Department of Justice

STATEMENT OF

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BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
HEALTH SUBCOMMITTEE
UNITED STATES HOUSE OF REPRESENTATIVES

FOR A HEARING ENTITLED

EXAMINING LEGISLATIVE PROPOSALS TO COMBAT OUR NATION'S DRUG ABUSE CRISIS

PRESENTED

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Statement of Jack Riley
Acting Deputy Administrator
Drug Enforcement Administration
Before the
Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
October 8, 2015

INTRODUCTION

Chairman Pitts, Ranking Member Green, and Members of the Subcommittee: on behalf of the approximately 9,000 employees of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss our Nation's two most pervasive drug issues of the day, specifically the epidemic opioid abuse and threat posed by dangerous synthetic drugs.

Drug overdoses are the leading cause of injury-related death here in the United States, eclipsing deaths from motor vehicle crashes.[1] There were over 43,000 overdose deaths in 2013, or approximately 120 per day, over half of which involved either a prescription opioid or heroin. These are our family members, friends, neighbors, and colleagues.

According to the 2014 National Survey on Drug Use and Health (NSDUH), 6.5 million people over the age of 12 used psychotherapeutic drugs for non-medical reasons during the past month. This represents 24 percent of the 27 million current illicit drug users and is second only to marijuana (22.2 million users) in terms of usage. There are more current users of psychotherapeutic drugs (i.e., pain relievers, tranquilizers, stimulants, and sedatives) for non-medical reasons than current users of cocaine, heroin, and hallucinogens combined.[2]

Approximately 435,000 Americans reported past month use of heroin in 2014.[3] Heroin use remains relatively low in the United States when compared to other drugs; however, the increase in the number of people using the drug in recent years – from 373,000 past year users in 2007 to 914,000 in 2014 – is troubling.[4]

The misuse of controlled opioid prescription drugs (CPD) and the growing use of heroin are being reported in the United States in unprecedented numbers. According to the United Nations' body which monitors treaty compliance, the International Narcotics Control Board

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[1] Centers for Disease Control and Prevention, Web-based Injury Statistics Query and Reporting System (WISQARS) [online], (2014), *available at*: http://www.cdc.gov/injury/wisqars/fatal.html.
[2] Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from http://www.samhsa.gov/data/.
[3] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2013 and 2014. Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014.
[4] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2013 and 2014. Table 1.1A Types of Illicit Drug Use in Lifetime, Past Year, and Past Month among Persons Aged 12 or Older: Numbers in Thousands, 2013 and 2014.

(INCB), the United States consumes 78 percent of the world's oxycodone and 99 percent of the world's hydrocodone[5], despite having only 5 percent of the world's population.

CONTROLLED PRESCRIPTION DRUGS (CPDs)

In 2014, over 4.3 million Americans aged 12 or older reported using prescription pain relievers non-medically within the past month. This makes nonmedical prescription opioid use more common than use of any category of illicit drug in the United States except for marijuana. Whereas the vast majority of nonmedical opioid CPD users do not go on to use heroin, this information provides valuable insight into the role that CPDs play in the opioid epidemic and underscores the need to ensure that practitioners are educated on proper prescribing of CPDs.

Black-market sales for opioid CPDs are typically five to ten times their retail value. DEA intelligence reveals the "street" cost of prescription opioids steadily increases with the relative strength of the drug. For example, generally, hydrocodone combination products (a Schedule II prescription drug and also the most prescribed CPD in the country)[6] can be purchased for $5 to $7 per tablet. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for $7 to $10 per tablet. Even stronger prescription drugs are sold for as much as $1 per milligram (mg). For example, 30 mg oxycodone (immediate release) and 30 mg oxymorphone (extended release) cost $30 to $40 per tablet. These increasing costs make it difficult to purchase in order to support the addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Data from NSDUH show that chronic and frequent users are more likely than recent initiates to buy opioid drugs from a dealer.[7] Not surprisingly, a small number of people who use prescription opioids non-medically turn to heroin, a much cheaper opioid, generally $10 per bag, which provides a similar "high" and keeps some individuals with opioid use disorders from experiencing painful withdrawal symptoms. This cycle has been repeatedly observed by law enforcement agencies. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by those who began using prescription opioids non-medically.[8]

Healthcare providers, as well as nonmedical users of CPDs are confirming this increase. According to some reporting by treatment providers, many individuals with serious opioid use disorders will use whichever drug is cheaper and/or available to them at the time.[9] Individuals with opioid use disorders who have switched to heroin are at high risk for accidental overdose. Unlike with prescription drugs, heroin purity and dosage amounts vary, and heroin is often cut

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[5] International Narcotics Control Board. March, 2015. "Report 2014: Estimated World Requirements for 2015 – Statistics for 2013," available at www.incb.org.

[6] On October 6, 2014, DEA published a final rule in the *Federal Register* to move hydrocodone combination products from Schedule III to Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services.

[7] SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2012-2013. Unpublished special tabulations (March 2015).

[8] U.S. Department of Justice, Drug Enforcement Administration, 2015 National Heroin Threat Assessment Summary, DEA Intelligence Report, April, 2015, *available at*: http://www.dea.gov/divisions/hq/2015/hq052215_National_Heroin_Threat_Assessment_Summary.pdf.

[9] U.S. Department of Justice, Drug Enforcement Administration, 2014 National Drug Threat Assessment Summary, November, 2014.

with other substances (e.g. fentanyl), all of which could cause individuals with lower tolerance to higher potency opioids to accidentally overdose.[10]

Some CPD users become dependent on opioid medications originally prescribed for a legitimate medical purpose.[11] A Substance Abuse and Mental Health Services Administration (SAMHSA) study found that four out of five recent new heroin users had previously used prescription pain relievers non-medically, although a very small proportion (3.6%) of those initiated heroin use in the following five-year period.[12] The reasons an individual may shift from one opiate to another vary, but today's heroin is higher in purity, less expensive, and often easier to obtain than illegal CPDs. Higher purity allows heroin to be smoked or snorted, thereby circumventing a barrier to entry (needle use) and avoiding the stigma associated with injection. However, many who smoke or snort are vulnerable to eventually injecting. Heroin users today tend to be younger, more affluent, and more ethnically and geographically diverse than ever before.[13]

Overdose deaths involving heroin are increasing at an alarming rate, having almost tripled since 2010. Today's heroin at the retail level costs less and is more potent than the heroin that DEA encountered a decade ago. It comes predominantly across the Southwest Border (SWB) and is produced with greater sophistication from powerful transnational criminal organizations (TCOs) like the Sinaloa Cartel. These Mexican-based TCOs are extremely dangerous and violent and continue to be the principal suppliers of heroin to the United States.

DEA RESPONSE TO THE NONMEDICAL USE OF CPDs

Nonmedical drug use cannot be addressed through law enforcement action alone. The Office of National Drug Control Policy's (ONDCP) 2011 Prescription Drug Abuse Prevention Plan, a multi-pronged approach that includes education, tracking and monitoring, proper medicine disposal, and enforcement is a science-based and practical way to address this national epidemic.

Education of the Drug Supply Chain:

DEA provides education and guidance to registrants, professional associations, and industry organizations on current pharmaceutical diversion and nonmedical use, new and existing programs, policies, legislation, and regulations. In fiscal year 2014, DEA conducted

[10] Stephen E. Lankenau, Michelle Teti, Karol Silva, Jennifer Jackson Bloom, Alex Harocopos, and Meghan Treese, Initiation into Prescription Opioid Misuse Among Young Injection Drug Users, Int J Drug Policy, Author manuscript; available in PMC 2013 Jan 1, Published in final edited form as: Int J Drug Policy, 2012 Jan; 23(1): 37-44. Published online 2011 Jun 20. doi: 1016/j.drugpo.2011.05.014. and; Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D., "Every 'Never' I Ever Said Came True": Transitions From Opioid Pills to Heroin Injecting, Int J Drug Policy, 2014 Mar;25(2):257-66. doi: 10.1016/j.drugpo.2013.10.004. Epub 2013 Oct 19.

[11] Pain, 2015 Apr; 156(4):569-76, doi: 10.1097/01.j.pain.0000460357.01998.f1, Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Vowles KE1, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN.

[12] Substance Abuse and Mental Health Services Administration, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, Department of Health and Human Services, and [August 2013], *available at*: http://www.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf.

[13] Cicero, T., Ellis, M., Surratt, H, Kurtz, S. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years, July, 2014.

over 150 such events and additionally through the first two quarters of fiscal year 2015 DEA has conducted 90 outreach and public education events, including:

DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conferences address pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of these conferences is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. DEA hosted 16 PDACs in eight states, with 2,197 attendees, and an additional 16 PDACs in eight states were scheduled for FY 2015. Since DEA began hosting PDACs in 2011 we have trained a total of 9,218 pharmacy professionals.

DEA has also routinely hosted its annual Manufacturers/Importers/Exporters Conference, with its most recent event culminating on September 23-24, 2015. This conference provides a forum to present federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices to prevent diversion while minimizing the impact on legitimate commerce. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Orders System (ARCOS) reporting, import/export permits and import/export declarations were discussed.

DEA also established its Distributor Initiative Program in 2005 to educate this registrant population on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. This program was initially designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes. Wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA educates distributors about their obligations under the Controlled Substances Act (CSA), as well as provides registrants with current trends and "red flags" that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer. The Distributor Conference was recently held on April 15-16, 2015, and consisted of approximately 220 industry leaders from over 130 companies.

Monitoring

Prescription drug monitoring programs (PDMPs) are typically State-run electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMP programs and encourages the use of these programs by medical professionals in detecting and preventing doctor shopping and other forms of diversion. Currently, 49 states have an operational PDMP (meaning collecting

data from dispensers and reporting information from the database to authorized users). DEA makes its registrant database available to any state, without a fee, for use in their PDMP, or other state agency charged with investigating healthcare fraud or controlled substance diversion.

While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent nonmedical prescription drug use and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge, as many drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous pain clinics and physicians. The National Association of Boards of Pharmacy (NABP) hosts NABP Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of PDMP data across state lines to authorized users. The program allows users of participating PMPs to securely exchange prescription data between certain states. Currently, PMPs in 30 states are participating in the program.

These programs, however, are only as good as the data that is in each system and the willingness of practitioners and pharmacists to use such systems on a consistent basis. As of June 2014, only 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.[14] DEA encourages all practitioners and pharmacists to use their state PDMP program.

Medication Disposal

On September 9, 2014, DEA issued a final rule, titled "Disposal of Controlled Substances." These regulations implement the Secure and Responsible Drug Disposal Act of 2010 and expand upon the previous methods of disposal by including disposal at drop-boxes in pharmacies and law enforcement agencies, mail back programs and drug deactivation systems if they render the product irretrievable. Through these regulations, DEA continues its national attention on the issue of nonmedical use of prescription drugs and related substance use disorders (SUDs), promotes awareness that one source of these drugs is often the home medicine cabinet, as 50.5% of persons aged 12 or older who used pain relievers non-medically in the past year got the pain relievers from a friend or relative for free[15], and provides a safe and legal method for the public to dispose of unused or expired CPDs.

Since 2010 DEA has simultaneously held its National Drug "Take Back" Initiative (NTBI) to provide a convenient and safe option to dispose of unused, expired and/or unwanted prescription drugs. DEA's most recent NTBI was held on September 26, 2015. As a result of all ten National Take Back Days, the DEA, in conjunction with its state, local, and tribal law

[14] PDMP Center of Excellence, Brandeis University. http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps, retrieved September 30, 2015.

[15] Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health, Table 6.47B, Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older, by Age Group: Percentages, Annual Averages Based on 2011-2012 and 2013-2014.

enforcement partners, has removed a total of 5.53 million pounds (2,762 tons) of medications from circulation.

Enforcement: Tactical Diversion Squads

DEA Tactical Diversion Squads (TDSs) investigate suspected violations of the CSA and other Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shoppers," prescription forgery rings, and practitioners and pharmacists who knowingly divert controlled substance pharmaceuticals).

Between March 2011 and March 2014, DEA increased the number of operational TDSs from 37 to 66. Case initiations increased from 691 in 2005 to 1,727 in 2014, while arrests increased from 105 in 2005 to 2,418 in 2014.

Enforcement: Diversion Groups

When the DEA was established in 1973, DEA regulated 480,000 registrants. Today, DEA regulates more than 1.5 million registrants. The expansion of the TDS groups has allowed Diversion Groups to concentrate on the regulatory aspects of enforcing the CSA. DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; importers; exporters; and narcotic treatment programs. This renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the CSA and its implementing regulations.

HEROIN AVAILABILITY TO THE U.S. MARKET

There are four major heroin-producing areas in the world, but heroin bound for the U.S. market originates predominantly from Mexico and, to a lesser extent, Colombia. The heroin market in the United States has been historically divided along the Mississippi River, with western markets using Mexican black tar and brown powder heroin, and eastern markets using white powder which, over the last two decades has been sourced primarily from Colombia. The largest, most lucrative heroin markets in the United States are the white powder markets in major eastern cities: New York City and the surrounding metropolitan areas, Philadelphia, Chicago, Boston and its surrounding cities, Washington, D.C., and Baltimore. With the growing number of individuals with an opioid use disorder in the United States, Mexican TCOs have seized upon a business opportunity to increase their profits. Mexican TCOs are now competing for the East Coast and Mid-Atlantic markets by introducing Mexican brown/black tar heroin as well as by developing new techniques to produce highly refined white powder heroin.

DEA has also seen a 50 percent increase in poppy cultivation in Mexico primarily in the State of Guerrero and the Mexican "Golden Triangle" which includes the states of Chihuahua, Sinaloa, and Durango. The increased cultivation results in a corresponding increase in heroin

production and trafficking from Mexico to the United States, and impacts both of our nations, by supporting the escalation of heroin use in the United States, as well as the instability and violence growing throughout areas in Mexico.

The majority of Mexican and Colombian heroin bound for the United States is smuggled into the United States via the SWB, and heroin seizures at the border have more than doubled, from 846 kilograms in 2009 to 2,196 kilograms in 2013.[16] During this time, the average seizure also increased from 2.9 kilograms to 3.8 kilograms. The distribution cells and the Mexican and South American traffickers who supply them are the main sources of heroin in the United States today. The threat of these organizations is magnified by the high level of violence associated with their attempts to control and expand drug distribution operations.

DEA has become increasingly alarmed over the addition of fentanyl into heroin sold on the streets as well as the use of fentanyl analogues such as acetyl fentanyl. One of the most potent Schedule II narcotics which is 25 to 40 times more potent than heroin,[17] fentanyl presents a serious increased risk of overdose death for a heroin user. In addition, this drug can be absorbed by the skin or inhaled, which makes it particularly dangerous for law enforcement officials who encounter the substance during the course of an enforcement operation. On March 18, 2015, DEA issued a nationwide alert to all U.S. law enforcement officials about the dangers of fentanyl and fentanyl analogues and related compounds. In addition, due to a recent spike in overdose deaths related to the use of acetyl fentanyl, on July 17, 2015, DEA used its emergency scheduling authority to place acetyl fentanyl in Schedule I of the CSA.

DEA RESPONSE TO THE HEROIN THREAT

Anti-Heroin Task Force Program

As directed by Congress, the Department of Justice has joined with ONDCP to convene an interagency task force to confront the growing use, abuse, and trafficking of heroin in America. DEA and more than 28 Federal agencies and their components are actively participating in this initiative. The task force expects to have a strategic plan for the President and Congress by the end of 2015.

International Enforcement: Sensitive Investigative Units

Funds requested for International Drug Enforcement Priorities will be used to support and expand a key element of DEA's international efforts: the Sensitive Investigative Unit (SIU) program. DEA's SIU program, nine of which are in the Western Hemisphere, helps build effective and vetted host nation units capable of conducting complex investigations targeting major TCOs. DEA currently mentors and supports 13 SIUs, which are staffed by over 900

[16] Drug Enforcement Administration, Unclassified Summary, 2014 National Drug Threat Assessment, Pg. 10, *available at*: http://www.dea.gov/resource-center/dir-ndta-unclass.pdf.

[17] Centers for Disease Control, Emergency Response Safety and Health Database, FENTANYL: Incapacitating Agent, http://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750022.html, accessed March 19, 2015; U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Drug & Chemical Evaluation Section, Fentanyl, March 2015.

foreign counterparts. The success of this program has unquestionably enhanced DEA's ability to fight drug trafficking on a global scale.

International Enforcement: Bilateral Investigations Units

Bilateral Investigations Units (BIUs) are one of DEA's most important tools for targeting, disrupting, and dismantling significant TCOs. The BIUs have used extraterritorial authorities to infiltrate, indict, arrest, and convict previously "untouchable" TCO leaders involved in drug trafficking.

SYNTHETIC DESIGNER DRUGS

In addition to the existing heroin abuse and nonmedical CPD use threats, new psychoactive substances (NPS), or synthetic designer drugs, represent the most recent area of concern for DEA. Synthetic designer drugs are dangerous chemical compounds with no known legitimate medical or industrial use and are not approved by the Food and Drug Adminstration for human consumption. These compounds pose a great danger to the public, especially children and teenagers, because they are perceived as "legal" alternatives to the illicit drugs they intend to mimic. The two most common categories of these synthetic drugs are synthetic cannabinoids and synthetic cathinones.

Synthetic cannabinoids (sometimes sold under brand names such as K2 or Spice) continue to be drugs of considerable concern. These depressant/hallucinogenic drugs are primarily sourced from China. Synthetic cannabinoid substances are typically prepared for packaging in the U.S., and marketed over the Internet, or supplied to retail distributors before being sold to the public at retail stores (e.g., "head shops," convenience stores, gas stations, and liquor stores). Laws governing the legality of the substances vary widely between states, and the chemical components are frequently altered, making it difficult for the DEA to schedule the substances.

Synthetic cathinone substances fall under the phenethylamine class of stimulant/hallucinogenic drugs, and are marketed as "bath salts" or "glass cleaner," among other street names. These substances are often labeled "not intended for human consumption" as a false means to defend against the Government's utilization of the federal Controlled Substance Analogue Enforcement Act. Synthetic cathinones are also widely available on the illicit street market, oftentimes being mixed with other drugs such as MDMA.

CURRENT CHALLENGES

Traffickers Adapting to the Law

Even though several NPS compounds have been controlled or banned through temporary scheduling or by legislative or administrative scheduling (per 21 USC 811 and 812), entrepreneurs procure new synthetic cannabinoid compounds with relative ease. Clandestine chemists can easily continue to provide retailers with "legal" products by developing/synthesizing new synthetic cannabinoid products that are not controlled. In fact, when DEA takes an action to temporarily schedule a substance, retailers begin selling new

versions of their products with new unregulated compounds in them. In addition, these same retailers are provided with spurious chemical analyses that purport to document that the new product line did not contain any controlled substance.

Over the past several years, DEA has identified hundreds of designer drugs from eight different structural classes, the vast majority of which are manufactured in China. There are a seemingly infinite number of possible new chemical compounds that are on the horizon. Manufacturers and distributors will continue to stay one step ahead of any state or Federal drug-specific banning or control action by introducing/repackaging new cannabinoid products that are not controlled.

There is also a large financial incentive that continues to drive the wholesale and retail distribution of these products. Information that DEA has obtained through the course of its investigations demonstrate that a $1,500 purchase of a bulk synthetic drug can generate as much as $250,000 of revenue at the retail level. It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for manufacturers, distributors, and retailers to seek/find substitute products that are not yet controlled or banned by Federal or state action.

Prosecutions Pursuant to the Analogue Act

A designer drug may or may not be a "controlled substance analogue" pursuant to the CSA. Even if a particular substance is widely regarded as a "controlled substance analogue" under the CSA, each criminal prosecution must establish that fact anew. The primary challenge to preventing the distribution and abuse of a controlled substance analogue, as opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is not automatically subject to control. In Analogue Act prosecutions, the Government must establish that the substance involved is a "controlled substance analogue" as defined by the CSA; accordingly, each prosecution is a new case even if the same substance is involved. Prosecutors must also prove that the substance was intended for human consumption.

In addition, without establishment and inclusion of specific sentencing equivalencies in the U.S. Sentencing Guidelines, prosecutors are required to produce evidence addressing the factors identified in the relevant guidelines. This typically results in prosecutors calling two expert witnesses to testify at every sentencing hearing to demonstrate that the substances in question fall within guideline definitions, a time consuming, resource intensive, and inefficient process. Different courts have reached very different results for the same substance which has resulted in disparate sentences for similarly situated offenders.

The above considerations, along with the increasing volume and endless variety of designer drugs available today and the sophisticated methods and routes of distribution, render the Controlled Substance Analogue Enforcement Act ineffective by itself as a tool to prevent diversion and abuse of designer drugs. The Synthetic Drug Abuse Prevention Act (SDAPA) approach to control specific, known, synthetic substances in some instances by description of chemical characteristics, was a swift and aggressive contribution to the overall effort to combat

the designer drug threat.[18] DEA will continue to identify ways to better combat the designer drug threat.

DEA RESPONSE TO THE THREAT OF SYNTHETIC DRUGS

Scheduling by Administrative Rulemaking: Temporary Control

By their nature, designer drugs are non-controlled substances. They can be controlled under the CSA either by Congress or by DEA through its administrative rulemaking authority. DEA may also temporarily place a substance into Schedule I of the CSA for a maximum of three years if such action is necessary to avoid imminent hazard to the public safety, it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. § 812), and if there is no exemption or approval in effect under 21 U.S.C. § 355 for the substance.

DEA has utilized its regulatory authority to place many synthetic cannabinoids and synthetic stimulants into the CSA pursuant to its temporary scheduling authority. Once a substance is temporarily controlled, DEA moves towards permanent control by requesting a scientific and medical evaluation from the Department of Health and Human Services (HHS), and gathering and analyzing additional scientific data and other information collected from all sources, including poison control centers, hospitals, and law enforcement agencies, in order to consider the additional factors warranting its permanent control. Since March 2011, DEA has temporarily controlled 32 synthetic designer drug substances, and 8 of these substances were subsequently controlled on a permanent basis. Seven of these 8 substances were permanently controlled by Congress through legislation, and DEA permanently controlled 1 of the 8 substances, methylone, through DEA's administrative authority. Twenty-four substances remain controlled on a temporary basis, and DEA has formally requested HHS to conduct a scientific and medical review and provide a scheduling recommendation for 20 of the 24 substances. DEA will continue working with the National Institute on Drug Abuse to collect information critical to the evaluation of a number of synthetic designer drug substances for consideration for both temporary and permanent scheduling.

Enforcement Operations

DEA's Operation Log Jam was initiated in 2011 and culminated in a nationwide takedown on July 25, 2012. This DEA Special Operations Division Operation resulted in multiple Organized Crime Drug Enforcement Task Forces (OCDETF) Operations throughout the U.S., including those in 25 federal districts. This operation was coordinated by DEA in cooperation with U.S. Immigration and Customs Enforcement's Homeland Security Investigations (HSI), the Federal Bureau of Investigations (FBI), U.S. Customs and Border Protection (CBP), and the Internal Revenue Service (IRS). The goals of this operation included the targeting of manufacturers, wholesale distributors, and retail distributors of designer drug products, the development of information on foreign based sources of supply, raising public awareness of the dangers associated with the use of these drugs and the development of leads for a Phase II initiative (Operation Synergy).

[18] S. 3190 (112th Congress). The SDAPA was introduced on May 16, 2012, but was not enacted.

Operation Log Jam resulted in 100 arrests; the execution of 300 search warrants and 80 consent searches, and the identification of 38 manufacturing sites. Law enforcement seized 196 kilograms of raw synthetic cathinones, 722 kilograms of raw synthetic cannabinoids, 167,187 packets of synthetic cathinones ready for distribution, 4,852,099 packets of synthetic cannabinoids ready for distribution, 4,766 kilograms of plant material treated with synthetic cannabinoids ready to be packaged, 21,933 kilograms of untreated plant material, over $45,000,000 in U.S. Currency and bank accounts, 88 vehicles, 77 firearms, additional assets valued at $5,688,500, and 1,096 gallons of acetone.

The information and evidence obtained during Operation Log Jam led investigators to initiate Project Synergy, the second phase of a national cooperative effort in combating the synthetic designer drug distribution, which also resulted in multiple OCDETF operations, in at least 13 federal districts. Project Synergy began in December 2012 and culminated in a nationwide take down on June 26, 2013 conducted by the DEA, HSI, FBI, CBP, and the IRS as well as domestic law enforcement departments in 45 states. This operation also included some of our international partners with joint operations being conducted with Australia, New Zealand, Canada, and Barbados.

As part of Project Synergy, the DEA conducted an enforcement operation in June 2013 in the Houston, Texas, area on a synthetic cannabinoid wholesale distributor who was selling AM-2201 and XLR11. During this operation, law enforcement seized enough synthetic cannabinoid products to gross approximately $21,000,000 in revenue at the retail level.

Project Synergy involved many investigations that culminated on June 26, 2013, and included 234 arrests, 416 search warrants and 68 consent searches that led to the seizure of 305 kilograms of raw synthetic cathinones; 1,278 kilograms of raw synthetic cannabinoids; 10,263 packets of synthetic cathinones and cannabinoids; 959 kilograms of treated plant material ready to be packaged; $53,201,595 in currency and assets, 132 vehicles and 141 weapons.

The second phase of Project Synergy culminated in May 2014 and involved law enforcement action in 29 states. More than 150 individuals were arrested and federal, state and local law enforcement authorities seized hundreds of thousands of individually packaged, ready to sell synthetic drugs as well as hundreds of kilograms of raw synthetic products to make thousands more. More than $20 million in cash and assets were seized.

More recently, the DEA coordinated Operation Spice in partnership with the OCDETF New York Strike Force and multiple other law enforcement agencies in New York City in September. This massive takedown targeted the local sale of dangerous designer synthetic drugs manufactured in China. The scheme, which operated in all five boroughs of New York City, allegedly involved the unlawful importation of at least 100 kilograms of illegal synthetic compounds, an amount sufficient to produce approximately 1,300 kilograms of dried product, or approximately 260,000 retail packets. As part the operation, five processing facilities were searched, as well as warehouses used to process, store, and distribute the drugs. In addition, over 80 stores and bodegas around New York City were searched. Over two million packets of synthetic drugs were seized. These packets were ready for street distribution, were concealed in over 100 laundry bags, and were ready for delivery.

CONCLUSION

The supply of heroin entering the United States feeds the increasing user demand for opioids which has been spurred, in part, by the rise of nonmedical prescription opioid use and the large numbers of people with active substance use disorders, many of whom have not yet been engaged by the treatment system. It is likely that this demand will continue to be met by ongoing diversion of prescription opioids and Mexican-based TCOs who are pushing to expand their profits. DEA will continue to address this threat by attacking the crime and violence perpetrated by the Mexican-based TCOs which have brought tremendous harm to our communities. Additionally, DEA's Office of Diversion Control will use all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit distribution of pharmaceutical controlled substances in violation of the CSA. The Anti-Heroin Task Force will develop a comprehensive strategy that will combine education; law enforcement; treatment and recovery; and a coordinated community response. Further, DEA is constantly monitoring the emergence of NPS, and we have identified hundreds of compounds. We look forward to continuing to work with Congress to find legislative solutions needed to address the threat posed by synthetic drugs.