Department of Justice

STATEMENT FOR THE RECORD

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BEFORE THE

SUBCOMMITTEE ON REGULATORY REFORM, COMMERCIAL AND ANTITRUST LAW
COMMITTEE ON THE JUDICIARY
U.S. HOUSE OF REPRESENTATIVES

FOR A HEARING ON

TREATING THE OPIOID EPIDEMIC: THE STATE OF COMPETITION IN THE MARKETS FOR ADDICTION MEDICINE

PRESENTED
SEPTEMBER 22, 2016

Statement for the Record
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Before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law
Committee on the Judiciary
U.S. House of Representatives
September 22, 2016

Chairman Marino, Ranking Member Johnson, and distinguished 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 most pervasive drug issue of the day: the opioid overdose epidemic, spurred by the use of controlled prescription drugs (CPD), heroin, and illicit fentanyl. DEA, along with the Department of Justice, is working to bring even greater attention to this epidemic through participation in events nationwide this week, in support of the Administration's Prescription Opioid and Heroin Epidemic Awareness Week.

THE OPIOID USE DISORDER EPIDEMIC

Today, drug overdoses are the leading cause of injury-related death in the United States, eclipsing deaths from motor vehicle crashes or firearms.[1] There were more than 47,000 overdose deaths in 2014, or approximately 129 per day, more than half (61 percent) of which involved either a prescription opioid or heroin.[2]

The latest National Survey on Drug Use and Health (NSDUH) released on September 8, 2016, shows that 6.4 million persons aged 12 or older reported current misuse of prescription-type psychotherapeutic drugs. Of that 6.4 million, 3.8 million reported current misuse of pain relievers.[3] In addition, the majority (53.7 percent) of those who misused pain relievers in the past 12 months obtained the drug from a friend or relative.

Approximately 329,000 Americans reported past-month use of heroin in 2015.[4] The increase in the number of people using the drug in recent years – from 373,000 past-year users in 2007 to 828,000 in 2015 – is troubling.[5] The misuse of controlled opioid prescription drugs and the growing use of heroin are being reported in the United States in unprecedented numbers.

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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] Rose A. Rudd, Noah Aleshire, Jon E. Zibbell, R. Matthew Gladden. Increases in Drug and Opioid Overdose Deaths - United States, 2000–2014 Morbidity and Mortality Weekly Report, 2016;64:1378-1382.
[3] Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/.
[4] Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/.
[5] Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/.

According to the United Nations' body that monitors treaty compliance, the International Narcotics Control Board (INCB), the United States consumes 78 percent of the world's oxycodone and 99 percent of the world's hydrocodone,[6] despite having only five percent of the world's population.

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)[7] can be purchased for $5 to $7 per tablet on the street. Slightly stronger drugs like oxycodone combined with acetaminophen (e.g., Percocet) can be purchased for $7 to $10 per tablet on the street. 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 on the street. The costs that ensue with greater tolerance make it difficult to purchase these drugs in order to support a developing substance use disorder, particularly when many first obtain these drugs for free from the family medicine cabinet or friends, or alternatively, may originally have received legitimate prescriptions for the treatment of pain. Data from NSDUH show that chronic and frequent users are more likely than recent initiates to buy opioid drugs from a dealer.[8] Not surprisingly, a small number of people who use prescription opioids non- medically – primarily those who are frequent nonmedical users or those with a prescription opioid use disorder – turn to heroin, a much cheaper opioid, generally $10 per bag, which provides a similar "high" and can keep some individuals who are dependent on opioids from experiencing painful withdrawal symptoms. In fact, nearly 80 percent of current heroin users report having used prescription opioids before initiating heroin use.[9] By comparison, in the 1960s, over 80 percent of those entering treatment for heroin began their opioid use with that drug.[10] 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.[11]

GROWING ABUSE OF FENTANYL AND FENTANYL DERIVATIVES

A very recent trend in the opioid use disorder epidemic arises out of counterfeit prescription drugs laced with fentanyl and fentanyl derivatives, as well as heroin laced with fentanyl. Fentanyl, like virtually all opioid analgesics used for medical purposes, is a Schedule II drug. It is an extremely potent analgesic widely used for anesthesia, and also pain control in people with serious pain problems, who are opioid tolerant.

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

[7] 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.

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

[9] Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013;132(1-2):95-100.

[10] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry. 2014;71(7):821-826.

[11] 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.

According to DEA's National Forensic Laboratory Information System (NFLIS), forensic laboratories across the country tested 13,002 fentanyl exhibits in 2015 – a 1,392 percent increase from the 934 fentanyl exhibits in 2013.[12] The trafficking of this drug, which is many times more potent than street level heroin, presents a significant risk of overdose to users as well as a risk to the law enforcement personnel who may come into contact with the substance during the course of their work.

The counterfeit products, purchased illicitly, bear markings consistent with authentic prescription pain relievers such as oxycodone and hydrocodone, which may lead an unsuspecting user to believe he or she is consuming a legitimate controlled prescription drug. These counterfeit products have been found to contain lethal doses of fentanyl or fentanyl derivatives and are responsible for some overdose death outbreaks. Determining if one of these fentanyl-laced counterfeit prescription pills contains fentanyl based on sight alone is impossible; the presence of fentanyl can only be detected upon laboratory testing.

Illicit fentanyl, fentanyl derivatives, and their immediate precursors are often produced in China.[13] From China, these substances are shipped through mail carriers directly to the United States, or alternatively, shipped directly to transnational criminal organizations (TCOs) in Mexico and the Caribbean. Once there, fentanyl or its derivatives are prepared to be mixed into the U.S. heroin supply domestically, or pressed into a pill form to give them markings consistent with authentic prescription pain relievers containing hydrocodone or oxycodone. They are then moved to the illicit U.S. market where demand for prescription opioids and heroin remains high. In some cases, traffickers have industrial pill presses shipped into the United States directly from China and operate fentanyl pill press mills domestically. Mexican TCOs have seized upon this business opportunity because of the profit potential of synthetic opioids, and have invested in growing their share of this market. Because of its low dosage range and potency, one kilogram of fentanyl purchased in China for $3,000 - $5,000 can generate upwards of $1.5 million in revenue on the illicit market.

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" tool marks consistent with 30 mg immediate release oxycodone pills. Laboratory analysis indicated that the pills did not contain oxycodone, but were instead a fentanyl derivative commonly known as "U-47700." U-47700 is a synthetic opioid which has not been studied for use in humans and has caused at least seventeen overdoses and several deaths in the United States. On September 7, 2016, DEA published a "notice of intent" to place U-47700 in Schedule I on a temporary basis.

DEA OVERSIGHT OF MEDICATION-ASSISTED TREATMENT (MAT)

The opioid epidemic has devastated millions of Americans and ultimately the strategy for ending the epidemic includes two central parts: 1) preventing people from developing an opioid use disorder and 2) ensuring that people with an opioid use disorder are able to access effective

[12] U.S. Department of Justice, Drug Enforcement Administration, National Forensic Laboratory Information System, Annual Reports 2004- 2015.
[13] DEA Intelligence Brief. Counterfeit Prescription Pills Containing Fentanyls: A Global Threat. DEA-DCT-DIB-021-16. July, 2016. Available at: https://www.dea.gov/docs/Counterfeit%20Prescription%20Pills.pdf.

treatment. The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) oversees medication-assisted treatment (MAT) for opioid dependence. DEA supports their efforts through regulation and oversight of controlled narcotic substances approved by the Food and Drug Administration (FDA) for use in MAT.

Buprenorphine combined with naloxone, buprenorphine alone, and long acting implantable buprenorphine; methadone; and naltrexone have all been approved by the FDA for use in MAT. DEA's authority to regulate a person or entity is based on whether the substance they wish to handle is a controlled substance pursuant to the Controlled Substances Act (CSA). It is important to note that whereas buprenorphine and methadone are controlled substances (Schedule III and II respectively) over which DEA has regulatory oversight, naloxone and naltrexone are not controlled substances, and therefore DEA has no regulatory oversight over their production and distribution.

Buprenorphine combined with Naloxone (e.g,. Suboxone, Bunavail and Zubsolv):

Approved for clinical use in October 2002 by the FDA, sublingual buprenorphine represents the latest advance in MAT. Medications such as buprenorphine, in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of opioid use disorder.[14] When taken as prescribed, buprenorphine is safe and effective.[15] Sublingual buprenorphine is the first controlled substance to treat opioid use disorder permitted to be prescribed or dispensed in physician offices, significantly increasing the scope of available treatment options.

Because buprenorphine is an opioid and classified under the CSA as a Schedule III narcotic controlled substance, like other opioids, it can produce effects such as euphoria or respiratory depression. However, buprenorphine's effects are weaker than hydrocodone, oxycodone, or heroin. Because of buprenorphine's opioid effects, it can be misused, particularly by people who do not have an opioid dependency.[16] Naloxone is added to buprenorphine to decrease the likelihood of diversion and misuse by crushing or injection.[17]

On October 17, 2000, Congress passed the Drug Addiction Treatment Act (DATA 2000) which permits qualified physicians to treat narcotic dependence with Schedules III-V narcotic controlled substances that have been approved by the FDA for that indication. This means that pursuant to DATA 2000, qualified U.S. physicians can offer buprenorphine for opioid dependency in various settings, including in an office, community hospital, health department, or correctional facility.[18]

[14] Substance Abuse and Mental Health Services Administration website, available at: http://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine. Retrieved on September 6, 2016.
[15] Ibid.
[16] Ibid.
[17] Ibid.
[18] Ibid.

The legislation waives the general statutory requirement for obtaining a separate DEA registration as a Narcotic Treatment Program (NTP) for qualified physicians administering, dispensing, and prescribing these specific FDA approved controlled substances. Physicians registered with the DEA as practitioners who apply and are qualified pursuant to DATA are issued a waiver and will be authorized to conduct maintenance and detoxification treatment using specifically approved Schedule III, IV, or V narcotic medications. Waivers are granted to qualified physicians, and under the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114-148), signed into law in July 2016, this waiver may also be granted to certain nurse practitioners and physicians assistants. Qualified practitioners who obtain the waiver may initially treat a maximum of 30 patients at a time. After one year, the practitioner may file a notification of intent (NOI) for approval to treat up to 100 patients at a time. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration with a business activity code to identify whether the physician is authorized to treat 30 or 100 patients. Presently, there are 22,918 physicians certified to treat 30 patients and 10,807 physicians certified to treat 100 patients.[19] Note, however, that a large number of these practitioners do not treat the maximum number of patients for which they are authorized.

Most recently, on July 8, 2016, the Secretary for the Department of Health and Human Services exercised her authority under DATA 2000, as amended, to use rulemaking to increase the maximum number of patients a qualified practitioner can treat with certain Schedule III- IV and V maintenance and detoxification medications such as buprenorphine. The final rule, which went into effect on August 8, 2016, raised the patient limit from 100 to 275 patients for those practitioners who have obtained additional credentialing in addiction medicine or addiction psychiatry or who practice in a qualified practice setting. Those practitioners that have had the waiver to treat 100 patients for at least a year may seek the increase to the higher limit by filing a NOI with CSAT. As of September 20, 2016, there are 1,148 registrants registered in the 275 category of DATA waived practitioners.

Under the authority of the CSA, DEA is authorized to conduct periodic on-site inspections of any of its registrants (currently 1.65 million). DATA-waived practitioners are subject to on-site inspections to ensure compliance with DATA and its implementing regulations.

FDA recently approved an implantable buprenorphine called Probuphine which releases buprenorphine into the blood at a steady state for up to six months. After patients are stabilized on sublingual buprenorphine they can be transitioned to Probuphine. This is expected to reduce diversion of buprenorphine because once the implant is in a patient's arm it can only be removed surgically.

Methadone (e.g. Dolophine, Methadose)

Methadone is an FDA approved Schedule II controlled substance which has been used for decades to treat people who are addicted to heroin and narcotic pain medicines. Methadone

[19] Substance Abuse and Mental Health Services Administration website, available at: http://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/physician-program-data. Retrieved September 6, 2016.

is offered in pill, liquid, and wafer forms and is taken once a day. It may also be used to treat pain; pain relief from a dose of methadone lasts about four to eight hours.[20]

By law, as a treatment for people with opioid use disorder, except in certain exceptional circumstances, methadone can only be dispensed through a narcotic treatment program (NTP) certified by SAMHSA and regulated by the DEA. Presently, DEA regulates 1,470 NTPs nationwide.[21] Today, NTPs are most commonly referred to as OTPs (Opioid Treatment Programs). After a period of stability (based on progress and proven, consistent compliance with the medication dosage), patients may be allowed to take methadone at home between program visits. As a Schedule II controlled substance, methadone must be used as instructed and carefully monitored especially upon initiation and when doses are adjusted. This is particularly important for patients who are allowed to take methadone at home whom are not required to take medication under observation at an NTP.

Naltrexone

Various forms of the drug naltrexone including the extended release injectable form (tradename, Vivitrol) is FDA approved for relapse prevention in detoxified opioid users. It blocks the effects of opioids while it is active in a patient's body. It is not a controlled substance and DEA has no oversight over its use.

Overdose reversal medicine Naloxone

Naloxone is a medicine used to reverse overdose and is frequently used on people who misuse opioids or who take too much pain medicine either via prescription or illicitly. It is not a controlled substance and DEA is not involved in its regulation except when combined with other controlled substances as in the discussion of buprenorphine/naloxone discussed above.

DEA RESPONSE TO THE NONMEDICAL USE OF CPDs

Nonmedical drug use cannot be addressed through law enforcement action alone. Any successful drug control strategy must be balanced and comprehensive, including a focus on both public health and public safety. It requires a coordinated effort by DEA together with our federal, state, and local government partners as well as private stakeholders.

The Office of National Drug Control Policy's (ONDCP) 2011 Prescription Drug Abuse Prevention Plan, together with the 2015 National Drug Control Strategy, comprise a multi-pronged approach that includes education, tracking and monitoring, proper medicine disposal, and enforcement, which represents a science-based and practical way to address this national epidemic.

[20] Substance Abuse and Mental Health Services Administration website, available at: http://www.samhsa.gov/medication-assisted-treatment/treatment/methadone. Retrieved September 6, 2016.
[21] Drug Enforcement Administration, Office of Diversion Control website, available at: https://www.deadiversion.usdoj.gov/webforms/odrRegSummaryReport.do. Retrieved September 6, 2016.

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 (FY) 2014, DEA conducted over 150 such events. In FY 2015, DEA conducted 221 events, and through the second quarter of FY 2016, DEA conducted 329 outreach and public education events raising the awareness of prescription drug misuse and the relationship to heroin, which reached thousands of DEA registrants, pharmacy students, and the general public.

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. In FY 2015, DEA hosted 14 PDACs in seven states. As of the second quarter of FY 2016, DEA hosted eight PDACS in four different states. Ten additional PDACS are planned in five more states during this fiscal year. Since DEA began hosting the PDACS, over 10,000 pharmacy employees have been trained.

DEA also routinely hosts an annual Manufacturers/Importers/Exporters Conference. 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. Last year, this event was attended by approximately 300 individuals representing this subset of DEA registrant community.

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 CSA, as well as provides registrants with current trends and "red flags" that might indicate that an order is suspicious. The most recent Distributor Conference was held on May 10-11, 2016.

DEA will continue to engage with and educate industry. On February 29, 2016, DEA's Diversion Control Division hosted a meeting with the leadership of drug supply chain trade associations to discuss areas of mutual concern.

Monitoring

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

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. Often, one need only cross state lines to avoid detection. Many drug traffickers and drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous pain clinics and physicians.

We and our federal partners are working to address these problems. Several federal entities, including SAMHSA, the Office of the National Coordinator for Health Information Technology, ONDCP, and the Bureau of Justice Assistance (BJA) are supporting efforts to improve interoperability among PDMPs through grants and other assistance. We also understand that the Centers for Disease Control and Prevention (CDC) supports work in states to enhance and maximize PDMPs as public health and clinical tools in its Prevention for States program.[22] Further, the Alliance of States with Prescription Drug Monitoring Programs, Brandeis University's PDMP Center of Excellence, and the Indian Health Service (IHS) are also partnering to improve interoperability between the IHS, its pharmacies and PDMPs. 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 PDMPs to securely exchange prescription data between certain states. As of August 2016, 43 states have executed MOUs to participate in NABP's InterConnect program, and 34 of these states are currently live.[23]

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. At present six states require all controlled substance prescribers to use the state's PDMP prior to prescribing a controlled substance: Kentucky, New Jersey, New Mexico, New York, Oklahoma, and Tennessee. DEA encourages all practitioners and pharmacists to use their state PDMP program.

[22]Centers for Disease Control and Prevention, National Center for Injury Prevention and Control Division of Unintentional Injury Prevention website, available at http://www.cdc.gov/drugoverdose/states/state_prevention.html. Retrieved on September 21, 2016.
[23] National Association of Boards of Pharmacy website, available at http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect. Retrieved on September 21, 2016.

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 to focus its national attention on the issue of nonmedical use of prescription drugs and related substance use disorders, and promotes awareness that one source of these drugs is often the home medicine cabinet. Over 50 percent 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.[24] These regulations establish the means for the public to dispose of unused or expired CPDs in a safe and legal manner.

Since 2010 DEA has 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 April 30, 2016. As a result of all eleven National Take Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of 6.4 million pounds of medications from circulation. The next National Drug Take Back Day is scheduled for October 22, 2016.

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 2016, DEA increased the number of operational TDSs from 37 to 76.

DEA's 360 Strategy

In response to the heroin and prescription opioid crisis**,** DEA is working with federal, state, and local partners to address increases in heroin abuse and availability. Recently, DEA has implemented a 360 Strategy to address this crisis. The strategy leverages existing federal, state, and local partnerships to address the problem on three different fronts: law enforcement, diversion control, and community outreach. The strategy is founded upon our continued enforcement activities directed at drug trafficking organizations and networks responsible for feeding the heroin and prescription opioid epidemic in our communities.

[24]Center for Behavioral Health Statistics and Quality. (2016). Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/.

While law enforcement plays a central role in the 360 Strategy, enforcement actions alone are not enough to make lasting changes in our communities. The 360 Strategy, therefore, also focuses on preventing diversion by providing education and training within the pharmaceutical community and to pursue those practitioners who are operating outside of the law. The final component of the strategy is a community effort designed to maximize all available resources to help communities turn around the recurring problems that have historically allowed the drug and violent crime problems to resurface after enforcement operations. Following is a summary of the three key facets of the 360 Strategy.

Enforcement: Targeting and stopping the most significant drug trafficking threats

The enforcement component of the 360 Strategy has several facets, all focusing on the roots of the drug trafficking problems that are plaguing our communities. Through our collective law enforcement experience, the DEA team knows that the drug problems are often unique to the communities we serve – the strategies that work in one particular area may not work in another. With that reality in mind, the leadership within DEA's Field Divisions works closely with the United States Attorneys and with state and local counterparts to identify the major drug trafficking threats and to develop appropriate enforcement strategies to effectively combat those problems.

In addition to the community-based enforcement approach, the 360 Strategy relies heavily on Project Rolling Thunder, an Organized Crime Drug Enforcement Task Forces supported law enforcement initiative that uses investigative techniques to identify and target the link between the cartels and the drug trafficking networks operating within the United States. The project targets the full spectrum of the criminal network, including the street-level drug dealers, distributors, suppliers, and the highest levels of the cartel leadership.

The foundation of DEA's 360 enforcement operations is built on our close working relationships with our federal, state, and local partners. In all major offices across the United States, DEA has established Task Forces made up of state and local law enforcement officers who work alongside DEA Special Agents to identify and target the most significant drug trafficking threats. Together, these partners will continue to devise and implement investigation strategies to address the drug problems facing our communities.

Diversion: Enlisting DEA's Registrant Population in the Fight against Prescription Opioid Misuse

As stated above, the nonmedical use of prescription opioids is a strong risk factor for heroin use, and the 1.6 million registrants involved in drug manufacture, wholesale distribution, and prescribing, are partners in our efforts to reduce opioid epidemic.

DEA will engage with industry, practitioners, and government health organizations to facilitate an honest and frank discussion about how non-medical use of CPDs is contributing to the current heroin epidemic and how overdose deaths involving both prescription and illicit opioids are devastating communities across the nation. Additionally, DEA is studying ways, in

collaboration with public health partners, to improve access to information that will help identify the nature of the drug problem plaguing a particular area.

Further, DEA will remain vigilant in identifying and pursuing prescribers and other registrants operating outside of the law. This process will be enhanced locally through the use of TDSs, which can mobilize to address regional or local issues, and additional diversion investigators.

Community: Leaving something lasting and positive in the communities we serve

After an enforcement operation targeting violent criminals, there's an opportunity for a prepared community to take advantage of the space and time created to better respond to drug use and addition in their midst and prevent new traffickers from moving in.

This program helps communities to achieve long-term solutions by addressing not only the immediate drug-trafficking problems, but also the underlying conditions that allow drug trafficking, drug use and related violence to flourish. DEA will not only work with federal, state and local agencies to bring greater enforcement resources to bear, but also marshal community groups and their resources to identify local drug use problems and barriers to resolving them, such as lack of treatment access. DEA will partner with other federal agencies and sources of expertise and funding to broaden the resources

The 360 Strategy was implemented in the following three cities – St. Louis, Missouri; Pittsburgh, Pennsylvania; and, Milwaukee, Wisconsin – allowing us to gauge the success of the strategy, and to adjust the strategy as necessary in order to prepare for implementation nationwide. In 2017, we plan to expand this program into the following four additional cities – Albuquerque, New Mexico; Charleston, West Virginia; Dayton, Ohio; and, Manchester, New Hampshire. Our enforcement efforts will continue across the United States with our law enforcement and community partners.