Department of Justice

STATEMENT OF

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BEFORE THE

UNITED STATES SENATE
CAUCUS ON INTERNATIONAL NARCOTICS CONTROL

FOR A HEARING ENTITLED

"AMERICA'S ADDICTION TO OPIOIDS: HEROIN AND PRESCRIPTION DRUGS"

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INTRODUCTION

Chairman Feinstein, Co-Chairman Grassley, and distinguished Members of the Caucus on International Narcotics Control, on behalf of Drug Enforcement Administrator Michele M. Leonhart and the men and women of the Drug Enforcement Administration (DEA), thank you for the opportunity to discuss the epidemic of pharmaceutical controlled substance abuse, specifically the relationship between prescription opioid diversion, misuse and abuse and heroin trafficking and use. DEA and other agencies have been concerned about the connection between prescription opioid diversion, misuse and abuse and rising heroin trafficking and use for several years.

According to the most recent National Survey on Drug Use and Health (NSDUH), there were 335,000 current heroin users in 2012, more than double the number in 2007 (161,000). The DEA believes the increased heroin use is driven by many factors, including an increase in the misuse (e.g., using more than medically indicated or using in a manner not medically indicated) and abuse (i.e., using in order to feel the psychoactive effects of the drug) of prescription psychotherapeutic drugs, specifically opioids. Increases in heroin purity and availability, the low street cost of heroin, expanded Mexican Drug Trafficking Organizations' involvement in the distribution of heroin, and the lack of public awareness of the risks of heroin use are also important contributing factors.

BACKGROUND

There has been some speculation that action to curb prescription drug diversion and non-medical use somehow "diverted" attention from the ongoing problem of heroin use and paved the way for abusers and traffickers to abandon prescription drugs in favor of heroin. However, the cycle of drug abuse is not that simple. To be sure, heroin use steadily increased as prescription drug abuse became an epidemic in this country. The problem of prescription drug abuse has increased exponentially in the last 15 years due to a combination of excessive prescribing, drug availability through friends and family, Internet trafficking, rogue pain clinics, prescribers who prescribe pharmaceutical controlled substances without a legitimate medical purpose or outside the usual course of professional practice, pharmacies that dispense illegitimate prescriptions, and supply chain wholesalers and manufacturers that fail to provide effective controls and procedures to guard against diversion—all of which fueled illicit access at the expense of public health and safety.

At the outset, it is important to note that the non-medical use of prescription opioids and heroin use can lead to addiction and death. We know that more than 16,000 people lost their lives in 2010 to overdoses involving prescription opioids. These deaths represent not just a statistic, but our family members, friends, neighbors and colleagues who join others who lost their lives to heroin as well as a myriad of other drugs.

The extent of the lives lost to illicit and licit drug overdoses must be put into context. Recently, the Centers for Disease Control and Prevention (CDC) reported its analysis revealing that 38,329 people died from a drug overdose in the United States in 2010.[1] Nearly 60 percent of those drug overdose deaths (22,134) involved pharmaceutical drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were involved in about three of every four pharmaceutical overdose deaths (16,651), confirming the predominant role opioid analgesics play in drug overdose deaths.[2]

The cycle of abuse between licit and illicit opioids requires us to recognize that what these individuals and communities are facing is not a heroin *or* a prescription drug problem. It is an *addiction* problem. Heroin use and prescription drug abuse are both addictions that begin with use and are sustained and promoted through increased trafficking. This serious public health problem can be addressed by education, appropriate screening and treatment, recovery support, and enforcement. These initiatives can be effective regardless of whether the problem is fed by heroin or prescription drugs. The DEA supports all of these initiatives to address both prescription drug misuse and abuse and heroin use.

ABUSE OF PHARMACEUTICAL CONTROLLED SUBSTANCES

According to the 2012 NSDUH, 6.8 million people over the age of 12 used psychotherapeutic drugs for non-medical reasons during the past month. This was higher than the users reported in 2011, but similar to the number of users reported between 2005 and 2010. This represents 29 percent of illicit drug users and is second only to marijuana in terms of popularity. There are more current users of psychotherapeutic drugs for non-medical reasons than current users of cocaine, heroin, and hallucinogens combined.

[1] Drug Overdose in the United States: Fact Sheet. www.cdc.gov/homeandrecreationalsafety/overdose/facts.html (accessed Marc. 18, 2014).

[2] Naloxone is an opiate antagonist that can rescue individuals who have overdosed on an opiate. Introduction of naloxone into the victim immediately reverses the affects of the opiate and can save a patient from the overdose. Naloxone is currently available as an injectable, however, police departments in several areas of the country such as Quincy, Massachusetts and Suffolk County, New York are using a nasal naloxone delivery method that is administered by police officers who are certified to carry and utilize the drug under established protocols. Police first responders generally arrive on the scene of an overdose well before emergency medical service personnel and in overdose situations, every second counts. The quicker that naloxone is administered the better chance for patient survival.

In 2012, 156,000 persons aged 12 or older used heroin for the first time within the previous 12 months, which was similar to estimates from 2007 to 2011. However, this was an increase from annual initiates during 2003 (92,000) and 2006 (90,000). Among recent initiates aged 12 to 49, the average age for first-time heroin use was 23.0 years, which was similar to the 2011 estimate (22.1 years).[3] Notably, a special analysis by the NSDUH indicates that 81 percent of heroin initiates between the ages of 12 and 49 in 2008-2010 had previously used pain relievers non-medically.[4]

Non-medical prescription opioid use, particularly by teens and young adults, can easily lead to heroin use. Black-market sales for prescription controlled substances 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 III prescription drug and also the most prescribed drug in the country)[5] can be purchased for as little as $5 to $7 per tablet. Stronger drugs like oxycodone combinations (e.g., Percocet, a schedule II drug) can be purchased for as little as $7 to $10 per tablet. Even stronger prescription drugs are sold for as much as $80.00 per tablet or more in the case of the previous formulation of OxyContin 80 mg, and $30.00 to $40.00 per tablet for 30 mg oxycodone single entity immediate release or the 30 mg oxymorphone extended release. These increasing costs make it difficult, especially for teens and young adults, to purchase in order to support their addiction, particularly when many first obtain these drugs for free from the family medicine cabinet or friends. Not surprisingly, some users of prescription opioids turn to heroin, a much cheaper opioid, generally $10 per bag, which provides a similar "high" and keeps the drug seeker/abuser from experiencing painful withdrawal symptoms. This cycle has been repeatedly confirmed. For some time now, law enforcement agencies across the country have been specifically reporting an increase in heroin use by teens and young adults who began their cycle of abuse with prescription opioids.

Healthcare providers and the victims they treat are confirming this increase. According to some reporting by treatment providers, many individuals addicted to opioids will use whichever drug is cheaper and/or available to them at the time. Individuals addicted to opioids are anecdotally known to switch back and forth between prescription opioids and heroin, depending on

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[3] Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health.

[4] Gfroerer, Joe and Muhuri, Pradip. Association between nonmedical pain reliever use and heroin initiation. Presentation at ONDCP Interagency Meeting on Heroin. June 28, 2012.

[5] On February 27, 2014, DEA published in the *Federal Register* a Notice of Proposed Rulemaking (NPRM) 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 and as supported by the DEA's own evaluation of relevant data. This NPRM proposes to impose the regulatory controls and sanctions applicable to schedule II substances on those who handle or propose to handle hydrocodone combination products. The NPRM is available on the DEA's website, www.dea.usdoj.gov. Members of the public are invited to submit comments or request a hearing. Electronic comments must be submitted, or written comments postmarked, by 11:59 p.m. Eastern Time on April 27, 2014. Requests for hearings must be submitted by March 31, 2014.

price and availability. Abusers who have recently 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 with other substances, all of which could cause individuals with less tolerance to higher potency opioids to accidentally overdose.

A HOLISTIC APPROACH TO NON-MEDICAL PRESCRIPTION DRUG USE, DIVERSION AND AVAILABILITY

Non-medical drug use cannot be addressed through law enforcement action alone. The Office of National Drug Control Policy's 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

The DEA educates the registrant population, including pharmacy personnel, as well as parents, community leaders and law enforcement personnel regarding diversion trends, the scope of the prescription drug diversion problem, and how to best address prescription drug diversion in communities throughout the United States.

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; to date, 34 separate PDACs have been held in 16 different states. Each one-day conference is held on a Saturday or a Sunday for the convenience of the pharmacy community. The conference is designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of this conference is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. In addition, the DEA Office of Diversion Control routinely makes presentations to the public, educators, community-based organizations, registrants, and their professional organizations, industry organizations, and law enforcement agencies regarding the diversion and non-medical use of pharmaceutical controlled substances.

DEA also established the Distributor Initiative Program in 2005 to educate registrants 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, 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.

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, 48 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). Additionally, 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. 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.

Medication Disposal

Another factor that contributes to the increase of prescription drug diversion is the availability of these drugs in the household. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users, accidental ingestion, or illegal distribution for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for treatment. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to use these medications non-medically. Removing household medication that is unwanted or no longer needed is a key component to limiting the availability of and access to these drugs by children and drug seekers for non-medical purposes.

DEA has responded to this problem by coordinating, every six months, Nationwide Prescription Drug Take-Back Days with our Federal, state, local, and tribal law enforcement partners. Prescription drug take-back days are convenient opportunities for the public to safely dispose of unused, unwanted or expired medications. Since September 2010, DEA has held seven Nationwide Prescription Drug Take-Back Days. On October 26, 2013, the most recent Nationwide Take Back Day, 647,211 pounds (324 tons) of prescription medications were collected from members of the public. Collectively, the seven Nationwide Take Back Days have removed a total of 3.4 million pounds (1,733 tons) of medication from circulation. The eighth national take-back day is scheduled for April 26, 2014.

In addition, DEA is fully engaged in ensuring proper disposal of controlled substances and is developing a final rule implementing the Secure and Responsible Drug Disposal Act. The Act authorizes DEA to promulgate regulations allowing additional ways for Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner. DEA's goal is to implement the Secure and Responsible Drug Disposal Act of 2010 by expanding the options available to safely and securely collect pharmaceutical controlled substances from ultimate users for purposes of disposal, to include: take-back events, mail-back programs, and collection receptacle locations. With the final regulations on the horizon, the DEA hopes that all Americans will be able to remove unwanted controlled substances more readily from their households, thereby helping to reduce diversion and the public health concerns regarding these substances.

Enforcement

Over the past several years, DEA has uncovered two types of illegal schemes used to divert powerful and addictive controlled substance pharmaceuticals. Florida was the epicenter of many illegal operations whereby hundreds of millions of dosage units of controlled substances were diverted into the illicit marketplace across the United States. Between 2005 and 2009, the diversion of millions of dosage units of schedule III hydrocodone products was facilitated by rogue internet pharmacies and unscrupulous prescribers who provided prescriptions to drug seekers utilizing these sites. The *Ryan Haight Online Pharmacy Consumer Protection Act* that took effect in April 2009 responded to the explosion of domestic rogue internet pharmacy diversion. This law, combined with intensified law enforcement and regulatory actions, virtually eliminated domestic-based rogue internet pharmacies that were involved in internet distribution of prescription opioids.

As the number of domestic, Internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics, particularly in Florida.[6] Instead of hydrocodone combination products, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a schedule II controlled substance that is just as dangerous as hydrocodone combination products when taken for a non- medical use. There was a sharp increase in pain clinics located in the tri-county area of South Florida (comprised of Broward, Miami-Dade, and Palm Beach Counties) in 2009. According to data provided by the State of Florida, by 2010, Broward County alone was home to approximately 142 rogue pain clinics. Federal, state and local law enforcement investigations identified thousands of drug seekers that routinely traveled to Florida-based rogue pain clinics to obtain pharmaceutical controlled and non-controlled substances, such as oxycodone, hydromorphone, methadone, tramadol, alprazolam, clonazepam, and carisoprodol. They then would travel back to their home states and illegally distribute the drugs that ultimately flooded the illicit market in states along the entire East Coast and the Midwest.

[6] It addition, the amount of heroin seized at the South West border increased over 300 percent from 2008 to 2013.

Not unexpectedly, increased diversion leads to increased enforcement activity. The National Forensic Laboratory Information System (NFLIS) collects results of drug chemistry analyses conducted by Federal, state, and local forensic laboratories across the country. As such, NFLIS can provide detailed analytical results of drugs seized by law enforcement, including trends in the diversion of pharmaceutical controlled substances into illegal markets. As of December 2013, 49 state laboratory systems, 96 local laboratory systems, and one territorial laboratory system were participating in NFLIS. In 2012, an estimated 1.6 million drug analysis records were reported to participating NFLIS state and local laboratories. The increase in opioid pain medication analyses conducted by NFLIS-reporting laboratories from 2001 to 2012 is staggering: 275 percent for oxycodone; 197 percent for hydrocodone; and 334 percent for morphine.

DEA intelligence reveals that heroin trafficking organizations are relocating to areas where non-medical use of prescription drugs on the rise. Correspondingly, NFLIS shows an increase in the heroin cases and reports[7]:

NFLIS Estimates						
	2008	**2009**	**2010**	**2011**	**2012**	**Jan - Jun 2013**
Heroin Reports	95,879	112,153	110,393	119,765	131,624	74,049
Heroin Cases	73,562	83,535	82,385	88,924	99,830	55,744
Total Reports	1,711,763	1,758,505	1,713,360	1,660,216	1,622,435	770,851
Total Cases	1,290,363	1,297,735	1,274,383	1,218,161	1,189,089	578,034
% Heroin Reports	5.60%	6.38%	6.44%	7.21%	8.11%	9.61%
% Heroin Cases	6.92%	7.95%	8.04%	9.24%	10.72%	12.25%

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 TDS's from 37 to 66. With the expansion of TDS groups across the United States, the number of diversion-related criminal and administrative cases has increased significantly.

[7] In NFLIS, a "case" is a law enforcement investigation; a "report'' is an analysis of an exhibit pertaining to an investigation. There are typically many reports in a single case.

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 Controlled Substances Act. DEA has steadily increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; pharmacies; importers; exporters; 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 Controlled Substances Act and its implementing regulations.

The TDS's and the Diversion Groups have brought their skills to bear on Florida-based pain clinics and as the pill mill threat is driven out of Florida and moves towards the north and northwest, DEA will continue to target the threat with the TDS groups' proven law enforcement skills, the Diversion Groups' regulatory expertise, and by educating registrants.

CONCLUSION

Non-medical prescription opioid use is a major factor contributing to the increase in heroin trafficking and use throughout the United States. Any long-term solution to reduce non-medical opioid use must include aggressive actions to address prescription drug diversion while educating the public about the dangers of the non-medical use of pharmaceuticals, educating practitioners on methods of diversion and trends of non-medical pharmaceutical use, and treating those individuals with substance use disorders. The increase in heroin use and non-medical prescription opioid use and trafficking leads to addiction. Preventing the availability of pharmaceutical controlled substances to non-medical users and educating practitioners and the public about pharmaceutical diversion, trafficking and abuse are priorities for the DEA. As such, DEA will continue to work in a cooperative effort with other Federal, state, local, and tribal officials, law enforcement, professional organizations, and community groups to address this epidemic. The DEA and our Federal, state, local, and tribal law enforcement and regulatory counterparts are attempting to control the diversion of prescription opioids into the illicit marketplace, as well as controlling the rise in heroin use. The increase in heroin use derives, in part, from the non-medical use of prescription opioids and the addiction made possible by abuse and availability. DEA and its partners will continue to address this epidemic through a holistic approach.