U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

February 26, 2015

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the House Energy and Commerce Subcommittee on Oversight and Investigations, on April 29, 2014, at a hearing entitled, "Examining the Growing Problems of Prescription Drug and Heroin Abuse." We hope that this information is of assistance to the Committee.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Peter J. Kadzik
Assistant Attorney General

Enclosure

cc: The Honorable Frank Pallone, Jr.
Ranking Member

Questions for the Record
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
U.S. Department of Justice

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
"Examining the Growing Problems of Prescription Drug and Heroin Abuse"
April 29, 2014

Questions Posed by the Honorable Michael C. Burgess

1. **Based on the available data, it appears that abuse of Immediate Release (IR) opioids involves the same risks as abuse of Extended Release (ER) opioids and is causing similarly large numbers of abuse and misuse problems. It is my understanding that FDA has treated them differently in terms of labeling, warnings, and REMS. Shouldn't IR and ER opioids be treated the same so that prescribers and patients receive the same important warnings about all opioids?**

Response:

This matter is not within the Drug Enforcement Administration's (DEA) jurisdiction. DEA respectfully defers to the Department of Health and Human Services (HHS).

Questions Posed by the Honorable Jan Schakowsky

1. **What are pharmaceutical companies doing to combat the prescription drug abuse problem, including the problem of popup clinics? It seems that pharmaceutical companies financially benefit from the prescription drug abuse problem and popup clinics, so I am interested in seeing what they are doing to help us combat the crisis.**

Response:

DEA regulations require non-practitioners such as wholesale distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Further, all DEA registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). One factor relevant to compliance with the security requirements is the "adequacy of the registrant's . . . system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations." 21 C.F.R. § 1301.71(b)(14).

In recent years, DEA has steadily increased the frequency of compliance inspections of specific categories of registrants, such as manufacturers (including bulk manufacturers), distributors, pharmacies, and certain practitioners. This renewed focus on oversight has enabled DEA to take a more proactive approach to educating registrants and ensuring that they understand and comply with the Controlled Substances Act (CSA) and its implementing regulations. DEA conducts approximately 6,000 regulatory inspections every year to ensure compliance with Federal laws and regulations. Each inspection entails close communication between DEA and the registrant to educate the registrant about proper procedures and to ensure corrective action is taken to comply with the law. These inspections typically result in remediation or continued compliance, and no further action is taken. DEA conducts compliance inspections of registered distributors every two years.

DEA's Distributor Initiative Program was implemented in late 2005 and was designed to educate wholesale distributors that 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 monitoring for suspicious orders. As stated above, wholesale distributors are required to design and operate a system that would disclose 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. Factors that should generally be considered include, but are not limited to: the type of drug(s) ordered (e.g., the breadth and schedule of controlled substances ordered), orders of unusual size, orders that deviate from a normal pattern, frequency of orders, and the percent of controlled and non-controlled substances ordered.

2. **What is the trend in the number of new opioid drugs being developed and/or approved? How will this affect prescription drug abuse? What is being done to combat the effects of an increased number of new opioid drugs entering the market?**

Response:

This matter is not within DEA's jurisdiction. DEA respectfully defers to the Department of Health and Human Services (HHS).

3. **Are most of the prescription opioid drugs that are abused Schedule II drugs? Which drugs are Schedule III? Are there more drugs that can/should be moved to Schedule II?**

Response:

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. § 812. The five schedules are categorized by potential for abuse, medical usefulness, and the potential for producing physical dependence and psychological dependence, and each schedule imposes a varying degree of controls and penalties. As a class of substances, prescription opioids generally have a high potential for abuse and this abuse is characterized by severe psychological or physical dependence. In addition to the schedule II substances, a few opioids and opioid formulations are placed under schedules III and IV. The determination of the appropriate schedule is done on a case-by-case basis with special consideration given to the scheduling recommendation provided by HHS.

The initial schedules of controlled substances established by Congress are found at 21 U.S.C. § 812(c), and the current list of all scheduled substances is published at 21 C.F.R. § 1308 and 21 U.S.C. § 812(a). In recent scheduling actions, DEA has placed a number of opioids under the CSA, including tapentadol in schedule II and tramadol in schedule IV. Additionally, on August 22, 2014, DEA after evaluating all available data, finalized the rescheduling of hydrocodone combination products from schedule III to schedule II. DEA will continue to monitor and collect information to evaluate drug scheduling and initiate actions to protect public health and safety, as appropriate.

The majority of prescription opioid drugs are placed under schedule II in the CSA. This placement is based on the drug or substance's relative potential for abuse. The findings required for placing a drug or other substance in schedule II are as follows: (a) it has a high potential for abuse; (b) it has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and (c) abuse of the drug or other substance may lead to severe psychological or physical dependence.

Please see the table below for a brief explanation of the schedules of controlled substances:

Schedule I	A) The drug or other substance has a high potential for abuse. B) The drug or other substance does not currently have an accepted medical use for treatment in the United States. C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
Schedule II	A) The drug or other substance has a high potential for abuse. B) The drug or other substances has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.
Schedule III	A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II. B) The drug or other substance has a currently accepted medical use for treatment in the United States. C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
Schedule IV	A) The drug or other substance has low potential for abuse relative to the drugs or other substances in schedule III. B) The drug or other substance has a currently accepted medical use for treatment in the United States. C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drug or other substances in schedule III.
Schedule V	A) The drug or other substance has low potential for abuse relative to the drugs or other substances in schedule IV. B) The drug or other substance has a currently accepted medical use for treatment in the United States. C) Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule IV.

21 U.S.C. § 812 (b)(1), (2), (3), (4), and (5).

4. According to Dr. Clark's testimony, 69% of those who used pain relievers non-medically in the past year obtained them from a friend or relative. What are we doing to combat the 69% of people who get opioids that they misuse from family and friends?

Response:

The Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan expands upon the current Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all four of these areas.

Education

The Department of Justice (Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites: www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local, and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. Each one-day PDAC is held on a Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.
- During FY 2013, DEA hosted 18 PDACs in eight states. Further, DEA hosted 16 PDACs in eight states during FY 2014. Since DEA began hosting PDACs in 2011, through September 14, 2014, more than 7,648 pharmacy professionals have attended these educational conferences. At this time, there are 16 proposed PDACs in eight states for FY 2015.
- The Manufacturers/Importers/Exporters Conference held on June 18-19, 2013, provided a forum to present Federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices to prevent diversion while minimizing the impact on legitimate commerce. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Orders System (ARCOS) reporting, import/export permits, and import/export declarations were

discussed. Approximately 370 people attended, representing more than 200 registrants.

- The Distributor Conference was held on October 22, 2013, and this conference provided an overview of Federal laws and regulations governing issues that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order reporting. Approximately 220 people attended, representing more than 130 registrants.
- To better assist DEA registrants with their understanding of the CSA and implementing regulations, manuals are drafted and made available to the public. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the Code of Federal Regulations (C.F.R.), and Federal Register Notices to obtain complete and accurate information. The following manuals are available via the DEA website:
    - Chemical Handler's Manual
    - Pharmacist's Manual
    - Practitioner's Manual

Additionally, as noted in the response to Question 1, above, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors that were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is through the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.[1] However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.[2] The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-state prescribers who issued controlled substance prescriptions during the prior

[1] This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in schedule II.

[2] The Brandeis University PDMP Center of Excellence, retrieved 12/18/14 http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps.

year).[3] While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June 2014, 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.[4]

The Department has also supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over $87 million from FY 2002 to FY 2014, including $7 million in FY 2014. The purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the CSA provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, to include (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

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[3] Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

[4] The Brandeis University PDMP Center of Excellence, retrieved 12/18/14 http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps.

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled Substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

Several DEA investigations of rogue pain clinics in Southern Florida have resulted in charges against 172 individuals, including 51 doctors and 24 clinic/pharmacy owners, the seizure of approximately 2.5 million dosage units of controlled substances, and approximately $16.6 million in currency, real property, and exotic cars. In addition, approximately 42 doctors and 11 pharmacies lost their DEA registrations. Approximately 192 doctors and 68 pharmacies voluntarily surrendered their DEA registrations.

In addition to the focus on criminal law enforcement, the Department also dedicates resources to civil and regulatory matters. DEA is pursuing additional actions when registrants and other

entities violate the law. For example, in March 2013, UPS agreed to a $40 million settlement with the Department of Justice for payments it received from illicit online pharmacies. This settlement is part of a non-prosecution agreement with the United States Attorney's Office for the Northern District of California (San Francisco) and is the result of a five-year investigation of 12 rogue internet pharmacies. This investigation resulted in 43 convictions, $34 million in seized assets, and forfeiture orders totaling $51 million.

In 2012, DEA pursued administrative actions against two CVS pharmacy stores in Florida, where these two registrants violated provisions of the CSA and committed acts that are inconsistent with the public interest by dispensing controlled substances to customers under circumstances indicating that the drugs were being diverted from legitimate channels, misused, or abused, and by failing to exercise their corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). In October 2012, the DEA Administrator issued a final order revoking the registrants' certificates of registration and denying any pending applications for renewal, stating that the misconduct was both egregious and of and extended duration, and undoubtedly caused extensive harm to the public interest. During 2013, DEA, together with the United States Attorneys' Offices for the Western District of Oklahoma and the Southern District of Florida, pursued significant regulatory and civil actions in two cases where registrants violated provisions of the CSA. In April 2013, CVS Pharmacy, Inc. executed an $11 million settlement agreement in which it agreed to pay a civil penalty for CSA violations and failure to keep proper records of pharmacy sales. In June 2013, Walgreens Corporation agreed to pay $80 million in civil penalties for the actions by their distribution center and six pharmacies in Florida, which resulted in the diversion of millions of dosage units of oxycodone, a powerful schedule II painkiller. Their actions helped fuel a prescription drug epidemic in the State of Florida over several years.

While some issues related to prescription drug abuse have worsened in recent years, particularly along the heroin-prescription opiate vector, the Department's continued focus on prescription drug abuse has yielded significant improvements in many areas. For example, the substantial civil penalties and settlements with CVS, Walgreens, and UPS described above have signaled the serious potential consequences for companies and registrants that fail to recognize the dangers of prescription drug abuse and follow the law regarding controlled substances. Further, the Department and DEA have observed significant changes in Florida, where rogue pain clinics have long been known to operate and have helped fuel the prescription drug abuse epidemic in several other states. According to the Florida Department of Health, the number of pain management clinics in Florida as of December 31, 2013, is 360, down from 635 at the end of FY 2010. In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011. As of September 30, 2014, there was only one Florida physician in the top 100 purchasers of oxycodone, as Florida law no longer allows practitioners to dispense schedule II and schedule III controlled substances, with the exception of some very limited circumstances (e.g., practitioners may dispense to patients who: are under hospice care; have undergone a surgical procedure, and a 14-day supply may be dispensed; are an inmate in a prison; or are a participant in an approved clinical trial). The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the Nation's principal enforcer of Federal drug laws and regulations.

Questions Posed by the Honorable Ben Ray Lujan

1. **As you may know, New Mexico has some of the highest rates of substance abuse and overdose in the country. In particular a challenge facing New Mexico is the lack of resources for prevention, treatment, rehabilitation, and the unique challenges which face our rural communities. Tell me about what your office is doing to address the challenges of rural districts like New Mexico.**

Response:

The Office of National Drug Control Policy's (ONDCP) Prescription Drug Abuse Prevention Plan expands upon the current Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all four of these areas.

In 2014, ONDCP awarded funds to the Southwest Border HIDTA-New Mexico Region for the Rio Arriba Community Empowerment (RACE) Project. Project RACE is a prevention initiative targeting the rates of drug overdose, student graduation, delinquency, and crime in Rio Arriba County. This project advances the National Drug Control Strategy prevention priorities by strengthening local efforts to prevent drug use in SMART (State, Metropolitan Area, Rural, Tribal) communities.

Education

The Department of Justice (Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites: www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local, and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

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- During FY 2013, DEA hosted 18 PDACs in eight states, two of which were held in Albuquerque, NM on March 2-3, 2013, with a total of 284 attendees. Further, DEA hosted 16 PDACs in eight states during FY 2014. Since DEA began hosting PDACs in 2011, through September 14, 2014, more than 7,648 pharmacy professionals have attended these educational conferences. There are 16 proposed PDACs in eight states for FY 2015.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is through the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.[5] However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.[6] The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Floridajust 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-state prescribers who issued controlled substance prescriptions during the prior year).[7] While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers.

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The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states, including New Mexico, have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June 2014, 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.[8]

The Department has also supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over $87 million from FY 2002 to FY 2014, including $7 million in FY 2014. The purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the Controlled Substance Act (CSA) provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, to include (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

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In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. One such TDS is located in Albuquerque, New Mexico. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

The Albuquerque District Office (ADO) Diversion Group and TDS traditionally covered the entire State of New Mexico, a significant task for a relatively small group of Diversion Investigators, DEA Special Agents, and Task Force Officers. In October 2013, recognizing the need to increase resource allocation in the State of New Mexico, DEA's El Paso Division (EPD) placed the southern portion of New Mexico under a regulatory and enforcement group based in the EPD. This move allowed an additional group of Diversion Investigators and Special Agents to focus on the southern New Mexico counties of Catron, Lincoln, Chavez, Grant, Sierra, Otero, Eddy, Lea, Luna, Dona Ana, and Hidalgo.

The ADO has developed a close relationship with regulatory, law enforcement, and prosecutorial counterparts at all levels of government in New Mexico. This has allowed the ADO to effectively use its resources and leverage the power of state government to help target the prescription drug epidemic.

The Diversion Groups and the TDS Groups based in Albuquerque and El Paso are regulatory and enforcement oriented, and are not traditionally focused on prevention, treatment, and rehabilitation, other than to work in a regulatory capacity of licensing narcotic treatment

programs. In 2014, the ADO and the United States Attorney's Office began working on a comprehensive program of cooperation based on a heroin and opioid epidemic community action plan first implemented in Northeast Ohio. Although law enforcement's role is limited, a new paradigm of cooperation between law enforcement, treatment facilities, medical boards, legislators, hospital administrators, and prescription drug manufacturers is being created.

Initiated by the United States Attorney's Office, the first H.O.P.E. (Heroin, Opioid, Prescription Drug and Education) conference will take place at a future date in 2015. The unique aspect of the overall strategy is not to develop new working groups, but rather to incorporate established treatment, counseling, law enforcement, rural community working groups, and legislative entities in a spirit of communication. The ADO Assistant Special Agent in Charge (ASAC) was asked to co-chair the law enforcement panel of this conference with an Assistant United States Attorney.

The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the nation's principal enforcer of drug laws.

2. **Substance abuse is a multifaceted challenge, and there is no silver bullet. What, in your experience and expertise, do you see as the largest impediments to decreasing prescription drug abuse and overdoses? Can you comment on the following challenges, and their relative magnitude in the persistent challenge of prescription drug abuse: The need to raise public consciousness to discard unneeded prescriptions? A lack of access to drug disposal and drop off for an informed public? Lack of insurance coverage and access to rehabilitation and treatment programs? Health care access shortages for those seeking treatment programs? The need to expand access to Naloxone to the public as prescription drug abuse continues to rise? A lack of funding for implementation of proven strategies? The need for legislation?**

Response:

DEA agrees that prescription drug abuse and overdoses are a complex problem with no simple solution. All of the factors you mention may play a part in decreasing prescription drug abuse and overdoses. To the extent that a need for additional legislation is identified, the Department would appreciate the opportunity to work with you, your staff, and the Committee. Please see the response to question 1, above, for further information regarding these issues.

Over the last several decades, even as enforcement and imprisonment rates have increased, the street-price for heroin-and other illicit drugs has decreased, leading to proliferation of this drug in virtually every state. In 2011 the ONDCP released its "Prescription Drug Abuse Prevention Plan with the goal to reduce non-medical use of prescription drugs by 15% in 5 years. What is the progress of this initiative? Is there evidence that this plan is having an impact? Can you comment further on the correlation between prescription drug abuse and heroin use, and if you expect to see a reduction in heroin use as prescription drug abuse decreases?

Response:

DEA respectfully defers to ONDCP on this matter.

3. **You can't talk about our prison system without discussing the prevalence of substance abuse and dependency that many inmates develop. I know we didn't have someone from the Bureau of Prisons at our hearing, but have you considered the potential impact of expanding rehabilitation programs for inmates, or programs to help the prison population stay off of drugs as they prepare to reenter civilian society? I know there is a call in my district for this approach. Further there is a need for more Adult and Juvenile Treatment facilities, and residential treatment facilities generally. Are there plans to expand access to these types programs in New Mexico?**

Response:

The Bureau of Prisons (BOP) places strong emphasis on preparing inmates for reentry. Excellent substance abuse programming is one of BOP's most significant endeavors toward this goal. Drug abuse education and substance abuse treatment are available in each of BOP's 121 institutions. There are also a total of 89 Residential Drug Abuse Programs (RDAP), which have been proven effective at reducing recidivism and relapse, and decreasing institution misconduct. These highly interactive programs have been designed using the most recent and effective evidence based practices. The addition of new programs in FY 2013 and FY 2014 has increased drug treatment capacity in BOP considerably.

Specifically, BOP has RDAP, Nonresidential Drug Abuse Treatment, and Drug Education. Drug Education is a psychoeducational course to encourage offenders with a history of drug use to review the choices they have made, including their choice to use drugs and the consequences of their choices. Inmates must review how those choices have affected them physically, socially, and psychologically. Drug abuse education takes the offender through the cycle of drug use and crime, and offers compelling evidence of how continued drug use can lead to a further criminality and related consequences. Drug abuse education is designed to motivate appropriate offenders to participate in nonresidential or residential drug abuse treatment, as needed.

The Nonresidential Drug Abuse Treatment program is designed as therapy groups to include a variety of clinical activities organized to treat complex psychological and behavioral problems. The activities are unified through the use of Cognitive Behavioral Therapy (CBT), which was selected as the theoretical model because of its proven effectiveness with the inmate population. A good percentage of inmates in BOP struggled with drugs, alcohol, and dysfunctional lifestyles before incarceration.

The RDAP provides nine to twelve months of intensive drug abuse treatment to inmates diagnosed with a drug use disorder. The RDAP targets behaviors that; reduce antisocial peer associations; promote positive relationships; increase self-control, self-management, and problem solving skills; end drug use; and replace lying and aggression with pro-social alternatives. This is an excellent treatment program and prepares inmates for their reentry into

society. BOP staff take great pride in operating clinically effective programs so that inmates do not persist in their drug use. For non-violent offenders, successful completion of RDAP, to include transitional treatment while in a Residential Reentry Center (halfway house), includes an early release incentive of up to one year off the term of incarceration. Thus, RDAP not only helps return inmates to their communities as law-abiding citizens, but also helps with institution crowding. Currently, inmates completing RDAP are receiving an average of 10.4 months off their sentences.

In coordination with the National Institute on Drug Abuse, BOP conducted a rigorous three-year outcome study of the RDAP. The study revealed that male participants were 16 percent less likely to recidivate and 15 percent less likely to relapse than similarly-situated inmates who do not participate in residential drug abuse treatment for up to three years after release. The analysis also found that female inmates who participate in RDAP are 18 percent less likely to recidivate than similarly situated female inmates who do not participate in treatment. This study demonstrates that BOP's RDAP makes a positive difference in the lives of inmates and improves public safety.

While BOP does not have a federal prison in New Mexico, federal offenders from all 50 states, to include New Mexico, are referred and receive treatment in federal facilities. There are three institutions in Arizona providing various drug treatment programs to include RDAP. The Arizona institutions include the Federal Prison Camp and the Federal Correctional Institution in Phoenix, and the Federal Correctional Institution in Safford. There is also a federal prison on the Texas/New Mexico border, Federal Correctional Institution El Paso, offering RDAP and other drug programs described above.

4. **I know advocacy groups in my district are always interested in greater access to grants. Who are the people in your office that I can direct citizen groups in New Mexico to so that there is greater partnership between the federal government and people on the ground who see the challenges New Mexicans face every day?**

Response:

This matter is not within DEA's jurisdiction, as DEA does not have grant authority. The Office of Justice Programs, the Office of Community Oriented Policing Services, and the Office on Violence Against Women are the primary grant-making components of the Department.

5. **What role do you see poverty playing in the current substance abuse trends? Have you seen greater economic development in communities where efforts to deter substance abuse has been effective? Do you have strategies that pair economic development with initiatives to reduce and treat substance abuse?**

Response:

DEA does not have any data regarding pairing economic development with initiatives to reduce and treat substance abuse as those matters fall outside of DEA's jurisdiction and expertise.

Attachment 2

Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

Questions Posed by the Honorable Michael C. Burgess

1. **The federal government has put a lot of money and effort on behalf of taxpayers into drug prevention, treatment and law enforcement. What is it about the current system that is not working?**

Response:

DEA agrees that prescription drug abuse and overdoses are complex problems with no simple solution. In order to better address prescription abuse, the Office of National Drug Control Policy (ONDCP) developed the Prescription Drug Abuse Prevention Plan, which expands upon the current Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. DEA plays an important role in all of these areas.

Education

The Department of Justice (Department) focuses on education as a crucial first step in preventing prescription drug abuse. Through its Demand Reduction Program, DEA delivers educational content via its websites: www.GetSmartAboutDrugs.com and www.JustThinkTwice.com. These websites serve as a resource to parents, caregivers, educators, professionals, and teens. DEA also focuses on reducing the demand for illicit drugs, including the abuse of prescription drugs, through its Red Ribbon Week programming, partnerships with other Federal, state, local, and non-profit organizations, and numerous publications made available to the general public.

DEA also provides education and guidance to industry professionals such as pharmacists, distributors, and manufacturers by delivering information to registrants, professional associations, and industry organizations on current diversion and abuse trends of pharmaceutical drugs and listed chemicals. DEA also provides information and guidance concerning new and existing programs, policies, legislation, and regulations. DEA's Diversion Control Program establishes and maintains liaison and working relationships with other Federal agencies, state and local governments, regulated industries, industry organizations, professionals, professional associations, and regulatory boards that interface with DEA regarding diversion matters. In Fiscal Year (FY) 2013, DEA conducted more than 114 public education and outreach events regarding prescription drug abuse. Because of the importance of these activities in addressing prescription drug abuse, the Department has included an Education and Outreach component to DEA's performance measures.

The following reflect the kinds of outreach initiatives undertaken by DEA's Diversion Control Program:

- DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country. Each one-day PDAC is held on a Saturday or Sunday for the convenience of the pharmacy community. The conferences are developed and designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. Topics addressed include pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners, with the objective of educating pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity.
- During FY 2013, DEA hosted 18 PDACs in eight states. Further, DEA hosted 16 PDACs in eight states during FY 2014. Since DEA began hosting PDACs in 2011, through September 14, 2014, more than 7,648 pharmacy professionals have attended these educational conferences. At this time, there are 16 proposed PDACs in eight states for FY 2015.
- The Manufacturers/Importers/Exporters Conference held on June 18-19, 2013, provided a forum to present Federal laws and regulations that affect the pharmaceutical and chemical manufacturing, importing, and exporting industry and to discuss practices to prevent diversion while minimizing the impact on legitimate commerce. In addition, topics such as quotas, year-end reporting, Automation of Reports and Consolidated Orders System (ARCOS) reporting, import/export permits, and import/export declarations were discussed. Approximately 370 people attended, representing more than 200 registrants.
- The Distributor Conference was held on October 22, 2013, and this conference provided an overview of Federal laws and regulations governing issues that affect pharmaceutical and chemical distributors, such as recordkeeping, ARCOS, and suspicious order reporting. Approximately 220 people attended, representing more than 130 registrants.
- To better assist DEA registrants with their understanding of the Controlled Substance Act (CSA) and implementing regulations, manuals are drafted and made available to the public. The manuals are not considered legal documents. Readers are instructed to refer to the most current copy of the CSA, the Narcotic Addict Treatment Act of 1974, the Drug Addiction Treatment Act of 2000, the Code of Federal Regulations (C.F.R.), and Federal Register Notices to obtain complete and accurate information. The following manuals are available via DEA the website:
    - Chemical Handler's Manual
    - Pharmacist's Manual
    - Practitioner's Manual

Additionally, DEA established the Distributor Initiative Program in August 2005 to educate and inform distributors of their responsibilities under the CSA and its implementing regulations by discussing suspicious order monitoring systems, reviewing sales and purchase data, and discussing national trends involving the abuse and diversion of controlled substances. This program was initially designed to educate wholesale distributors that were supplying controlled substances to rogue Internet pharmacies and, more recently, to diverting pain clinics and pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes.

Monitoring

One of the best ways to combat the rising tide of prescription drug abuse is through the implementation and use of Prescription Drug Monitoring Programs (PDMPs). PDMPs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists.[9] However, in many states with operational PDMPs, participation by prescribers and dispensers is voluntary, with utilization rates well below 50%.[10] The Brandeis University Center of Excellence developed a PDMP Management Tool, which recommends calculating the number of in-state prescribers with PDMP accounts as a percentage of the number of in-state prescribers who issued controlled substance prescriptions during the prior year. Based on this calculation, for example, in Florida just 18% of the in-state prescribers who issued more than one controlled substance prescription have registered to use the database (11,408 in-state prescribers signed up for PDMP accounts out of the 62,238 in-state prescribers who issued controlled substance prescriptions during the prior year).[11] While PDMPs are valuable tools for prescribers, pharmacists, and law enforcement agencies to identify, detect, and prevent prescription drug abuse and diversion, PDMPs do have some limits in their use for detecting diversion at the retail level. For example, the use of PDMPs is limited across state lines because interconnectivity remains a challenge; at the same time, many drug traffickers and other drug seekers willingly travel hundreds of miles to gain easy access to unscrupulous prescribers and dispensers. This issue will become less of a hurdle as states continue to enroll in the National Association of Boards of Pharmacy Prescription Monitoring Program (PMP) InterConnect, which facilitates the transfer of prescription monitoring program data across state lines to authorized users. As of December 31, 2014, PMPs in 27 states are enrolled in the program.

The Department continues to support and encourage the development and maintenance of Prescription Drug Monitoring Programs at the state level. Currently, 49 states have an operational PDMP (meaning collecting data from dispensers and reporting information from the database to authorized users). The District of Columbia has enacted legislation enabling the establishment of a PDMP; Missouri has no PDMP. As of June, 2014, 20 states had laws mandating that prescribers and in some cases dispensers enroll with their state's PDMP, and 22 states had laws mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances.[12]

The Department has supported the development of PDMPs through the Harold Rogers Prescription Drug Monitoring grant program, distributing a total of over $87 million from FY 2002 to FY 2014, including $7 million in FY 2014. The purpose of this grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze

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[9] This statement applies to all schedules. However, while many prescription monitoring programs cover all schedules, some programs apply only to controlled substances in schedule II.

[10] The Brandeis University PDMP Center of Excellence, retrieved 12/18/14 http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps.

[11] Electronic-Florida Online Reporting of Controlled Substances Evaluation, 2013-2014 Prescription Drug Monitoring Program Annual Report, published December 1, 2014.

[12] The Brandeis University PDMP Center of Excellence, retrieved 12/18/14 http://www.pdmpexcellence.org/content/mandating-medical-provider-participation-pdmps.

controlled substance prescription data. It focuses on providing help for states that want to establish a PDMP or expand an existing PDMP. In 2012, the Department provided further policy guidance on data sharing efforts among state PDMPs, a critical aspect of the program.

Proper Medication Disposal

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, enacted in October 2010 (Pub. L. 111-273) (Disposal Act), the CSA provided no legal means for ultimate users to transfer possession of controlled substance medications to other individuals for disposal. The Disposal Act amends the CSA to authorize ultimate users and Long Term Care Facilities (LTCFs) to deliver controlled substances to another authorized person for the purpose of disposal in accordance with regulations promulgated by DEA.

On September 9, 2014, DEA published in the Federal Register the final rule on the Disposal of Controlled Substances. The final rule became effective on October 9, 2014, and it implements the Disposal Act by establishing requirements that allow authorized registrants to develop secure, ongoing, and responsible methods for ultimate users and LTCFs to dispose of pharmaceutical controlled substances. The final rule expands the options available to collect controlled substances from ultimate users for the purpose of disposal, to include (1) take-back events; (2) mail-back programs; and (3) collection receptacle locations. These regulations contain specific provisions that:

- Recognize the continuing authority of law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles;
- Allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles; and
- Allow authorized retail pharmacies and hospitals/clinics with an on-site pharmacy to voluntarily maintain collection receptacles at long term care facilities.

In addition, DEA conducted nine Prescription Drug Take-Back Days from September 2010 to September 2014. Each take-back day provided the public with thousands of sites nationwide to turn in their unwanted or expired prescription drugs safely and securely. On September 26, 2014, the most recent National Prescription Drug Take-Back Day, 617,150 pounds (309 tons) of prescription medications were collected from members of the public. As a result of all nine National Prescription Drug Take-Back Days, DEA, in conjunction with its state, local, and tribal law enforcement partners, has removed a total of just under 4.9 million pounds (2,411 tons) of medications from circulation. Although law enforcement continues to have discretion with respect to take-back events, DEA discontinued this nationwide program because the new final rule on the Disposal of Controlled substances provides the public with expanded options to safely and responsibly dispose of their unused and unwanted, lawfully-possessed pharmaceutical controlled substances through collection receptacles and mail-back packages. This rule allows for ongoing medication disposal, thereby ridding the home of unused or unwanted drugs that pose a poisoning hazard or can be diverted.

Enforcement

The Department, via DEA's Diversion Control Program, is using all criminal and regulatory tools possible to identify, target, disrupt, and dismantle individuals and organizations responsible for the illicit manufacture and distribution of pharmaceutical controlled substances in violation of the CSA. The deployment of Tactical Diversion Squads (TDSs) is DEA's primary method of criminal law enforcement in the Diversion Control Program. The recent expansion of the TDS program has resulted in 66 operational TDSs throughout the United States, covering 41 states, Puerto Rico, and the District of Columbia. These TDSs incorporate the enforcement, investigative, and regulatory skill sets of DEA Special Agents, Diversion Investigators, other Federal law enforcement, and state and local Task Force Officers. The expansion of the TDS groups has enabled the Diversion Groups to concentrate on the regulatory aspects of the Diversion Control Program.

Several DEA investigations of rogue pain clinics in Southern Florida have resulted in charges against 172 individuals, including 51 doctors and 24 clinic/pharmacy owners, the seizure of approximately 2.5 million dosage units of controlled substances, and approximately $16.6 million in currency, real property, and exotic cars. In addition, approximately 42 doctors and 11 pharmacies lost their DEA registrations. Approximately 192 doctors and 68 pharmacies voluntarily surrendered their DEA registrations.

In addition to the focus on criminal law enforcement, the Department also dedicates resources to civil and regulatory matters. DEA is pursuing additional actions when registrants and other entities violate the law. For example, in March 2013, UPS agreed to a $40 million settlement with the Department of Justice for payments it received from illicit online pharmacies. This settlement is part of a non-prosecution agreement with the United States Attorney's Office for the Northern District of California (San Francisco) and is the result of a five-year investigation of 12 rogue internet pharmacies. This investigation resulted in 43 convictions, $34 million in seized assets, and forfeiture orders totaling $51 million.

In 2012, DEA pursued administrative actions against two CVS pharmacy stores in Florida, where these two registrants violated provisions of the CSA and committed acts that are inconsistent with the public interest, by dispensing controlled substances to customers under circumstances indicating that the drugs were diverted from legitimate channels, misused, or abused, and by failing to exercise their corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). In October 2012, the DEA Administrator issued a final order revoking the registrants' certificates of registration and denying any pending applications for renewal, stating that the misconduct was both egregious and for an extended duration, and undoubtedly caused extensive harm to the public interest. During 2013, DEA, together with the United States Attorneys' Offices for the Western District of Oklahoma and the Southern District of Florida, pursued significant regulatory and civil actions in two cases where registrants violated provisions of the CSA. In April 2013, CVS Pharmacy, Inc. executed an $11 million settlement agreement in which it agreed to pay a civil penalty for CSA violations and failure to keep proper records of pharmacy sales. In June 2013, Walgreens Corporation agreed to pay $80 million in civil penalties for the actions by their distribution center and six pharmacies in Florida, which resulted in the diversion

of millions of dosage units of oxycodone, a powerful schedule II painkiller. Their actions helped fuel a prescription drug epidemic in the State of Florida over several years.

While some issues related to prescription drug abuse have worsened in recent years, particularly along the heroin-prescription opiate vector, the Department's continued focus on prescription drug abuse has yielded significant improvements in many areas. For example, the substantial civil penalties and settlements with CVS, Walgreens, and UPS described above have signaled the serious potential consequences for companies and registrants that fail to recognize the dangers of prescription drug abuse and follow the law regarding controlled substances. Further, the Department and DEA have observed significant changes in Florida, where rogue pain clinics have long been known to operate and have helped fuel the prescription drug abuse epidemic in several other states. According to the Florida Department of Health, the number of pain management clinics in Florida as of December 31, 2013, is 360, down from 635 at the end of FY 2010. In 2010, 90 of the top 100 oxycodone-purchasing physicians in the country were in Florida, but that number dropped to 13 in 2011. As of September 30, 2014, there was only one Florida physician in the top 100 purchasers of oxycodone, as Florida law no longer allows practitioners to dispense schedule II and schedule III controlled substances, with the exception of some very limited circumstances (e.g., practitioners may dispense to patients who: are under hospice care; have undergone a surgical procedure, and a 14-day supply may be dispensed; are an inmate in a prison; are a participant in an approved clinical trial). The Department will continue to direct efforts towards the issue of prescription drug abuse, with DEA leading as the Nation's principal enforcer of Federal drug laws and regulations.

2. What is the cost of a single dose of Naloxone? Is the cost of Nalaxone a barrier to making the antidote more readily available?

Response:

DEA does not have data or information responsive to this question as it falls outside of DEA's jurisdiction.

Questions Posed by the Honorable Steve Scalise

1. **According to the GAO report, there are 15 federal agencies and 76 abuse prevention or treatment programs. The GAO report identified overlap in 59 of the 76 programs. Please discuss what your agency is doing to address that overlap and the problems addressed in the GAO report.**

Response:

DEA does not have data or information responsive to this question as it falls outside of DEA's jurisdiction.