeling narcotic shipments, and modifying chemicals so they are not controlled in the United States. To reduce flows of fentanyl and fentanyl-like substances to the United States, U.S. regulators should reexamine policies and procedures for banning and controlling dangerous chemicals and work with their Chinese counterparts to improve regulations governing chemical exports.

A Dangerous and Increasingly Abundant Drug

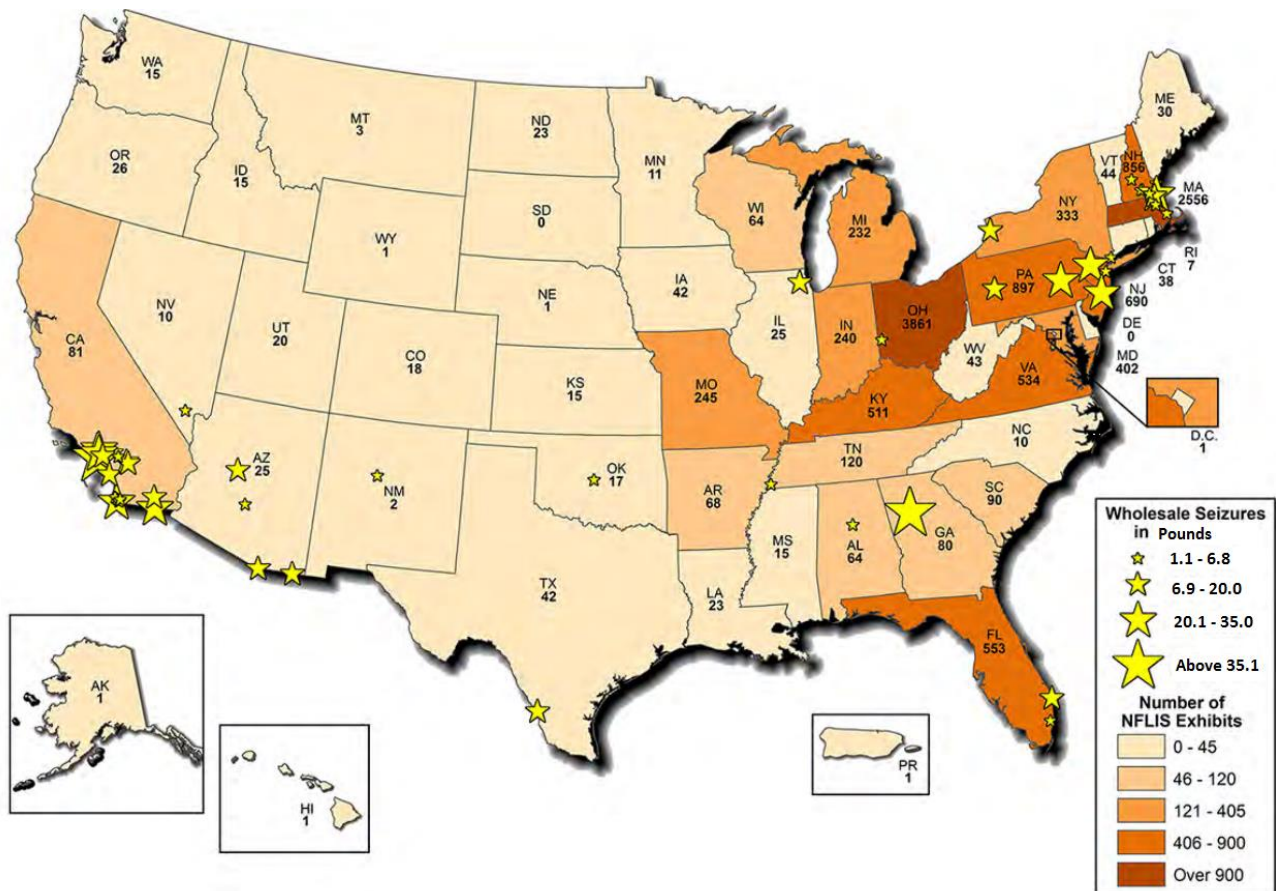
A cheap, synthetically produced opioid known as fentanyl has spawned a deadly drug crisis in the United States.¹ Fentanyl, a powerful synthetic painkiller about 50 times more potent than heroin and 100 times stronger than morphine, is a Schedule II drug—meaning it is legally available only through a nonrefillable prescription.² After being introduced more than 50 years ago as an intravenous anesthetic, fentanyl was approved for treating severe pain (typically for advanced cancer patients) in the early 1990s and has since become a more commonly prescribed painkiller, with U.S. doctors writing 6.65 million fentanyl prescriptions in 2014.³ The drug is commonly prescribed in the form of transdermal patches or lozenges, but it can be diverted from its medical applications and misused by removing the gel contents from patches and injecting or ingesting the drug, or compressing it into pill form.⁴

Recreational use of illicitly obtained fentanyl and other new psychoactive substances (NPS) has spread across the United States, with the DEA issuing nationwide health and public safety alerts in March 2015 and June 2016 about the dangers of fentanyl.⁵ In part, fentanyl is an attractive alternative to other opioids like heroin and oxycodone because it is more potent, with users typically requiring less than a milligram of the drug for a single use.⁶ In fact, fentanyl is so potent that touching or inhaling just two milligrams (or about two grains of salt) can be lethal, presenting a threat not just to drug users, but also to law enforcement personnel investigating the scene of a fentanyl overdose or production locations.⁷ Fentanyl is also appealing to drug users because it is inexpensive; producing 25 grams of finished fentanyl costs about \$810.⁸ The combination of the drug's potency and affordability has made fentanyl an increasingly common drug in the United States, often mixed with heroin or cocaine—either intentionally or without the user's knowledge—to increase its euphoric effects.⁹

U.S. health and law enforcement officials have seen a recent spike in fentanyl-related abuse and overdoses.¹⁰ A January 2016 report from the Centers for Disease Control and Prevention indicated 5,544 deaths from overdoses of illicitly manufactured synthetic opioids occurred in the United States in 2014, a 79 percent increase year-on-year.¹¹ The death rate from synthetic opioids, including fentanyl, increased by another 72.2 percent year-on-year in 2015.¹²

A substantial portion of the increase is attributable to the increased availability of illicit fentanyl, which the U.S. Customs and Border Protection reports is the most frequently seized synthetic opioid.¹³ In 2015, U.S. law enforcement seized a record amount (approximately 368 pounds) of illicit fentanyl.¹⁴ As seen in Figure 1, there was widespread fentanyl use nationwide in 2015, with laboratories in every state finding fentanyl in forensic tests, according to the National Forensic Laboratory Information System (NFLIS).¹⁵ Increased fentanyl use is most common in areas where white powder heroin is prevalent—particularly across the eastern United States—because fentanyl is often mixed with or disguised as white powder heroin.¹⁶ Although more recent data on fentanyl use are not yet available, it is clear the fentanyl crisis has continued to worsen. Between January and March 2016, counterfeit pills containing fentanyl led to nine deaths in Pinellas County, Florida, and in March and April 2016 authorities recorded 52 overdoses and ten deaths due to fentanyl in Sacramento, California.¹⁷ In November 2016, Virginia Governor Terry McAuliffe announced that the state’s opioid addiction crisis had become a public health emergency, with the number of fatal opioid overdoses expected to rise 77 percent by the end of 2016 compared to 2011.¹⁸ Fentanyl also garnered national media attention in June 2016 when the Midwest Medical Examiner’s Office concluded U.S. singer-songwriter Prince died from an accidental fentanyl overdose.¹⁹

Figure 1: Fentanyl Exhibits Tested, 2015, and Wholesale Seizures, 2013–2015



narcotic controls.²² To this end, the DEA works with the U.S. Department of Health and Human Services—specifically the Food and Drug Administration (FDA)—to regulate and control illicit drugs and chemicals.²³ Pursuant to the CSA, the DEA and FDA are jointly charged with updating and revising the list of controlled and banned chemicals by classifying them into five schedules of controlled substances.²⁴ Most fentanyl products are either Schedule I chemicals—meaning they have no accepted medical use and a high potential for abuse—or Schedule II chemicals, which have a strong potential for abuse but some legitimate medical uses.²⁵ Because the process for scheduling chemicals is time intensive, the DEA has increasingly utilized temporary scheduling procedures to introduce interim restrictions on substances while they are considered for permanent scheduling.²⁶

Along with regulating chemicals, the DEA also coordinates with several other federal agencies to support enforcement efforts.²⁷ Among the agencies that work with the DEA to investigate and enforce drug laws are the Federal Bureau of Investigation; the U.S. Marshals Service; the Bureau of Alcohol, Tobacco, Firearms, and Explosives; the U.S. Department of Homeland Security; and the U.S. Postal Inspection Service.²⁸ In addition, the DEA coordinates with the White House Office of National Drug Control Policy, which engages with foreign governments and domestic programs to ensure a coordinated and comprehensive counternarcotic approach.²⁹ The DEA also works with the White House’s High Intensity Drug Trafficking Areas Program, which has funded 752 federal and local initiatives to prevent and treat drug use, share intelligence among law enforcement agencies, and assess narcotic threats at the federal, state, and local levels.³⁰

As drug trafficking has increased nationwide, federal drug agencies—and the DEA in particular—have ramped up cooperation with their state and local counterparts, providing financial and personnel support for state-led counternarcotic enforcement operations.³¹ In 2016, for instance, the DEA State and Local Task Force Program managed 271 state and local task forces and provided over 2,200 DEA special agents to work in conjunction with more than 2,500 state and local officers to enhance enforcement and detection capabilities.³² Although U.S. states and territories have their own regulatory framework to enforce drug laws, the DEA and FDA can place chemicals on the U.S. list of controlled substances, thereby banning or controlling them nationwide.³³ Thus, states have less authority than the federal government to shape counternarcotic regulations, with scheduling decisions made by the DEA and FDA superseding those made at the state level.³⁴

The White House and Congress have sought to enhance the DEA and other agencies’ abilities to combat chemical flows and production. In 2012, for example, the Synthetic Drug Abuse Prevention Act was signed into law to enhance counternarcotic enforcement and streamline the DEA’s role in detection and enforcement.³⁵ The Synthetic Drug Abuse Prevention Act banned more than 20 chemical compounds used in synthetic drugs, doubled the review period for temporarily scheduled substances from 18 to 36 months, and expanded the DEA’s temporary scheduling authority to allow the DEA to more quickly ban new chemicals.³⁶ In 2016, bills were introduced in the U.S. House of Representatives (H.R. 3537) and U.S. Senate (S. 3224) that would have added 22 substances to the CSA, including three derivatives of fentanyl (butyryl fentanyl, beta-hydroxythiofentanyl, and acetyl fentanyl).³⁷ In January 2017, a resolution was introduced in the Senate (S. 10) to name the use of illicit fentanyl a public health crisis in the United States, encourage further measures to increase fentanyl treatment and prevention, and support additional efforts in partnership with the Mexican and Chinese governments to reduce trafficking.³⁸

Fentanyl Flows from China

According to U.S. law enforcement and drug investigators, China is the main supplier of fentanyl to the United States, Mexico, and Canada.³⁹ Because illicit fentanyl is not widely used in China, authorities place little emphasis on controlling its production and export.⁴⁰ Chinese chemical manufacturers export a range of fentanyl products to the United States, including raw fentanyl, fentanyl precursors, fentanyl analogues,* fentanyl-laced counterfeit prescription drugs like oxycodone, and pill presses and other machinery necessary for fentanyl production.⁴¹ These products are sent to small-scale drug distributors and criminal organizations across the United States who package and sell the product.⁴² According to the DEA, hundreds of thousands of counterfeit pills—some containing deadly amounts of fentanyl—as well as an unknown quantity of other fentanyl products have been brought into the United

* Fentanyl analogues have chemical structures differing only slightly from the pharmaceutical-grade version of the drug. Karen Howlett et al., “How Canada Got Addicted to Fentanyl,” *Globe and Mail*, August 24, 2016. <http://www.theglobeandmail.com/news/investigations/a-killer-high-how-canada-got-addicted-tofentanyl/article29570025/>.

States from China over the last several years.⁴³ Unlike previous opioid epidemics, including a temporary spike in U.S. fentanyl use in 2006 that was traced to a single clandestine lab in Mexico, fentanyl sold in the United States is now being processed by many individual distributors across the country.⁴⁴ The diffused nature of the problem has made it difficult for law enforcement to contain.⁴⁵ Illegally obtained pill presses, for example, allow small-scale milling operations in the United States to package between 3,000 and 5,000 pills per hour of illicit fentanyl and other NPS.⁴⁶ U.S. law enforcement have already busted several domestic milling operations, including a raid of a clandestine milling operation in a New York residential building in January 2016 that resulted in the seizure of 6,000 fentanyl pills.⁴⁷ A similar fentanyl scheme involving three pill presses was discovered and dismantled in Los Angeles two months later.⁴⁸ The equipment and materials needed for illicit fentanyl production are easily obtainable from China, reducing the barriers to entry for illicit producers and increasing the availability of fentanyl and other NPS.⁴⁹

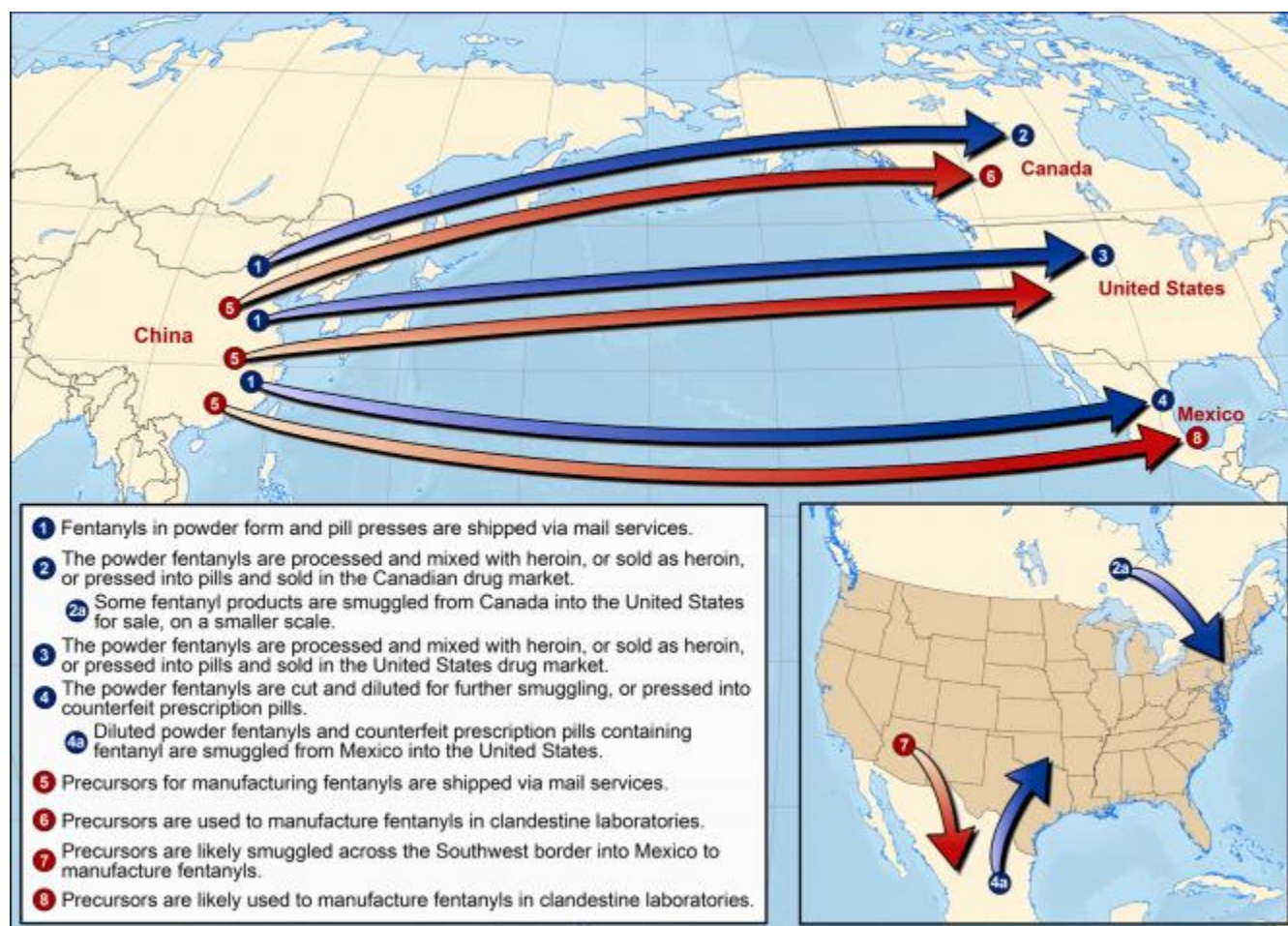
According to the DEA, Chinese fentanyl exports are also shipped to individuals and organizations in Canada and Mexico (see Figure 2).⁵⁰ Mexico is rarely the final destination for illicit drug shipments, however; most fentanyl products sent to Mexico are repackaged and smuggled into the United States.⁵¹ Mexican cartels act as the country's primary conduit for Chinese fentanyl destined for the United States, purchasing bulk shipments and trafficking it—either alone or mixed with other drugs like heroin—across the U.S. border.⁵² The illicit nature of these smuggling operations makes it difficult to quantify the volume of fentanyl flows from Mexico to the United States, but public reporting suggests synthetic opioids are increasingly being trafficked across the southwest border of the United States or delivered through mail couriers.⁵³ In 2015, U.S. border agents seized around 200 pounds of fentanyl and other synthetic opioids from Mexico, up from just eight pounds in 2014.⁵⁴ According to DEA officials, fentanyl trafficking from Canada to the United States is limited when contrasted with flows from Mexico and China.⁵⁵

In response to the growing fentanyl crisis, the U.S. and Chinese governments have taken steps to address illicit chemical flows. In October 2015, China added 116 synthetic chemicals—including six fentanyl products—to its list of controlled chemical substances.* In all, China now controls for 19 types of fentanyl-related substances, although many fentanyl precursors, including N-Phenethyl-4-piperidinone (NPP), are still not controlled (for a full list of known fentanyl precursors, see Appendix I, “Fentanyl Precursors”).⁵⁶ According to a factsheet released by the U.S. National Security Council following the G20 Summit in September 2016, China has also “committed to targeting U.S.-bound exports of substances controlled in the United States, but not in China,”† along with a vague agreement between the two countries to improve coordination and information sharing on controlled substances and chemicals of concern.⁵⁷ Additionally, in October 2016 U.S. Secretary of State John Kerry wrote a letter to the UN secretary-general requesting that NPP and anilino-N-phenethylpiperidine (ANPP), two of the most common precursor chemicals used to manufacture fentanyl, be added to the list of controlled chemicals under the 1988 U.N. Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.⁵⁸ In the letter, Secretary Kerry asked that the UN Commission on Narcotic Drugs be ready to make a decision on controlling fentanyl precursors during its next meeting in March 2017.⁵⁹ China is an original signatory to the 1988 UN Convention, and thus would be bound to abide by the Commission's ruling.⁶⁰

* The fentanyl products banned in China in October 2015 include acetyl-fentanyl, butyryl-fentanyl, beta-hydroxythio-fentanyl, para-fluoro-fentanyl, iso-butyryl-fentanyl, and ocfentanyl. China Food and Drug Administration, *Notification of the Issuance of Managing Non-Medicinal Narcotics and Psychoactive Drugs*, September 29, 2015. Staff translation. <http://www.sfda.gov.cn/WS01/CL0056/130753.html>.

† A factsheet released by China's Ministry of Foreign Affairs following the G20 Summit indicated that the United States and China will exchange lists of synthetic drugs and drug analogues. However, the Chinese statement did not include a commitment to target U.S.-bound exports of substances controlled in the United States that are not controlled in China. China's Ministry of Foreign Affairs, *List of Achievements from Sino-US Head of State Meeting in Hangzhou*, September 4, 2016. Staff translation. <http://www.fmprc.gov.cn/web/zyxw/t1394413.shtml>.

Figure 2: Illicit Fentanyl and Fentanyl Precursor Flows from China



Source: U.S. Drug Enforcement Administration, “Counterfeit Prescription Pills Containing Fentanyls: A Global Threat,” July 2016, 3. <https://www.dea.gov/docs/Counterfeit%20Prescription%20Pills.pdf>.

China’s Chemical and Pharmaceutical Production

China is a global source of illicit fentanyl and other NPS because the country’s vast chemical and pharmaceutical industries are weakly regulated and poorly monitored.* China’s pharmaceutical market is the second largest in the world by revenue, consisting of more than 5,000 companies with a revenue of \$105 billion in 2014 (the United States’ \$380 billion pharmaceutical industry is the largest in the world).⁶¹ Unlike the United States, which produces costly, high-value compounds, China’s pharmaceutical industry relies on mass production of inexpensive generic drugs and pharmaceutical ingredients for revenue.⁶² The Chinese government has prioritized pharmaceutical production as a “high-value-added industry,” providing export tax rebates to encourage pharmaceutical companies to export their products.⁶³ As a result, China is currently the world’s largest manufacturer and top exporter of pharmaceutical ingredients.⁶⁴

In addition, China’s numerous nonpharmaceutical chemical companies legally produce massive quantities of chemicals every day.⁶⁵ The U.S. Department of State estimates that nationwide, China has more than 160,000 chemical companies operating legally and illegally, with some facilities manufacturing tons of chemicals every week and others producing over one million pills daily.⁶⁶ China’s total profits from chemical production increased to \$60 billion in the first 11 months of 2015, up 6.8 percent compared to the same period in 2014.⁶⁷ Although

* For more on China’s pharmaceutical and chemical industries and exports of illicit chemicals to the United States, see Sean O’Connor, “Meth Precursor Chemicals from China: Implications for the United States,” *U.S.-China Economic and Security Review Commission*, July 18, 2016. http://origin.www.uscc.gov/sites/default/files/Research/Staff%20Report_PrecursorChemicalReport%20071816_0.pdf.

specific data on China's production and export of fentanyl and its analogues are not available, documents attached to Secretary Kerry's letter to the UN secretary-general indicated that of the more than 178 global suppliers of NPP and 79 global suppliers of ANPP, more than half are located in China.⁶⁸

Chinese law enforcement and drug investigators are unable to effectively regulate the high volume of drugs and chemicals the country produces.⁶⁹ In many cases, the chemicals used to produce fentanyl and fentanyl-like products are illegally diverted from legitimate pharmaceutical uses, with criminals taking advantage of inadequate enforcement protocols to produce unregulated chemicals and NPS.⁷⁰ Until 2014, a regulatory loophole allowed Chinese chemical companies to operate in a gray area of oversight, freeing them from inspection requirements and other certification systems.⁷¹ That loophole was closed in 2014 when China's State Administration of Work Safety implemented new regulations on chemical production to improve management of nonpharmaceutical businesses, including enforcing stricter licensing requirements.⁷²

Even under the new regulations, Chinese pharmaceutical and chemical companies continue to divert chemicals from legitimate pharmaceutical uses and adulterate legitimate pharmaceuticals during production.⁷³ This makes drug enforcement within China difficult, as many manufacturers of fentanyl and other NPS are legitimate companies legally producing chemicals.⁷⁴ Although some of these chemical manufacturers knowingly ship their products to the United States for illicit purposes, Chinese chemical and pharmaceutical exporters continue to operate with little oversight.⁷⁵ An October 2016 investigation by the Associated Press, for instance, identified 12 Chinese businesses that would export lethal synthetic opioids to the United States without any hesitation.⁷⁶ In an interview with National Public Radio, David Armstrong, a reporter for the online health news site *STAT News*, explained that many Chinese law enforcement officials appear to make little effort to uncover the source of the buyer or determine whether the products will be used for a legitimate purpose.⁷⁷ The United States' ability to conduct drug inspections in China has also been obstructed by Chinese regulators, with several recorded instances of Chinese law enforcement and drug regulators delaying visa approvals for FDA officials and deleting laboratory test records.⁷⁸ The Chinese government, however, maintains that U.S. claims of China-sourced opioid shipments are exaggerated.⁷⁹

China's regulatory shortcomings are exacerbated by the fragmented and disorganized administrative system overseeing chemical production and exports.⁸⁰ Chinese government agencies involved in drafting, overseeing, and enforcing chemical regulations and export requirements include the China Food and Drug Administration, State Council Leading Group on Product Quality and Food Safety, National Narcotics Control Commission, Anti-Smuggling Bureau within the General Administration of Customs, Ministry of Chemical Industry, Ministry of Agriculture, Ministry of Commerce, and General Administration of Quality Supervision, Inspection, and Quarantine.⁸¹ With so many agencies involved in regulating chemical production and exports, bureaucratic infighting can prevent the government from carrying out precise and effective counternarcotic operations.⁸²

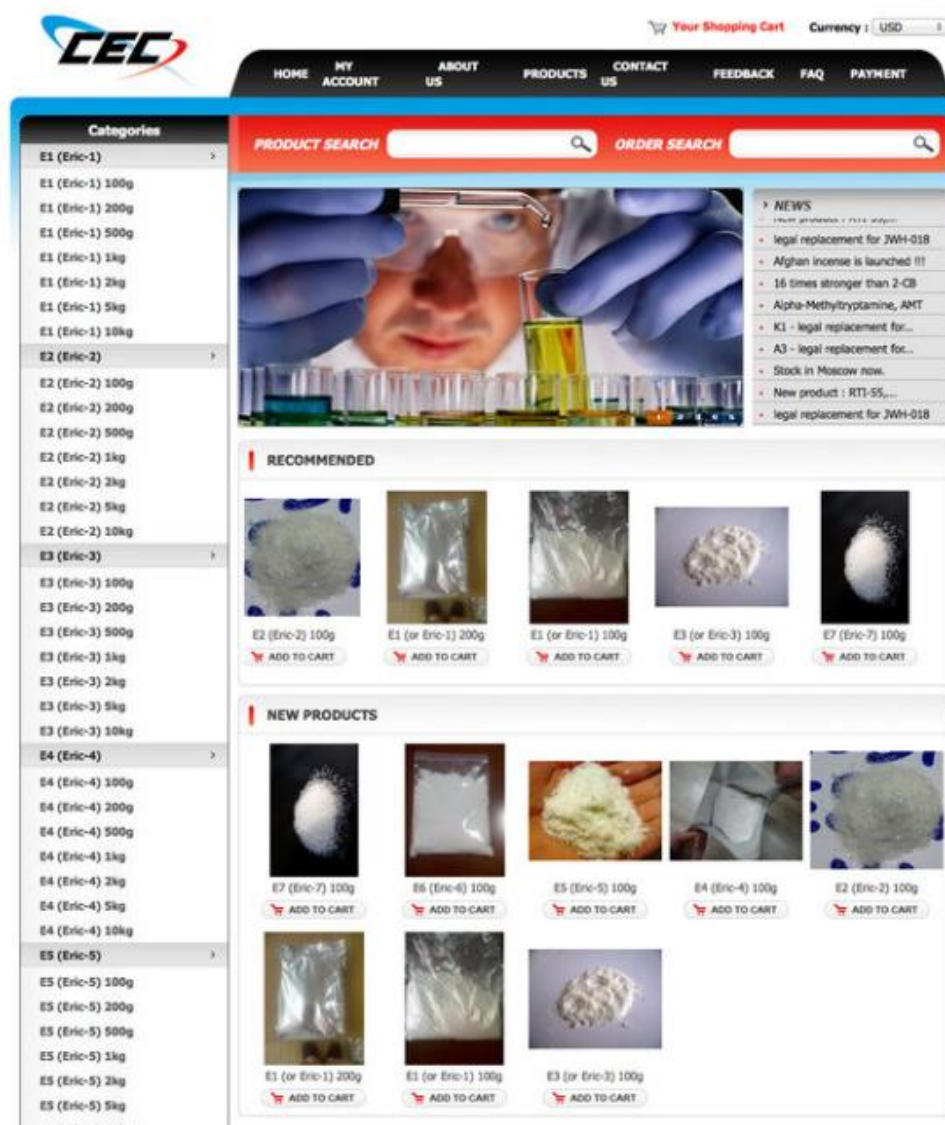
Deficient local drug inspection and enforcement capabilities, coupled with corrupt practices among local officials, also limit the effectiveness of China's chemical regulations.⁸³ With thousands of pharmaceutical companies and hundreds of thousands of chemical companies around the country churning out massive quantities of products daily, regulators are unable to adequately inspect all production and distribution facilities.⁸⁴ Instead, Chinese law enforcement personnel are mainly concentrated in urban centers, leading to increased drug activity in rural areas and poorer communities.⁸⁵ According to Jeremy Haft, a professor at Georgetown University, the insufficient presence of law enforcement has made it easy for small, unregistered drug labs to evade authorities.⁸⁶ Professor Haft explains, "If there's a threat of law enforcement, [the chemical company can] shut down quickly and disappear, only to open up again in another form somewhere else."⁸⁷ Compounding the problem is China's rampant corruption, particularly among local leaders who may actively work to undermine chemical production regulations.⁸⁸ Although Beijing has begun cracking down on local government corruption in recent years—expelling 41 officials from Yunnan Province for drug use in 2014—many officials are still susceptible to bribery from drug producers, particularly in localities where regulators are underpaid and overworked.⁸⁹

Chinese Exporters Circumvent U.S. Chemical Regulations

The increasing sophistication of Chinese chemical exporters poses new challenges to U.S. counternarcotic efforts.⁹⁰ The Internet in particular has contributed to fentanyl's increased availability in North America.⁹¹ Not only can all forms of chemicals and fentanyl-making products be bought online at relatively low prices from Chinese

distributors, but chemical manufacturers in China are also able to mask their identities using online ordering systems.⁹² One popular online marketplace for synthetic drugs is the English-language website of China Enriching Chemistry, a Shanghai company, where distributors and consumers of illicit chemicals buy and sell illicit substances anonymously (see Figure 3).⁹³ Such online marketplaces eliminate many of the market barriers and significantly reduce the risks associated with purchasing fentanyl.⁹⁴ In addition, fentanyl products are often mailed through a chain of forwarding systems, further limiting authorities' ability to track and identify the source of the shipment.⁹⁵ In fact, avoiding detection has become so simple that many Chinese narcotic distributors will guarantee customers a second shipment if the first is seized by law enforcement.⁹⁶

Figure 3: Example of a Chinese Online Marketplace for Synthetic Drugs



Source: Dan Levin, "In China, Illegal Drugs Are Sold Online in an Unbridled Market," *New York Times*, June 21, 2015. http://www.nytimes.com/2015/06/22/world/asia/in-china-illegal-drugs-are-sold-online-in-an-unbridled-market.html?_r=0.

Chemical exporters in China also avoid detection by mislabeling shipments.⁹⁷ Fentanyl suppliers use various methods to mislabel shipments, with some concealing the powder in silica packages placed alongside everyday items.⁹⁸ Others giftwrap shipments or label them as household products like detergent to avoid detection.⁹⁹ Shipments of pill presses from China are also mislabeled to evade U.S. regulations, with many Chinese exporters

shipping pill presses part by part to avoid additional scrutiny from customs officials.*¹⁰⁰ While it is difficult to estimate the total volume of fentanyl products being imported in mislabeled shipments, reports indicate these operations are occurring on a massive scale. In July 2013, for example, one Chinese supplier transported nearly 2,000 pounds of controlled chemicals to Florida by sending separate shipments, each containing four to seven pounds of the illicit chemicals.¹⁰¹

In addition, U.S. law enforcement officials are often unable to identify and seize potentially harmful drugs or precursor chemicals because Chinese manufacturers modify the chemicals to create new, unregulated substances.¹⁰² After banning fentanyl exports as part of the 116 banned chemicals announced in October 2015, for example, Chinese manufacturers began producing and openly selling a new form of the drug called furanyl fentanyl.¹⁰³ Because of its modified chemical structure, furanyl fentanyl was not controlled in the United States or China, and thus could not be seized by U.S. authorities until September 2016, when it was classified as a Schedule I drug.[†]¹⁰⁴ This cycle is emblematic of what DEA spokesman Russell Baer describes as “a challenging process” for scheduling chemicals.¹⁰⁵ In an interview with *STAT News* in April 2016, Mr. Baer explained that the DEA “will seek to put furanyl fentanyl on the list [of controlled substances], and then [the Chinese] will tweak one molecule, and in two months we will be discussing that one.”¹⁰⁶ After furanyl fentanyl was scheduled and controlled, a new drug called carfentanil entered into circulation.¹⁰⁷ Carfentanil is an animal tranquilizer that is 100 times more potent than fentanyl, and has been linked to overdoses across the country, including in Kentucky, Florida, and Ohio.¹⁰⁸ Although carfentanil is controlled in the United States, it is not controlled in China, where it is legally produced and sold.¹⁰⁹ Even if China bans carfentanil, however, counternarcotic experts warn it will only lead to the export of new synthetic substances, much like how bans on fentanyl and furanyl fentanyl led to increased exports of carfentanil.¹¹⁰

Drugs trafficked into the United States from Mexico present an additional avenue for Chinese exporters to evade U.S. regulations.¹¹¹ As another major destination of Chinese fentanyl exports, Mexico faces the same regulatory challenges as the United States, with online ordering systems, mislabeled shipments, and modified chemicals limiting officials’ ability to implement effective counternarcotic enforcement and tracking mechanisms.¹¹² Compounding these problems are reports that Mexican officials remain wary of enforcing more stringent fentanyl policies.¹¹³ According to a June 2016 article in the *Wall Street Journal*, an unnamed Mexican official indicated the Mexican government is hesitant to press China too aggressively on fentanyl trade for fear of economic retribution.¹¹⁴ Although no other public evidence exists to date that supports these claims, the Mexican government’s unwavering cooperation with international counternarcotic efforts is essential to combatting flows of fentanyl and other NPS from China.

* Although the United States requires all pill press imports to be reported and approved by the DEA, there are no laws in China regulating the production or sale of pill presses. Records and Reports of Listed Chemicals and Certain Machines, codified at 21 C.F.R. § 1310.05(c) (2015); U.S. Drug Enforcement Administration, *Counterfeit Prescription Pills Containing Fentanyls: A Global Threat*, July 2016, 7, <https://www.dea.gov/docs/Counterfeit%20Prescription%20Pills.pdf>.

† Schedule I drugs have no accepted medical use and a high potential for abuse. Schedules of Controlled Substances: Temporary Placement of Furanyl Fentanyl into Schedule I, codified at 21 C.F.R. § 1308 (September 2016).

Conclusions

Because the majority of fentanyl products found in the United States originate in China, it is essential for U.S. counternarcotic personnel to enhance cooperation with their Chinese counterparts.¹¹⁵ The Chinese government has strengthened regulations governing chemical and pharmaceutical production—including a crackdown on local government corruption and scheduling a range of new NPS—yet Chinese law enforcement and drug investigators remain unable to effectively regulate the high volume of drugs and chemicals the country produces. In many cases, the chemicals used to produce fentanyl and fentanyl-like products are diverted from legitimate pharmaceutical uses in China, with criminals taking advantage of inadequate enforcement protocols to produce unregulated chemicals and NPS.

Although the primary obstacles to controlling fentanyl and NPS flows lie in China, scheduling and chemical control procedures in the United States are also marred by inefficiencies that create a backlog of scheduling requests. Even with legislative efforts streamlining and enhancing counternarcotic enforcement, officials at the U.S. Department of Justice indicate the process for scheduling new chemicals remains time intensive, requiring coordination among several government entities that can stall authorization procedures.¹¹⁶ Moreover, Chinese exporters continue to replace and modify chemicals in circulation as quickly as they are banned, necessitating further adjustments in scheduling procedures to account for new or altered substances.

Drug analysts and law enforcement personnel have identified the following gaps in counternarcotic enforcement, which have contributed to the ongoing synthetic opioid epidemic in the United States:

- China's regulations governing chemical production and exports remain fragmented and disorganized, with several government agencies and departments tasked with controlling and enforcing chemical laws. Because of the many agencies involved, bureaucratic infighting can prevent the Chinese government from carrying out precise and effective counternarcotic operations.
- Under current laws, U.S. drug enforcement agencies like the DEA and FDA must jointly approve new chemical controls. As a result, the process for scheduling new chemicals can be stalled by authorization procedures, extending the process for permanently controlling new substances that may present an imminent health and safety threat.
- Under current laws, analogues and derivatives of known illicit products must be identified and controlled before they can be seized by drug enforcement personnel. However, U.S. drug enforcement agencies schedule chemicals one by one, rather than entire classes at a time, delaying seizures of new and potentially dangerous substances. As a result, modified versions of banned chemicals cannot be seized until they are permanently or temporarily controlled.

Appendix

Known Fentanyl Precursors

N-phenethyl-4-piperdone	1-benzyl-4-piperidone
4-anilino-4-phenethyl-4-piperidine	Aniline
N-[1-(2-phenylethyl)-4-piperidyl]-N-phenylacetamide	Bromoethylbenzene
4-anilino-n-phenethyl-4-piperidine	Chloroethylbenzene
Acetamide N-phenethyl-N-[1-(2-phenethyl)-4-piperidiny]	Phenethylamine
N-phenethyl-piperidone	4-piperidone
Propionyl chloride	Ethacrylate
Propionic anhydride	Methacrylate

Source: Official, U.S. Drug Enforcement Administration, interview with Commission staff, September 13, 2016.

Endnotes

- ¹ U.S. Drug Enforcement Administration, *DEA Warning to Police and Public: Fentanyl Exposure Kills*, June 10, 2016. <https://www.dea.gov/divisions/hq/2016/hq061016.shtml>.
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