



Department of Justice

STATEMENT FOR THE RECORD OF

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BEFORE THE

**SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES**

ENTITLED

"PRESCRIPTION DRUG DIVERSION: COMBATING THE SCOURGE"

PRESENTED ON

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**Statement for the Record of
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United States Department of Justice**

**Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
United States House of Representatives**

**“Prescription Drug Diversion: Combating the Scourge”
March 1, 2012**

Chairman Bono-Mack, Ranking Member G. K. Butterfield, and distinguished Members of the Subcommittee, on behalf of the men and women of the Drug Enforcement Administration (DEA), I am honored to have the opportunity to appear before you today to provide testimony concerning the Drug Enforcement Administration’s efforts in combating prescription drug abuse.

Overview

Every day prescription drugs are abused in the United States at an alarming rate. Leading indicators show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the adverse consequences associated with such actions. These indicators include, but are not limited to: the National Survey on Drug Use and Health, Monitoring the Future Study, Partnership Attitude Tracking Study, Drug Abuse Warning Network (DAWN) data, Treatment Episode Data Set, American Association of Poison Control Centers’ National Poison Data System, CDC’s National Vital Statistics System, and the National Forensic Laboratory Information System (NFLIS).

- According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2010 National Survey on Drug Use and Health (NSDUH), 7 million Americans were current (past month) non-medical users of psychotherapeutic drugs, significantly higher (by 12 percent) compared to 6.2 million in 2008. Over three-quarters of that number, 5.1 million Americans, reported non-medical use of pain relievers.
- The NSDUH survey also indicated that the non-medical use of prescription drugs was second only to marijuana abuse. On average, more than 6,600 people 12 years and older initiate use of a controlled substance pharmaceutical drug for non-medical purposes every day.

- The Centers for Disease Control and Prevention (CDC) reported that the number of poisoning deaths involving any opioid analgesics increased from 4030 in 1999 to 14,800 in 2008, more than tripling in 8 years.¹
- SAMHSA's Treatment Episode Data Set shows that between 1999 and 2009 the number of admissions to substance abuse treatment that reported any pain reliever abuse increased more than sixfold.
- According to DAWN data, the number of emergency department visits involving the misuse or abuse of pharmaceuticals increased by 98.4 percent between 2004 and 2009. The prescription drugs most implicated were opiate/opioid pain relievers, oxycodone products increased 242 percent, and hydrocodone products increased 124 percent.
- The approximate number of cases submitted by state and local law enforcement to forensic labs between 2001 and 2010 increased significantly (331 percent for oxycodone, 253 percent for hydrocodone, and 281 percent for methadone).

Statistics concerning the abuse of pharmaceutical controlled substances and prescription medication also reveal disturbing trends. Persons aged 12 years and older who used prescription drugs non-medically in the past month exceeded the number of current users of cocaine, heroin, hallucinogens, and methamphetamine combined.² The number of new initiates for narcotic pain relievers is second only to marijuana use.³

Another factor that may contribute to the overall upward trend of abuse is that teenagers and young adults believe that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana and methamphetamine. The 2008 PATS study noted that 41 percent of teenagers mistakenly believe that prescription medications are “much safer” than illegal drugs.⁴ Because prescription medications are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacists, teens and young adults often have a false sense of security regarding these potent and sometimes dangerous medications. This false sense of security can end in tragedy. In 2010, 1 in 4 teens admitted to using a prescription drug not prescribed to them by a doctor at some point in their lives.⁵ Teens continue to report that their parents do not talk to them about the risks of prescription drugs in the same manner as they discuss other substances of abuse.⁶

The 2011 Monitoring the Future (MTF) study reported use rates for two narcotic drugs, OxyContin (oxycodone) and Vicodin (hydrocodone and acetaminophen). According to the MTF

¹ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, August 20, 2010.

² Substance Abuse and Mental Health Services Administration. Results from the 2010 National Survey on Drug Use and Health.

³ Ibid, p. 49.

⁴ Partnership for a Drug-Free America, 2008 Partnership Attitude Tracking Study, Key Findings.

⁵ Partnership for a Drug-Free America, 2010 Partnership Attitude Tracking Study.

⁶ 2010 Partnership Attitude Tracking Study, p.18.

study annual prevalence for OxyContin in 2011 was 1.8%, 3.9% and 4.9% in grades 8, 10, and 12 respectively and annual prevalence for Vicodin was 2.1%, 5.9% and 8.1% in grades 8, 10, and 12.⁷ The MTF study stated, “One group of drugs that is not down much from peak levels is *narcotics other than heroin*; their continued high rate of use is a disturbing finding.”⁸ On average, every day 2,046, 12-17 year olds abuse a prescription pain reliever for the first time.⁹

The economic impact on the United States from the non-medical use of prescription opioids in 2006 was estimated at \$53.4 billion, (\$42 billion in lost productivity, \$8.2 billion in criminal justice costs, \$2.2 billion in treatment costs, and \$944 million in medical complications).¹⁰

The Growing Pain Pill Epidemic in Florida

Over the past several years, the DEA has seen two major schemes used to divert powerful and addictive controlled substance pharmaceuticals. Circa 2005-2009, hydrocodone combination products (e.g. Vicodin), which are schedule III controlled substances, were illegally diverted through unscrupulous prescribers as well as rogue internet pharmacies. Florida was the epicenter for many of the illegal operations whereby tens of millions of dosage units of hydrocodone were diverted into the illicit marketplace across the United States.

Congress addressed the problem of rogue internet pharmacies with the passage of the Ryan Haight Online Pharmacy Consumer Protection Act that took effect in April 2009. This action, combined with intensified law enforcement actions, virtually eliminated domestic-based rogue internet pharmacies.

As the number of domestic-based rogue, internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics, particularly in Florida. Instead of hydrocodone, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a schedule II controlled substance that is more potent than hydrocodone. Again, Florida was and remains the epicenter for these illegal pain clinic operations. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based rogue pain clinics to obtain a supply of oxycodone, which is in turn illegally redistributed in states along the entire East Coast and the Midwest.

The State of Florida has attempted to address this problem through a patchwork of legislation. Current state legislation restricts a physician’s ability to dispense oxycodone from a pain clinic. These rogue operations adapted by issuing illegitimate prescriptions for oxycodone rather than dispensing directly to the “patient,” and DEA and other law enforcement agencies saw an increase in the volume of oxycodone dispensed from various pharmacies across the state. DEA also saw a sharp increase in the number of new pharmacy applications in the State of

⁷ 2011 Monitoring the Future Study: *Overview of Key Findings 2011*, p. 33. University of Michigan, Ann Arbor.

⁸ *Ibid*, p. 11.

⁹ Substance Abuse and Mental Health Services Administration, 2010 National Survey on Drug Use and Health.

¹⁰ *Clinical Journal of Pain*, Hansen, RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD. “Economic costs of nonmedical use of prescription opioids. *Clinical Journal of Pain*, 2011 Mar-Apr; 27(3):194-202.

Florida. Further investigation of pharmacy applicants revealed “straw purchases” of pharmacies that showed ties to established rogue pain clinics. The purchase of pharmacies is part of the scheme by rogue pain clinic owners to circumvent Florida laws: if a pain clinic cannot lawfully dispense drugs directly to a “patient,” then the pain clinic will issue illegitimate prescriptions to “patients,” and the pain clinic pharmacy will dispense drugs based on those illegitimate prescriptions. DEA has instituted a program to investigate Florida-based pharmacy applicants prior to issuing a DEA registration, a regulatory step normally reserved for the State Board of Pharmacy.

DEA registered pharmacies are generally supplied by DEA registered wholesale distributors. Rogue pain clinics, pharmacies that fill illegitimate prescriptions for pain clinic “patients”, and the wholesale distributors who supply these pharmacies have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted. Consequently, the registrants involved-- practitioners, pharmacies, and wholesale distributors that do not comply with the Controlled Substances Act (CSA) and its implementing regulations-- are allowing millions of dosage units of controlled substances to pour into the illicit market, posing an imminent danger to the public health and safety. The damage to society from these drugs flooding into the illicit market is evident by the number of deaths associated with pharmaceutical abuse.

According to the Florida Medical Examiner’s Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just one of five drugs or drug classes: methadone, oxycodone, hydrocodone, all benzodiazepines, or morphine. This is an average of 11.2 persons dying in the State of Florida every day. Since many of the drug seekers who frequent the rogue Florida pain clinics return to their state of residency, there are surely more deaths and injuries caused from the drugs that are diverted from these clinics than just those reported by the Florida Medical Examiner’s Office.

The Closed-System of Distribution and the Regulatory Scheme

The Food and Drug Administration, through the Federal Food, Drug and Cosmetic Act, generally regulates pharmaceutical drugs. However, due to their potential for abuse and danger to public health and safety, Congress recognized the need for greater scrutiny over controlled substances. As such, they established a separate and distinct framework under the CSA and implementing regulations that creates a closed-system of distribution for all controlled substances and listed chemicals. *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) (“[I]t cannot be overemphasized that the ...[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls.”). Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA. Congress acted to halt “the widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572.

This closed-system is specifically designed with checks and balances between registrants to ensure that controlled substances are not diverted. For example, registrants must adhere to

many security, recordkeeping and reporting requirements. Also, a practitioner can only dispense/prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. 21 CFR § 1306.04. In order to obtain and maintain a distributor registration, a distributor must be able to “maintain ... effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels...” 21 USC § 823(b)(1). With respect to the wholesale distributors who supply pharmacies with controlled substances, “*The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances.*” 21 CFR § 1301.74. When all registrants are complicit in diversion schemes, similar to the pain clinic scheme in Florida, these necessary checks and balances collapse.

The Drug Enforcement Administration & the Diversion Control Program

Restructuring

The increase in the abuse of prescription drugs is fueled by many factors, including the development and marketing of new pharmaceutical controlled substances, and ever-changing methods of diversion such as rogue Internet pharmacy schemes or rogue pain clinics. Just as illicit drug traffickers and organizations adapt to law enforcement methods, pharmaceutical traffickers adapt to and circumvent laws that attempt to stop the flow of controlled substance pharmaceuticals into the illicit market. Attempts to prevent, detect, and reduce the diversion and abuse of controlled substance pharmaceuticals continue to evolve. The DEA has taken action on several fronts over the past few years to help reduce this growing problem.

In October 2008, the then Acting Administrator authorized a two-pronged reorganization of the Diversion Control Program. The first prong involved a substantial expansion in the number of Tactical Diversion Squads (TDS) and their deployment throughout the United States. This approach would provide a significant increase in the number of Special Agents and Task Force Officers who possess the requisite law enforcement authorities needed when conducting criminal investigations, i.e. the ability to conduct surveillance, make arrests and execute search warrants. The second prong of the reorganization plan called for a renewed focus on DEA’s regulatory oversight of more than 1.4 million DEA registrants.

Expansion of Tactical Diversion Squads

Tactical Diversion Squads (TDS) investigate suspected violations of the CSA and other appropriate 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 Task Force Officers (who come from a variety of state and local law enforcement agencies). TDS groups are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., “doctor shopping,” prescription forgery rings, and doctors or pharmacists who illegally divert controlled substance pharmaceuticals). Tactical Diversion Squads develop sources of information and disseminate intelligence to appropriate elements for the development of leads and subjects of investigations. As of February 17, 2012, 46 operational TDS groups are located throughout the United States; however, several are not yet fully staffed. DEA plans to add

several more TDS groups over the next few years. With the expansion of TDS groups across the U.S., the number of diversion-related criminal and administrative cases has increased. These TDS groups have also been able to increase the number of diversion-related Priority Target Organization (PTO) investigations. PTO investigations focus on those criminal organizations or groups that significantly impact local, regional or national areas of the country.

The restructuring of the Diversion Control Program has allowed investigative efforts to focus on specific problem areas. For example, DEA, working with its State and local partners, has put forth a substantial investigative effort towards rogue clinics which has been dubbed *Operation Pill Nation I*. This operation involved the mobilization of eleven Tactical Diversion Squads from across the United States to marshal with the Miami TDS and other State and local agencies in a concerted effort to attack and dismantle the hundreds of rogue pain clinics that continue to plague south Florida. On February 23, 2011, DEA as part of *Operation Pill Nation I*, conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown. As of February 21, 2012, *Operation Pill Nation I* resulted in 47 arrests, including 27 doctors; the issuance of 34 Immediate Suspension Orders against 63 DEA registrations; 92 DEA registrations being surrendered for cause; and the seizure of more than \$18.9 million in assets.

DEA conducted a similar operation in the central Florida area dubbed *Operation Pill Nation II*. As of January 31, 2012, *Operation Pill Nation II* resulted in 57 arrests, including 8 doctors and 3 pharmacists; the issuance of 4 Immediate Suspension Orders; 6 DEA registrations being surrendered for cause; and the seizure of approximately \$311,995.00 in assets.

Enhanced Regulatory Oversight

DEA is also using its regulatory authority to ensure that DEA registrants maintain effective controls against diversion by complying with all aspects of the CSA and its implementing regulations. One way DEA attempts to accomplish this is through our Distributor Initiative Program. This program was implemented in late 2005 and was designed to educate wholesale distributors who were supplying diversion schemes such as rogue Internet pharmacies and more recently rogue pain clinics and rogue pharmacies. The goal of the program is to cut off the source of supply to these or other schemes through effective due diligence and suspicious order reporting. As stated above, wholesale distributors are required to design and operate a system that would detect suspicious orders to the registrant and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA provides registrants with information such as “red flags”, trending information, and data analysis that they should be aware of prior to distributing controlled substances. These warning signs include, but are not limited to, 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, location of the customer, and the percent of controlled versus non-controlled substances ordered.

DEA’s enhanced regulatory oversight and investigative efforts have resulted in the identification of various distributors who failed to adhere to their regulatory responsibilities. Consequently, DEA took administrative action against these distributors, and also referred them for civil action. These investigations resulted in record-breaking civil fines (McKesson Drug

Corporation paid \$13.25 million in April 2008 and Cardinal Health paid \$34 million in October 2008).

DEA has and will continue to vigorously pursue criminal, administrative and civil actions against registrants who fail to comply with all aspect of the CSA and its implementing regulations as required. More recent examples include, but are not limited to, actions against wholesale distributors such as Harvard Drugs, Keysource, and Sunrise

Due to the recent rise in the number of new pharmacy applications in the State of Florida, DEA is also using its regulatory oversight authority to conduct in-depth investigations of pharmacy applicants in order to determine whether to issue a DEA registration to handle controlled substances. These efforts have thwarted a significant number of attempts by individuals associated with rogue pain clinics to open a new pharmacy and thereby circumvent newly established laws within the state.

Scheduling Actions

The abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as the “trinity” or “holy trinity”, and is typically hydrocodone or oxycodone used in combination with alprazolam and carisoprodol.

To address this problem, DEA published a Final Rule in the Federal Register on December 12, 2011, scheduling carisoprodol as a schedule IV controlled substance, effective January 11, 2012.¹¹

DEA has also been working with the Food and Drug Administration to determine whether hydrocodone-combination products should be moved from schedule III to schedule II of the Controlled Substances Act.

The Family Medicine Cabinet & Proper Disposal

Another factor that contributes to the increase of prescription drug abuse 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 for abuse, 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 abuse medications. For example, the 2010 Partnership Attitude Tracking Study (PATS) noted that 51 percent of those surveyed believe that

¹¹ See: Federal Register Notice 76 FR 77330, December 12, 2011.

most teens get prescription drugs from their own family's medicine cabinets.¹² The Administration recognizes the issue of prescription drug abuse as described in the 2011 Prescription Drug Abuse Prevention Plan. One of the items set forth in the Plan is to increase prescription return/take-back and disposal programs.¹³

On September 25, 2010, DEA coordinated the first-ever National Take-Back Initiative. Working with more than 3,000 state and local law enforcement partners, take-back sites were established at more than 4,000 locations across the United States. Since then DEA, in conjunction with its state, local and tribal law enforcement partners, along with numerous other governmental and private groups,¹⁴ have conducted two other Take-Back Days. This massive undertaking has resulted in the collection of more than 498 tons of unwanted or expired medications.

In October 2010, Congress passed and the President signed into law the Secure and Responsible Drug Disposal Act of 2010. DEA has been working diligently to promulgate the regulations pertinent to this Act. As part of this effort, DEA conducted a public meeting on January 19 and 20, 2011, to receive information regarding the development of procedures for the surrender of unwanted controlled substances by ultimate users and long term care facilities. Specifically, this meeting allowed all interested persons—the general public including ultimate users, pharmacies, law enforcement personnel, reverse distributors, and other third parties—to express their views regarding safe and effective methods of disposal of controlled substances. The Act and implementing regulations will provide the basic framework that will allow Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner. In the interim, DEA is coordinating another National Take-Back Initiative on April 28, 2012.

Conclusion

Prescription drug abuse is a serious problem. Reducing prescription drug abuse is vital to the health and welfare of the American people and is a priority for this Administration. DEA has the statutory responsibility of enforcing the Controlled Substances Act and its implementing regulations. Efforts towards this end help to minimize the availability of pharmaceutical controlled substances to non-medical users and preserve the integrity of the closed-system of

¹² Partnership for a Drug-Free America, The Partnership Attitude Tracking Study (PATS) Teens 2010 Report.

¹³ 2011 Prescription Drug Abuse Prevention Plan: *Epidemic: Responding to America's Prescription Drug Crisis*, pp. 7 & 8.

¹⁴ Other governmental and private groups include: the Office of National Drug Control Policy, the Department of Justice, Indian Health Services, Bureau of Indian Affairs, Substance Abuse and Mental Health Administration, Department of Education, Environmental Protection Agency, National Institute of Drug Abuse, Department of Transportation, Health Resources and Services Administration, National Association of Attorneys General, National District Attorneys Association, National Association of Chiefs of Police, National Sheriffs Association, National Association of Drug Court Professionals, Fraternal Order of Police, National Organization of Black Law Enforcement Executives, Partnership at Drugfree.org, Federation of State Medical Boards, National Association of Boards of Pharmacy, American Association of Poison Control Centers, Community Anti-drug Coalitions of America, D.A.R.E. America, Senior Corps, Veterans and Military Families, Home Instead Senior Care, Law Enforcement Explorer's Association, Save Our Society from Drugs, School Nurses Association, and the National Family Partnership.

distribution. Despite the many hurdles outlined herein we are making progress. DEA is identifying and investigating threats of diversion at all levels of the distribution chain. DEA's enhanced criminal and regulatory oversight is forcing all levels of the pharmaceutical industry to comply with the CSA. When necessary, DEA takes action to revoke the registration of the affected registrant. Manufacturers are now sending letters to their wholesale distributor customers warning them of their due diligence obligations and that their lack of customer monitoring will result in a discontinuation of business. States have also stepped up their focus on preventing the diversion of pharmaceuticals. Forty-eight states have now enacted legislation to implement a Prescription Drug Monitoring Program within their state which will ultimately identify and limit medications dispensed to drug seekers and doctor shoppers. Federal, State and local officials, law enforcement, professional organizations and community groups continue to work together to fight this epidemic. Progress is being made, but we have a long way to go.

Chairman Bono-Mack, Ranking Member Butterfield, and distinguished Members of the Subcommittee, thank you for the opportunity to appear today to discuss this important issue.