



Department of Justice

STATEMENT

OF

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BEFORE THE

**CAUCUS ON INTERNATIONAL NARCOTICS CONTROL
UNITED STATES SENATE**

AT A HEARING ENTITLED

“RESPONDING TO THE PRESCRIPTION DRUG ABUSE EPIDEMIC”

PRESENTED

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**Statement for the Record of
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**Caucus on International Narcotics Control
United States Senate**

**“Responding to the Prescription Drug Abuse Epidemic”
July 18, 2012**

Senator Feinstein and distinguished Members of the Caucus, 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 diversion.

Overview

The abuse of prescription drugs continues to plague the nation at an alarming rate, crossing all age, gender, racial and socioeconomic boundaries. Studies show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the adverse consequences associated with such actions. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2010 National Survey on Drug Use and Health (NSDUH)—the most recent NSDUH, the number and percentage of persons aged 12 or older who were current nonmedical users of psychotherapeutic drugs in 2010 (7.0 million or 2.7 percent) were similar to those in 2009 (7.0 million or 2.8 percent) and to those in 2002 (6.3 million or 2.7 percent). The overall rate of current illicit drug use among persons aged 12 or older in 2010 (8.9 percent) was similar to the rate in 2009 (8.7 percent), but it was higher than the rates in 2002 through 2008.

Statistics concerning the abuse of pharmaceutical controlled substances are alarming. 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.¹ Among this population, the number of new initiates who used narcotic pain relievers is second only to the number of new initiates who used marijuana.² On average, every day 2,046 12-17 year olds abuse a prescription pain reliever for the first time.³ This is particularly disturbing because prescription opiate abuse by teens and young adults can lead to heroin abuse. DEA intelligence has shown that the “street” cost of prescription opiates, as high as \$80.00 per tablet or more in the case of OxyContin 80 mg, and \$30.00 to \$40.00 per tablet for 30 mg oxycodone single entity immediate release, makes it difficult for teens and young adults to purchase the drugs to continue use in support of their addiction. As a result, intelligence

¹ Substance Abuse and Mental Health Services Administration. Results from the 2010 National Survey on Drug Use and Health.

² Ibid, p. 49.

³ Substance Abuse and Mental Health Services Administration, 2010 National Survey on Drug Use and Health.

indicates that some turn to heroin, a much cheaper opiate that will provide a similar “high” and keep the drug seeker/abuser from experiencing painful withdrawal symptoms. This cycle is confirmed by police agencies throughout the country, who are now reporting an increase in heroin use by teens and young adults who began their cycle of abuse with prescription opiates.

This cycle of abuse can be traced to the mistaken belief of teens and young adults that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana and methamphetamine. The 2008 Partnership Attitude Tracking Study (PATS) 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 dangerous medications. 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

As you may expect, this increased abuse leads to increased diversion, and, in turn, 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 September 2011, 47 state laboratory systems, 94 local laboratory systems, and one territorial laboratory system participated in NFLIS. In 2010, approximately 1.7 million drug analysis records were reported to NFLIS. The increase in opiate pain medication analyses conducted by NFLIS-reporting laboratories from 2001 to 2010 is staggering: 322 percent for oxycodone; 240 percent for hydrocodone; and 253 percent for morphine.

This problem cannot be addressed through law enforcement action alone. We will never be able to “arrest our way” out of this problem. A multi-pronged approach that includes education, monitoring, proper medication disposal, enforcement, and treatment is the best way to address this national epidemic. One role of DEA, in addition to enforcing the Controlled Substances Act (CSA), is to educate the registrant population—including health care providers—on their obligations under the CSA, as well as to educate parents, community leaders and law enforcement personnel regarding diversion trends, the scope of the problem, and how to best address prescription drug diversion in communities throughout the United States.

DEA is also fully engaged in ensuring proper disposal of controlled substances. The 2011 PATS noted that the number of parents who agree with the statement “anyone can access prescription medicines in the medicine cabinet” is up from 50 percent in 2010 to 64 percent in 2011, indicating the medications are more readily available to anyone in their homes.⁷ DEA has

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.

⁷ Partnership for a Drug-Free America, 2011 Partnership Attitude Tracking Study, Key Findings.

responded to this problem by coordinating National Prescription Drug Take-Back events with our Federal, state and local law enforcement partners approximately every 6 months. Removing from the household medicine cabinet 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/or drug seekers for non-medical purposes.

The Closed-System of Distribution and the Regulatory Scheme

The Food and Drug Administration, through the Federal Food, Drug, and Cosmetic Act, generally regulates the safety and efficacy of pharmaceutical drugs. However, due to their potential for abuse and danger to public health and safety, Congress recognized the need for greater control over abused and addictive substances. As such, it established a separate and distinct framework under the CSA 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 to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain as well as the registrants within the health care delivery system. All registrants must adhere to specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion. Adherence to these requirements at every level of the delivery and supply chain will reduce the opportunities for diversion.

For example, in order to obtain and maintain a controlled substance manufacturer or distributor registration, each manufacturer and distributor must maintain effective control against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. 21 USC §§ 823(a)-(e). This statutory requirement is buttressed by the regulation that requires non-practitioner registrants, e.g., wholesale distributors who supply pharmacies with controlled substances, to “...*design and operate a system to disclose...suspicious orders of controlled substances.*” 21 CFR § 1301.74. If a wholesaler receives an order for controlled substances that he knows or should know is suspicious, he must report that order to the local DEA office and the order should not be fulfilled until the suspicious nature of the order is resolved, i.e., the distributor has adequately investigated the order and determined that the ordered drugs are not likely to be diverted. This proactive monitoring and vigilance by wholesalers could have prevented millions of controlled substance dosage units from being diverted by illegal internet “pharmacies” from 2006 to 2009. Instead, several wholesalers fulfilled orders they knew or should have known were suspicious, even after being reminded of their responsibilities and obligations under the CSA. Some wholesalers, including McKesson, Cardinal Health and Amerisource Bergen were ultimately held responsible for their role in facilitating the internet diversion of controlled substances and paid civil penalties and entered

into compliance memorandums of agreement with the government. They were also forced to cease distribution operations by suspension of their DEA registrations.

Registrants in the healthcare delivery chain who have direct contact with patients, such as prescribers and pharmacists, must adhere to additional requirements when prescribing or dispensing controlled substances. For example, a practitioner such as a physician, dentist, veterinarian, or mid-level practitioner can only dispense/prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. *“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”* 21 CFR §1306.04(a); *United States v. Moore*, 423 US 122 (1975). While the vast majority of practitioners act in accordance with the law, this requirement is disregarded at rogue pain clinics operating throughout the United States. Rather than providing medical care, they utilize the façade of medical care as a front for illegal controlled substance distribution activities. The “physicians” that operate in rogue pain clinics are feeding the addiction of drug seekers. These clinics have minimal physician patient interaction and generally provide the medication requested by the patient (patient directed prescribing) without question. There is no attempt to determine the underlying cause of pain and the standard accepted medical practice is disregarded. Most of the practitioners that write prescriptions in these facilities are committing criminal and civil violations of the CSA. If the practitioners in these clinics would abide by the requirement to issue a prescription only for a legitimate medical purpose and in the usual course of professional practice, drug seekers would not have the opportunity to feed their addiction and/or distribute pharmaceutical controlled substances into the illicit market.

Ultimately, the last line of defense against diversion is the pharmacist that receives the prescription for medication dispensing. The pharmacist is obligated to ensure that a prescription for a controlled substance is legitimate before dispensing the medication to the patient. *“The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription . . . and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”* 21 CFR §1306.04(a). The pharmacist is the “drug expert” in the healthcare delivery system and is well equipped to review a prescription to determine if it is legitimate. If more pharmacists questioned the validity of prescriptions issued by rogue pain clinic physicians and refused to fill the prescriptions based upon their professional judgment, diversion would be significantly decreased. The exercise of their “corresponding responsibility”, in many instances, is an opportunity for pharmacists to save lives.

Recent Schemes to Divert Prescription Controlled Substances

Over the past several years, DEA Diversion Investigators and Special Agents have 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.

DEA would like to again thank Congress, and particularly members of this Caucus, for their leadership in responding to the explosion of domestic rogue internet pharmacy diversion with the passage of the *Ryan Haight Online Pharmacy Consumer Protection Act* that took effect in April 2009. This law, combined with intensified law enforcement and regulatory actions, virtually eliminated domestic-based rogue internet pharmacies.

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. Instead of hydrocodone, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a Schedule II controlled substance that is just as dangerous as hydrocodone 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 substances to include 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.

More recently, Federal, state and local law enforcement agencies have tracked the expansion of these clinics to other states including Georgia, Tennessee, Ohio, Missouri, Texas, California and Pennsylvania. Some of the clinic owners moved operations out of Florida to avoid increased law enforcement and regulatory pressure and the legislation that was passed in the State of Florida to address the problem. Dispensing controlled substances from these clinics was a huge source of income for clinic owners. In response, state legislation in Florida now restricts a physician's ability to dispense oxycodone and other controlled substances from a pain clinic. However, rogue pain clinic owners and practitioners adapted by issuing illegitimate prescriptions for oxycodone and other controlled substances rather than dispensing directly to the "patient." DEA and other law enforcement agencies saw an immediate and significant increase in the volume of oxycodone dispensed from various pharmacies across the state.

Seeing their profits going to dispensing pharmacies across the state, clinic owners began purchasing pharmacies and locating them with 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. As a result of this scheme, there was a sharp increase in the number of new pharmacy registration applications in the State of Florida. The rise in the number of new pharmacy applications in Florida lead DEA to initiate on-site investigations of all pharmacy

applications in Florida,⁸ rather than rely upon state licensure to ensure that the applicants have the requisite skill and experience to safely and responsibly dispense controlled substances, sufficient knowledge of applicable federal law and regulations, and that the applicants intend to comply with federal law and regulations.

Further investigation of pharmacy applicants revealed “straw purchases” of pharmacies that had ties to established rogue pain clinics. During the on-site investigations, DEA personnel interviewed numerous applicants with backgrounds ranging from a drywall installer, truck driver, bartender/exotic dancer, lawn service owner, and the spouse of a pain clinic owner. Many of the applicants had little or no experience with pharmacy operations. To date, this initiative has conducted four deployments to Florida. As a result, DEA has thus far obtained withdrawal of applications from 109 retail pharmacies and one (1) distributor. Of these, the majority of the retail pharmacy withdrawals and the distributor were located in South Florida. As a result of this and other initiatives in Florida, 147 existing retail pharmacies have surrendered their registrations (again, the majority of which were in South Florida). Preventing these pharmacies from conducting business undoubtedly prevented millions of dosage units of controlled substances from entering the illicit market and closed an avenue of distribution and source of income for the rogue pain clinics. This initiative is on-going.

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 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.

For example, according to the Florida Medical Examiner’s Office, there has been 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. 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.

⁸ On-site investigations of registrant applicants are conducted by DEA pursuant to its authority under 21 U.S.C. 822(f) and 21 CFR 1301.31.

The Drug Enforcement Administration Response to the Prescription Drug Abuse Crisis

Restructuring

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. As such, law enforcement attempts to prevent, detect, and reduce the diversion 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 provides 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. With more Diversion Investigators available to concentrate on the regulatory aspects of the Diversion Control Program, DEA increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; importers; exporters; narcotic treatment programs; DATA-waived practitioners; researchers; and chemical handlers. 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 implementing regulations.

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 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 shopping," prescription forgery rings, and practitioners or pharmacists who divert controlled substance pharmaceuticals).

As of July 8, 2012, 48 Operational TDS groups are located throughout the United States. 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 significantly. For example, between FY 2008 and FY 2011, regulatory inspections increased from 708 to 4,448 (a 528% increase), and administrative actions, including Orders To Show Cause and Immediate Suspension Orders, increased from 70 to 131 (a 87% increase). An Order To Show Cause commences administrative action against a registrant, and is a document in which DEA provides notice to the registrant that the registrant may show cause, at an administrative hearing or through submission of documentary evidence, as to why the DEA should not revoke their registration or deny their application for a DEA registration on the basis

of any of the enumerated statutory factors.. An Immediate Suspension Order is an administrative action in which the DEA Administrator simultaneously suspends the registrant's DEA registration with the commencement of Order to Show Cause proceedings because their continued registration pending the administrative proceeding would pose an imminent danger to the public health or safety.

Between FY 2008 and FY 2011, these TDS groups have also increased the number of diversion-related Priority Target Organization (PTO) investigations from 243 to 403 (a 65% increase). PTO investigations focus on those criminal organizations or groups that significantly impact local, regional or national areas of the country. On October 1, 2011, DEA began tracking non-criminal PTO investigations, which encompass regulatory, civil and administrative investigations. Since its inception, there have been 29 designated non-criminal PTO investigations.

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, put forth a substantial investigative effort towards rogue clinics, 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 May 01, 2012, *Operation Pill Nation II* has resulted in 58 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.

Renewed Oversight

DEA uses its regulatory authority to ensure that DEA registrants comply with all aspects of the CSA and its implementing regulations, particularly maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. 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 controlled substances to rogue Internet pharmacies and more recently to rogue pain clinics and rogue 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. As stated above, 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 an order is suspicious, such as 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 location of the customer.

DEA has identified various distributors who failed to adhere to their regulatory responsibilities to maintain effective controls against diversion, and took administrative action and also referred them for civil action. These investigations resulted in record-breaking civil penalties (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. In February 2012, the DEA Administrator again used her authority under the CSA to immediately suspend the registrations of Cardinal Health's Lakeland, Florida facility and two Sanford, Florida based CVS pharmacies after making a determination that the continued operation of these facilities (with respect to controlled substances) while pending administrative proceedings to revoke their registrations posed an imminent danger to the public health or safety. While the outcome of the administrative proceedings regarding the CVS facilities is pending before the DEA Administrator, a Memorandum of Agreement has been reached between DEA and Cardinal Health regarding their conduct, which includes a suspension of their Lakeland facility registration for a period of two years.

Scheduling Actions

The abuse of prescription drugs is not isolated to just one drug. Drug seekers and addicts routinely abuse controlled and non-controlled prescription medications in combination to enhance the effects of the drugs. This activity significantly increases the risk of potential harm to the individual. One of the most popular combinations is the "trinity" or "holy trinity", a combination of hydrocodone or oxycodone with a benzodiazepine such as alprazolam, and a muscle relaxant such as 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, 2012.⁹

The Family Medicine Cabinet & Proper 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 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

⁹ See: Federal Register Notice 76 FR 77330, December 12, 2011.

persons, especially teenagers, who seek to abuse medications. For example, the 2010 NSDUH estimates that 71 percent of persons 12 and older who used pain relievers non-medically in the past 12 months obtained them (either for free, bought them or stole them) from a friend or relative the last time they abused them. 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.¹⁰

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,¹¹ has conducted three additional Take-Back Days. This massive undertaking has resulted in the collection of more than 774 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 in 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 authorizes additional ways for Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner.

In the interim, DEA continues to coordinate the National Take-Back Initiative until the disposal regulations are in place. Through this initiative, DEA and its Federal, state and local law enforcement partners have made clear their steadfast commitment to reducing the potential for diversion by securely collecting controlled substances from ultimate users and disposing of them safely.

¹⁰ 2011 Prescription Drug Abuse Prevention Plan: *Epidemic: Responding to America's Prescription Drug Crisis*, pp. 7 & 8.

¹¹ 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.

Conclusion

DEA registrants throughout all levels of the healthcare delivery system must play a role in identifying and preventing drug diversion. Unfortunately, when any level of the distribution chain fails, opportunities for controlled substance diversion will occur. Therefore, it is vital that the registrant population and the health care professionals that support the registrants understand their obligations under the CSA and its implementing regulations to ensure that the system cannot be exploited for the purposes of drug diversion.

Congress granted DEA the statutory responsibility to enforce the CSA and its implementing regulations, and these are responsibilities DEA takes extremely seriously. DEA carries out this authority through criminal and civil investigations as well as administrative and regulatory inspections. Reducing diversion will ultimately reduce the availability of controlled substance prescription drugs to the drug seeking non-medical users. DEA Diversion Investigators and Special Agents are identifying and investigating diversion at all levels of the distribution chain. DEA's criminal and regulatory oversight is forcing the registrants within the drug delivery system, from the manufacturers of controlled substances to the pharmacies delivering the medication to the patients, to review their operations and ensure that they are in compliance with the CSA. When necessary, DEA takes action to revoke the registration of a company or individual who fails to maintain compliance with the CSA. Manufacturers are now sending letters to their wholesale distributor customers warning them of their obligations and that their lack of customer monitoring will result in a discontinuation of business. Distributors are carefully scrutinizing customer orders, looking for facts and circumstances that may be indicative of diversion and if warranted, stopping the sales and reporting the suspicious orders. Pharmacists, as the medication experts in the healthcare delivery system, are exercising their professional judgment and more closely scrutinizing prescriptions before dispensing medication. However, as in all professions, there will be some that choose the allure of easy money. This is also referred to as greed, historically a common motive in illegal drug distribution operations. We do not want to allow the prescription drug epidemic to be fueled by a small number of recalcitrant controlled substance registrants and health care professionals who do not live up to their responsibilities under the law.

Minimizing the availability of pharmaceutical controlled substances to non-medical users and maintaining the integrity of the closed-system of distribution are priorities for the Drug Enforcement Administration. States, counties and municipalities have stepped up their focus on preventing the diversion of pharmaceutical controlled substances. Forty-nine states have now enacted legislation to implement Prescription Drug Monitoring Programs that will ultimately identify and limit medications dispensed to drug seekers and doctor shoppers and improve patient care. Federal, state and local officials, law enforcement, professional organizations and community groups continue to work together to fight this epidemic through take-back events and education of children, parents, educators and health care professionals. Federal proposed regulations that would allow additional ways for individuals to securely dispose of unwanted or unused controlled substance medications are currently under review in the interagency process.

Senators and distinguished Members of the Caucus, thank you for the opportunity to appear today to discuss this important issue.