



Department of Justice

STATEMENT FOR THE RECORD OF

MICHELE M. LEONHART
ADMINISTRATOR
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON CRIME AND TERRORISM
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

ENTITLED

“RESPONDING TO THE PRESCRIPTION DRUG EPIDEMIC: STRATEGIES FOR
REDUCING ABUSE, MISUSE, DIVERSION, AND FRAUD”

PRESENTED ON

MAY 24, 2011

**Statement for the Record of
Michele M. Leonhart
Administrator
Drug Enforcement Administration
United States Department of Justice**

**Subcommittee on Crime and Terrorism
Committee on the Judiciary
United States Senate**

**“Responding to the Prescription Drug Epidemic: Strategies for Reducing Abuse, Misuse,
Diversion, and Fraud”
May 24, 2011**

Chairman Whitehouse, Ranking Member Kyl, 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 dangers of prescription drug abuse.

Overview

The diversion and abuse of pharmaceutical controlled substances is a significant and growing problem in the United States. Leading indicators show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the 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 (PATS), Drug Abuse Warning Network (DAWN) data, Treatment Episode Data Set, American Poison Control Centers data, and the National Forensic Laboratory Information System (NFLIS).

- According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2009 National Survey on Drug Use and Health (NSDUH), 7 million Americans were current non-medical users of psychotherapeutic drugs, significantly higher by 12 percent compared to 2008. Over three-quarters of that number, 5.3 million Americans, abused 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 7,000 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 4,041 in 1999 to 14,459 in 2007, more than tripling in 8 years.¹
- SAMHSA's Treatment Episode Data Set shows that between 1998 and 2008 the number of persons admitted for treatment that reported any pain reliever abuse increased more than fourfold.
- 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 2009 increased significantly (330 percent for oxycodone, 314 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 In this age range, prescription drug abuse 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, about 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 2010 Monitoring the Future study reported that Vicodin, a brand name pain reliever containing the narcotic hydrocodone, is one of the most commonly abused drugs among 12th

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 2009 National Survey on Drug Use and Health.

³ Ibid, p. 14.

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.

graders: in 2010, about 1 in 13 (8%) reported non-medical use in the previous year.⁷ On average, every day 2,100 12-17 year olds abuse a prescription pain reliever for the first time.⁸

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).⁹

Drug Enforcement Administration & the Diversion Control Program

Under the Controlled Substances Act (CSA), Congress established a “closed system” of distribution designed to prevent the diversion of controlled substances. In furtherance of the closed system, no controlled substance may be transferred between two entities unless the entities are DEA registrants or exempt from registration. To maintain the closed system, every entity that manufactures or distributes controlled substances, or proposes to engage in the manufacture or distribution of any controlled substance, must obtain a DEA registration authorizing such activity. In addition to the requirement that DEA registrants maintain copious records of all transactions involving controlled substances, the closed system is monitored by the Automation of Reports and Consolidated Orders System (ARCOS).

The Automation of Reports and Consolidated Orders System (ARCOS)

The Automation of Reports and Consolidated Orders System (ARCOS) is DEA’s database that captures controlled substance activity from the point of manufacture and/or distribution to the point of sale to the retail level registrant (e.g., pharmacies, hospitals, practitioners, teaching institutions, researchers, analytical labs, importers/exporters, and Narcotic Treatment Programs). Approximately 1,100 manufacturers and distributors report data to ARCOS. Just under 70.9 million transactions were reported to ARCOS in 2010. Manufacturers of bulk and/or dosage form controlled substances must report inventories, acquisitions, and dispositions of all substances in schedules I and II, schedule III narcotics, and Gamma-Hydroxybutyric Acid (GHB) in Schedule III. Additionally, manufacturers must report synthesizing activities involving all substances in schedules I and II, schedule III narcotics, Gamma-Hydroxybutyric Acid (GHB) substances in schedule III, and selected psychotropic controlled substances in schedules III and IV.

Distributors of bulk and/or dosage form controlled substances must report inventories, acquisitions, and dispositions of all substances in schedules I and II, schedule III narcotics, and Gamma-Hydroxybutyric Acid (GHB) substances in schedule III. Once the substance has been sold to the retail level registrant, ARCOS does not capture further transaction information (i.e., from practitioner to end user, from pharmacy to end user, etc.).

⁷ 2010 Monitoring the Future Study. University of Michigan, Ann Arbor.

⁸ Substance Abuse and Mental Health Services Administration, 2009 National Survey on Drug Use and Health..

⁹ Hansen, RN et al. 2011. “Economic costs of non-medical use of prescription opioids. *Clinical Journal of Pain*, Mar-April; 27(3):194-2-2.

The Quota System

DEA establishes manufacturing and procurement quotas each year for schedule I and II controlled substances in order to avoid the overproduction of these substances, for the purpose of reducing the risk of diversion to illicit traffic. Accordingly, the quota system serves the vital purpose of reducing the risk of diversion. Pursuant to 21 U.S.C. § 826(a), the Attorney General is required to determine “the total quantity and establish production quotas for each basic class of controlled substance in schedule I and II . . . to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.” These determinations, which are known as aggregate production quotas, “represent those quantities of controlled substances that may be produced in the United States in” the relevant calendar year. The aggregate production quota is then allocated among those registered manufacturers who apply for, and demonstrate a need for, a manufacturing quota.

Pursuant to DEA regulation, a registrant seeking a manufacturing quota is required to submit an application form justifying the quantity it seeks to manufacture. The completed form must provide, for the particular basic class, the data for the current and preceding 2 calendar years to include: 1) its authorized individual manufacturing quota; 2) the actual or estimated quantity manufactured; 3) the actual or estimated or net disposal; 4) the actual or estimated inventory allowance; and 5) the actual or estimated inventory as of December 31. In addition to the desired individual manufacturing quota which is being sought, the applicant is required to state any additional factors which the applicant finds relevant to the fixing of his individual manufacturing quota, including the trend of (and recent changes in) his and the national rate of net disposal, his production cycle and current inventory position, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes) and recent unforeseen emergencies such as floods and fires.

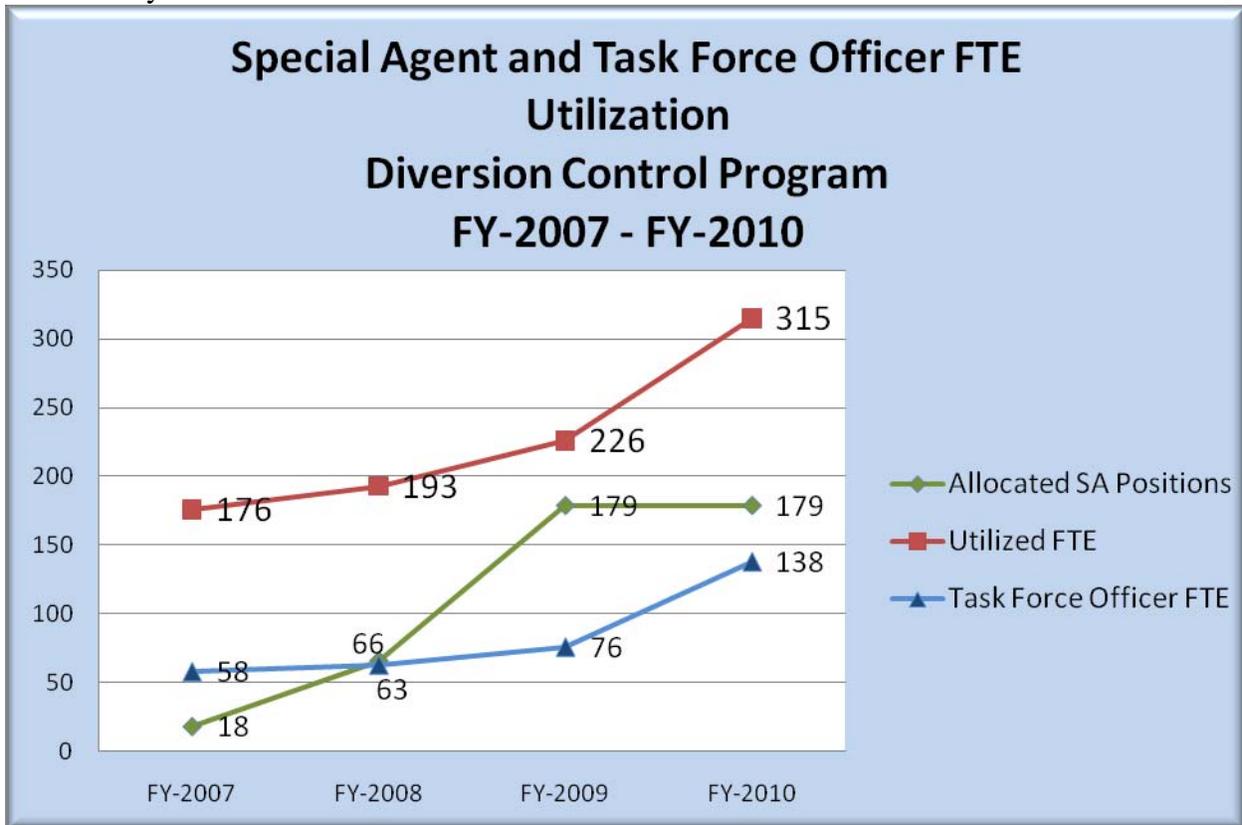
Restructuring

The substantial increase in the abuse of prescription drugs is fueled by many factors, including the development and marketing of new controlled substances, and ever-changing methods of diversion such as rogue Internet pharmacy schemes or rogue pain clinics. 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 1.3 million DEA registrants.

Expansion of Tactical Diversion Squads

Tactical Diversion Squads (TDS) investigate suspected violations of the Controlled Substances Act 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 and listed chemicals). Tactical Diversion Squads develop sources of information and disseminate intelligence to appropriate elements for the development of leads and targets. As of May 13, 2011, DEA has 37 operational TDS groups. DEA plans to add 26 more TDS groups over the next few years. With the expansion of Tactical Diversion Squads across the U.S., the number of diversion-related criminal cases has increased. These Tactical Diversion Squads 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. In addition, the Special Agent (SA) and Task Force Officer (TFO) work hours dedicated to diversion-related criminal cases has also increased dramatically.



Changes in Regulatory Investigations

As stated above, the second prong to the reorganization plan was to provide for enhanced regulatory oversight of more than 1.3 million registrants, a number which grows at an annual rate of approximately 2.5 percent. These registrants conduct a variety of business activities and vary in size and complexity. This portion of the plan required DEA to hire additional Diversion Investigators (DI) and create a new training curriculum. In FY 2009, the Office of Diversion Control developed and instituted this new training curriculum, which was designed to retrain and retool all Diversion Investigators in regulatory investigations. As of December 2010, all Diversion Investigators completed this training.

With more Diversion Investigators focused on the regulatory aspects of the Diversion Control Program, DEA increased the frequency of scheduled inspections to improve its regulatory oversight. As a result, the President's FY 2011 budget request of 60 more DI positions was authorized, and the FY 2012 budget requests an additional 50 DI positions. This renewed focus on regulatory control has enabled DEA to take a more proactive approach on multiple fronts to ensure that DEA registrants are complying with the Controlled Substances Act and implementing regulations. For example, DEA has revised its timetable regarding the frequency with which it will inspect/audit specific registrant categories such as controlled substance manufacturers (which includes bulk manufacturers); distributors; importers; exporters; narcotic treatment programs; DATA-waived practitioners; researchers; and chemical handlers.

DEA's efforts are also aimed at ensuring that DEA registrants maintain effective controls against diversion by designing and operating systems that disclose to the registrant suspicious orders for controlled substances. In 2005, DEA established the Distributor Initiative Program to remind distributors of their responsibilities under the CSA and its implementing regulations concerning suspicious orders. Since its inception in August 2005 through May 13, 2011, DEA has briefed 75 DEA-registered corporations/companies comprising 215 distribution centers concerning illegal Internet pharmacy operations and rogue pain clinics. As a result, some distributors have voluntarily stopped selling or voluntarily restricted sales of controlled substances to certain domestic pharmacies and practitioners. Some distributors have also cut off the supply of controlled substance pharmaceuticals to certain customers as a result of their own intensified efforts spurred by the Distributor Initiative Program. From June 2006 through May 13, 2011, distributors have refused to sell controlled substances to approximately 1,517 customers that the distributors believed were placing suspicious orders for controlled substances.

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 penalty action which resulted in record-breaking civil penalties negotiated with the registrant, e.g., \$13.25 million civil penalty paid by McKesson Drug Corporation in April 2008; \$34 million civil penalty paid by Cardinal Health in October 2008; and \$75 million civil penalty in addition to \$2.6 million in civil forfeitures against CVS Corporation in October 2010. And in April 2011, the Harvard Drug Group agreed to pay a civil penalty of \$8 million.

Addition of Intelligence Research Specialist Positions

Due to the ever-increasing complexities of diversion investigations, another much-needed enhancement to the Diversion Control Program was the addition of Intelligence Research Specialists dedicated to working these types of investigations. Before FY 2006, the Diversion Control Program had no authorized Intelligence Research Specialist (IRS) positions allocated to the Program. In FY 2006, 40 IRS positions were allocated to the DCP with another 33 allocated in FY 2007. Even with this increase in positions, more IRS work hours are attributed to the Diversion Control Program than are allocated. As a result, DEA requested and was authorized to increase by 14 IRS positions in the Diversion Control Program in FY 2011. In addition, another increase of 9 IRS positions is requested in FY 2012. The inclusion of this job series into the Diversion Control Program will help DEA conduct its investigations more efficiently and effectively.

Level of Effort by Drug Type

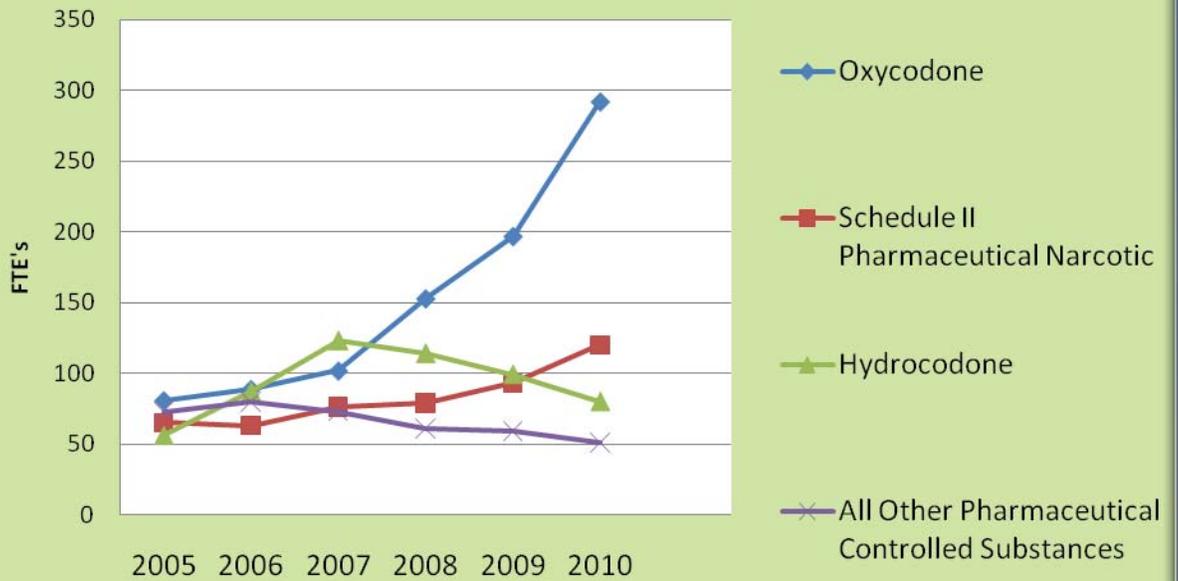
The restructuring of the Diversion Control Program has allowed investigative efforts to focus on specific problem areas, as shown in the charts below. For example, cases focused on oxycodone increased by 210 percent between FY 2005 and FY 2010, but have decreased for those involving hydrocodone, due to a significant decrease in domestic rogue internet pharmacies.

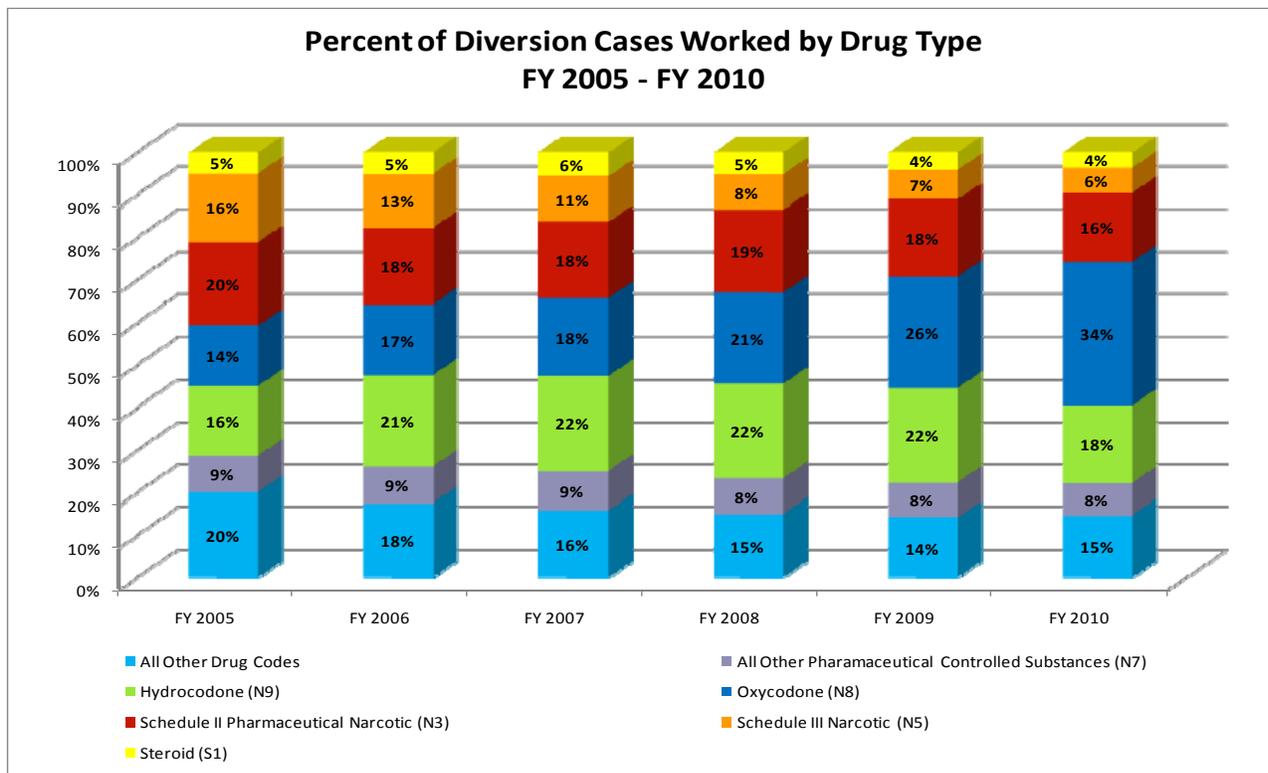
Between fiscal years 2006 and 2009, rogue Internet pharmacies were a major source of diversion. The rogue Internet pharmacies were responsible for the diversion of tens of millions of dosage units of hydrocodone. DEA responded to these rogue operations with investigations such as *Operation Baywatch*, *Operation CyberRx*, *Operation Lightning Strike*, *Operation TexRx*, and *Operation Control/Alt/Delete*. Although many domestic rogue Internet pharmacies that distributed controlled substances were eliminated after the Ryan Haight Act was implemented in April 2009, the problem has not been resolved with regard to foreign-based Internet pharmacies, and we continue to take steps to address it. In addition, rogue domestic Internet pharmacies selling mostly non-controlled substance and exempted¹⁰ prescription drugs, including Carisoprodol, Tramadol, and what are commonly known as “lifestyle drugs,” continue to pose a significant challenge.

What followed in the wake of these rogue Internet pharmacies was an almost immediate shift in the method of diversion and the type of pharmaceutical drugs being diverted. Today, a plethora of rogue pain clinics line the streets of south Florida. They supply drug seekers and pill distributors from up and down the entire East Coast with dangerous and powerful pharmaceuticals. Within these pill mills, the legitimate practice of medicine has given way to unadulterated greed. However, unlike the rogue Internet pharmacies, the practitioners at these rogue clinics are not dispensing hydrocodone, a schedule III controlled substance. They are dispensing and prescribing oxycodone, a schedule II controlled substance.

¹⁰ “Exempted prescription products” are prescription drugs that contain certain nonnarcotic controlled substances yet are exempt from some provisions of the Controlled Substances Act. 21 C.F.R. § 1308.32. One example of an exempted prescription product is butalbital (brand name Fioricet), which would otherwise be a schedule III controlled substance because it contains a derivative of barbituric acid.

Diversion Control Program Core Personnel FTE Utilization by Top Four Drug Types FY-2005 - FY-2010





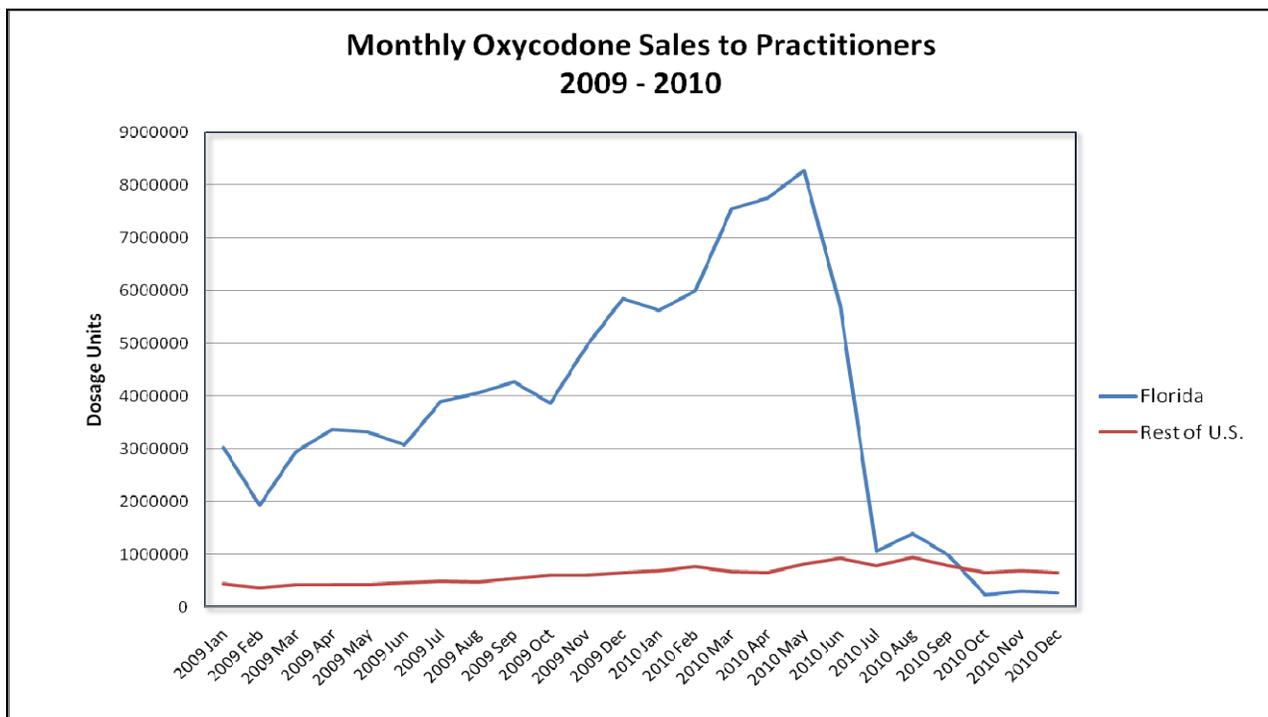
DEA, working with its state and local partners, has put forth a substantial investigative effort towards these rogue clinics which has been dubbed *Operation Pill Nation*. This operation involved the mobilization of eleven Tactical Diversion Squads from across the United States to marshal with the Miami 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, as part of *Operation Pill Nation* DEA conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown which included:

- 21 search warrants executed at clinics, residences, and other locations in south Florida;
- 25 arrested on various federal and state drug and money laundering charges, of which 5 were medical doctors and 5 were pain clinic owners;
- Seizure of approximately \$7 million in assets (\$3 million dollars in US currency and a variety of other real property, jewelry, and assets including 62 vehicles, some of which were exotic cars); and
- Immediate Suspension Orders issued against 14 DEA registrations, 1 Order to Show Cause issued against 3 DEA registrations, and the surrender of 7 DEA registrations.

As of April 12, 2011, *Operation Pill Nation* has resulted in the surrender of 83 DEA registrations (71 physicians, 8 pharmacies and 4 wholesale distributors); Immediate Suspension Orders issued against 63 DEA registrations (held by 37 physicians, 1 distributor); Orders to Show Cause issued against 6 DEA registrations; 38 clinics closed; and 32 arrests (12 physicians, 5 clinic owners and 15 clinic employees). Additionally, more than \$16.4 million in assets have been seized thus far as a result of this operation (\$11.9 million in US currency and approximately

\$4.5 million in vehicles, jewelry, real property, and other assets). One of the wholesale distributors has agreed to pay a civil fine of \$8 million.

One component of the strategy for *Operation Pill Nation* is to identify the wholesale distributors that are supplying the controlled substances to these rogue pain clinics. In June 2010, DEA took administrative action against four wholesale distributors that were supplying rogue pain clinics in south Florida. Subsequent to that action, sales of oxycodone to dispensing practitioners in Florida plummeted. Florida also implemented legislation (effective October 2010) that limits a practitioner’s ability to dispense controlled substance medications to what a patient would need in a 72-hour period.



In addition to *Operation Pill Nation*, Tactical Diversion Squads and Diversion Groups across the United States continue to investigate large-scale diversion schemes. These investigations often result in the immediate suspension, revocation, or surrender of a registrant’s DEA registration and in many cases in parallel civil and criminal proceedings.

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 therapy. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to abuse medications. For example, the 2009 NSDUH

indicates that 70 percent of Americans 12 and older who used pain relievers non-medically in the past year obtained the drugs from a friend or relative.¹¹ The Administration recognizes the issue of prescription drug abuse as described in the *National Drug Control Strategy*. One of the action items set forth in the Strategy is to increase prescription return/take-back and disposal programs.¹²

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. This massive undertaking resulted in the collection of 121 tons of unwanted or expired medications that were summarily disposed of.

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. On January 19 and 20, 2011, DEA conducted a public meeting to discuss 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.

DEA is working diligently to promulgate disposal regulations. In the interim, DEA launched a second National Take-Back Initiative on April 30, 2011. Americans participating in the DEA's second nationwide event turned in more than 376,593 pounds (188 tons) of unwanted or expired medications for safe and proper disposal at the 5,361 take-back sites that were available in all 50 states, plus Guam, Puerto Rico, and in the U.S. Virgin Islands. This is 55 percent more than the 242,000 pounds (121 tons) the public brought in during last September's event.

The DEA's Take-Back events are a significant piece of the White House's prescription drug abuse prevention strategy released last month by the White House Office of National Drug Control Policy (ONDCP). Purging America's home medicine cabinets of neglected drugs is one of four action areas, or pillars, for reducing prescription drug abuse and diversion laid out in *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. The other pillars include education of health care providers, patients, parents and youth; establishing prescription drug monitoring programs in all the states; and increased enforcement to address doctor shopping and pill mills.

Numerous national organizations joined the DEA and its state and local partners in putting on last April's Take Back Day, including ONDCP; the American Association of Poison Control Centers; the Community Anti-Drug Coalitions of America; D.A.R.E. America; the

¹¹ Substance Abuse and Mental Health Services Administration. Results from the 2009 National Survey on Drug Use and Health.

¹² 2010 National Drug Control Strategy, p. 32

Federation of State Medical Boards; various agencies of the U. S. Department of Health and Human Services; the International Association of Chiefs of Police; the National Association of Attorneys General; the National Family Partnership; the National Organization of Black Law Enforcement Executives; the National Association of Boards of Pharmacy; the National District Attorneys Association; the National Sheriffs' Association; and The Partnership at Drugfree.org.

Conclusion

Prescription drug abuse is a serious problem. 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 distribution. Reducing prescription drug abuse is vital to the health and welfare of the American people and is a priority for this Administration.

Chairman Whitehouse, Ranking Member Kyl, and distinguished Members of the Subcommittee, thank you for the opportunity to appear today to discuss this important issue.