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Report to Congressional Requesters

August 2011

PRESCRIPTION DRUG CONTROL

DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results

GAO-11-744

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GAO Accountability * Integrity * Reliability

Highlights

Highlights of GAO-11-744, a report to congressional requesters

Why GAO Did This Study

The Drug Enforcement Administration's (DEA) Diversion Control Program is responsible for enforcing the Controlled Substances Act (CSA) and ensuring the availability of prescription drugs such as pain relievers and stimulants while preventing their diversion for abuse. The CSA requires entities handling controlled substances—such as manufacturers, pharmacies, and physicians, among others-- to register with DEA, which conducts regulatory investigations of registrants, as well as criminal investigations. GAO was asked (1) how DEA manages diversion investigation efforts, and (2) how DEA ensures policies and procedures are followed for investigations and the extent to which it determines the results of its efforts. GAO reviewed DEA policies and procedures, and interviewed DEA, state, and local officials at eleven locations which were selected on the basis of volume of cases handled, geographic diversity, and other considerations. These observations are not generalizable, but provided insights on DEA operations.

What GAO Recommends

GAO recommends DEA reassess the program's performance measures to better link them to the goal of reducing diversion. DEA did not concur. GAO continues to believe the measures could be enhanced as discussed in this report.

View GAO-11-744. For more information, contact Eileen Larence at (202) 512-8777 or larencee@gao.gov.

What GAO Found

To respond to the increasing rate of criminal diversion of prescription drugs and a growing registrant population, DEA has expanded its resources and targeted its investigation strategies to collaborate with state and local entities and enhance the effectiveness of its diversion investigations. Specifically, the agency expanded its use of Tactical Diversion Squads (squads) of DEA personnel as well as other federal, state, and local partners investigating diversion schemes to maximize resources and improve efforts to investigate criminal diversion. DEA currently has 40 squads across the country and plans to establish more. According to squad participants and DEA officials GAO contacted, the squads have improved communication and coordination and simplified information sharing for investigations. Because of the growing registrant population and noncompliance by some with the CSA and implementing regulations, DEA renewed its focus on regulatory oversight of registrants to better ensure compliance. By using the squads to free up resources previously dedicated to both criminal and regulatory cases, DEA used those resources to increase regulatory investigations of the registrants. As a result, the number of regulatory investigations more than tripled between fiscal years 2009 and 2010. DEA also conducted outreach to specific registrant types to inform them of regulatory responsibilities and prepare them for regulatory investigations.

DEA has taken steps to ensure that investigators follow policies and procedures for such investigations, but could better assess how its efforts are reducing the diversion of prescription drugs. To ensure that diversion investigators and special agents have the necessary skills to carry out their responsibilities and that DEA monitors the extent to which policies and procedures are followed during investigations, DEA has established internal controls related to guidance, training, and oversight of investigations. These controls include providing and updating guidance to investigators to follow during investigations, providing initial and on-going training to investigators, and monitoring the quality of investigations through a combination of direct supervisory reviews, self-inspections, and on-site internal inspections by DEA's Office of Inspections. Recent reports from on-site internal inspections of each of DEA's field divisions did not identify any widespread or systematic issues related to the timeliness and overall quality of diversion investigations. Given DEA's increased focus on investigations in response to growing prescription drug diversion, it is critical for DEA to determine the extent to which these additional efforts are reducing diversion. DEA has established performance measures for the Diversion Control Program, but these measures do not clearly demonstrate the effect the additional efforts are having on the diversion problem the program seeks to address. For example, for its overall performance measure of the diversion control program, DEA is tracking the development and implementation of an internal information technology project. By more closely linking performance measures to the goal of reducing diversion, DEA could better capture the results of the Diversion Control program to help inform decision makers in allocating resources.

Contents

Abbreviations

ARCOS	Automated Reports and Consolidated Orders System
CSA	Controlled Substances Act
CPOT	Consolidated Priority Organization Target
DEA	Drug Enforcement Administration
DOJ	Department of Justice
DWP	Drug Addiction Treatment Act waived physician
FBI	Federal Bureau of Investigation
HHS	Department of Health and Human Services
IRS	Internal Revenue Service
OMB	Office of Management and Budget
ONDCP	Office of National Drug Control Policy
PTO	Priority Target Organization
RapTOR	Rapid Targeting Online Reports Tool
SIP	Self-Inspection Program

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

August 26, 2011

The Honorable Chaka Fattah
Ranking Member
Subcommittee on Commerce, Justice, Science and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable C.A. Dutch Ruppersberger
House of Representatives

According to the Office of National Drug Control Policy (ONDCP), the abuse of controlled prescription drugs such as pain relievers, depressants, and stimulants is the nation's fastest-growing drug problem. Although such prescription drugs have legitimate medical uses, they also pose a potential for abuse and addiction and, thus, being diverted for nonmedical illicit uses. To prevent diversion, the Controlled Substances Act (CSA) was enacted in 1970 to regulate and facilitate the use of controlled substances, including certain drugs, for legitimate medical, scientific, research, and industrial purposes while preventing them from being diverted for illegal uses.[1] However, according to recent government data, the diversion of such drugs has risen in recent years as have the corresponding prevalence of addiction and the cost of lives lost. ONDCP has reported that prescription drugs now rank second for the most commonly abused category of drugs, behind only marijuana. In 2010, the Substance Abuse and Mental Health Services Administration reported that the proportion of all substance abuse treatment admissions aged 12 or older that reported any pain reliever abuse increased more than fourfold from 1998 to 2008.[2] In terms of the economic costs, a study by

[1] Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified as amended at 21 U.S.C. §§ 801-890, 901-971). According to the CSA, the term "controlled substance" means a drug or other substance, or immediate precursor, that is included in one of five classification schedules. A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. The order of the schedules reflects substances that are progressively less dangerous and addictive. The term "controlled substance" as used in this report includes controlled prescription drugs.

[2] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, *The TEDS Report: Substance Abuse Treatment Admissions Involving Abuse of Pain Relievers: 1998 and 2008*. (Rockville, Md.: July 15, 2010).

the University of Washington estimated the cost of the abuse of prescription pain relievers in 2006 to be $53.4 billion.[3]

Controlled substances can be diverted in many different ways, and new methods continue to evolve over time. Diversion can occur as a result of illegal or improper prescribing, prescription forgery, pharmacy thefts, or "doctor shopping" where an individual—who may or may not have legitimate medical needs—goes to several doctors to obtain a prescription from each doctor. Diversion can also occur through illegal sales of controlled substances, such as drugs sold by physicians, patients, or pharmacists, as well as individuals obtaining these substances without a valid prescription through Internet pharmacies or pain clinics.[4] According to DEA, from fiscal years 2006 through 2009, rogue Internet pharmacies were a major source of this problem, where individuals could obtain controlled substances through Internet pharmacies without establishing a legitimate doctor/patient relationship. Following increased enforcement actions against rogue Internet pharmacies, another source emerged in the form of rogue pain clinics where prescriptions for controlled substances could similarly be obtained without a legitimate medical need. These pain clinics have proliferated in states such as Florida and Texas.

Controlled substance diversion poses a unique challenge because of the need to balance prevention, education, and enforcement with the need for legitimate access. Within the Drug Enforcement Administration (DEA), the Office of Diversion Control is directly responsible for enforcing the provisions of the CSA as they pertain to ensuring the availability of substances such as prescription drugs and listed chemicals for legitimate uses while preventing their diversion. As part of the provisions to control

[3] Given the limitations and uncertainties of the methods and sources used in this study, these results should be interpreted with caution and regarded as approximations only. See Ryan N. Hansen, Gerry Oster, John Edelsberg, George E. Woody, and Sean D. Sullivan, "Economic Costs of Nonmedical Use of Prescription Opiods," *Clinical Journal of Pain,* vol. 27, no. 3 (2011).

[4] We have previously issued reports related to the diversion and abuse of prescription drugs. See GAO, *Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States*, GAO-09-957 (Washington, D.C.: September 2009); GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem,* GAO-04-110 (Washington, D.C.: December 2003); and GAO, *Prescription Drugs*: *State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D.C.: May 2002).

access to such substances, the CSA requires businesses, entities, or individuals that import, export, manufacture, distribute, dispense, conduct research with respect to, or administer controlled substances to register with the DEA. One of the key activities of the Office of Diversion Control is to conduct investigations—regulatory investigations to monitor compliance of the registrants with the CSA and its implementing regulations, and criminal investigations into instances of potential criminal diversion.

Because of the rising diversion and illicit use of controlled prescription drugs, you asked us to review DEA's management of its diversion control investigations to combat this problem.[5] Specifically, this report answers the following questions:

1. How does DEA manage its investigation efforts to address the growing and evolving nature of prescription drug diversion?
2. How does DEA help ensure that policies and procedures are followed for diversion investigations and to what extent does it determine the results of its efforts on the diversion problem?

To address the first objective, we reviewed DEA policies and procedures on how DEA carries out its investigative responsibilities, including program documents such as DEA's current strategic plan and budget justification submissions for fiscal years 2008 to 2012.[6] We also analyzed DEA data for fiscal years 2007 to 2010 on case volumes for investigations and data on number of personnel working on DEA's Tactical Diversion Squads (squads).[7] We reviewed information from agency officials regarding the data and the systems and procedures used to maintain it. From this review we determined that the data were sufficiently reliable for

[5] We are currently conducting a separate review examining the trends in misuse and abuse of prescription pain relievers and how federal agencies, including DEA, educate the public and health care providers about misuse and abuse of such drugs.

[6] We reviewed DEA's budget justification submissions for fiscal years 2008 to 2012 because we wanted to review the five most recent budget justifications available.

[7] We reviewed DEA data on case volumes for investigations and data on the number of personnel working on DEA's Tactical Diversion Squads for fiscal years 2007 to 2010 because we wanted to focus our analysis on the most recent 4-year period. Tactical Diversion Squads are teams of DEA diversion personnel, as well as other federal, state, and local law enforcement personnel, whose mission is to detect, investigate, disrupt, and refer for prosecution, violators of federal and state controlled substance statutes pertaining to drug diversion.

the purposes of this report. We also interviewed DEA program officials involved in overseeing and managing diversion control investigations and program officials involved in diversion investigations at 5 of DEA's 21 field divisions. These included Seattle, Washington; Houston, Texas; Miami, Florida; Washington, D.C.; and Atlanta, Georgia. As part of these interviews, we obtained DEA program officials' perspectives on how they carry out diversion investigations and how they work with other federal, state, and local agencies, as well as registrants in carrying out investigatory activities. These field divisions were selected on the basis of a mix of criteria such as the range of the highest volumes of regulatory and criminal cases and civil penalties; geographic diversity; and other considerations. Within each field division, we also contacted and interviewed officials of state boards of pharmacy and medicine to obtain information on how DEA coordinates with their agencies. In order to better understand how DEA is using its squads to respond to criminal diversion, we interviewed DEA officials and officials from state and local agencies participating in the squads to obtain information on how criminal diversion investigations are carried out and how DEA coordinates those investigations. The 10 squads selected for these interviews were Baltimore, Maryland; Worcester, Massachusetts; Houston, Texas; Kansas City, Missouri; Miami, Florida; New Orleans, Louisiana; Oakland, California; Seattle, Washington; Tampa, Florida; and Washington, D.C., and were chosen based on a mix of criteria such as the range of the highest volume of cases handled, length of time in operation, and the participation of state and local agencies. Our results are not generalizable across all field divisions or squads but provide a broad overview and understanding of diversion investigations, as well as how DEA has managed these investigations and coordinates with other non-DEA partners. We also interviewed officials with associations representing pharmacies and distributors, as well as pharmacies and distributors identified by these associations, to obtain regulated industry's perspective on how DEA carries out its regulatory responsibilities and interacts with this industry. The information we obtained from interviewing officials with these associations as well as officials with pharmacies and distributors that were identified by the associations, cannot be generalized across the entire population of pharmacy and distributor operators. However, the information gathered in these interviews provided us with perspectives from regulated industry on how DEA has implemented its diversion control efforts and how it interacts with industry in monitoring compliance with the CSA.

To address the second objective, we compared criteria in *Standards for Internal Control in the Federal Government* to (1) DEA's control activities

related to human capital management and (2) DEA's monitoring mechanisms to identify what actions it has taken to ensure its employees are informed and follow required policies and procedures.[8] We also reviewed DEA policies and procedures in its manuals for Diversion Investigators and Special Agents, as well as documents related to DEA training courses conducted for program personnel to determine DEA's efforts to ensure its employees have the required knowledge to conduct diversion investigations. We reviewed the most recent on-site internal inspection reports for each of DEA's 21 field divisions, ranging from fiscal years 2005 to 2010 to determine what issues, if any, were identified with respect to diversion investigations.[9] At headquarters, we interviewed DEA program officials in the Office of Training, Office of Inspections, and the Regulatory Section. Our purpose was to determine what actions they take to train employees on required policies and procedures and conduct reviews of employee work products. We also reviewed DEA's Strategic Plan Fiscal Years 2009-2014 to identify DEA's plans for ongoing monitoring efforts. To determine how DEA measures the results of its efforts against the diversion problem, we reviewed DEA's Strategic Plan Fiscal Years 2009-2014, as well as the corresponding performance measures DEA has designated for the diversion control program as reported in its budget justifications for fiscal years 2008 through 2012. We compared DEA's identified performance measures with best practices for performance measurement identified in our previous guidance and work regarding the implementation of the Government Performance and Results Act to determine the extent to which the measures could be used

[8] GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD 00-21.3.1 (Washington, D.C.: November 1999). Internal control is an integral component of an organization's management that provides reasonable assurance that the following objectives are being achieved: effectiveness and efficiency of operations, reliability of financial reporting, and compliance with applicable laws and regulations. These standards, issued pursuant to the requirements of the Federal Managers' Financial Integrity Act of 1982 (FMFIA), provide the overall framework for establishing and maintaining internal control in the federal government. Also pursuant to FMFIA, the Office of Management and Budget issued Circular A-123, revised December 21, 2004, to provide the specific requirements for assessing the reporting on internal controls. Internal control standards and the definition of internal control in Circular A-123 are based on GAO's *Standards for Internal Control in the Federal Government*.

[9] We reviewed the on-site internal inspection reports for DEA's 21 field divisions for fiscal years 2005 to 2010 because we requested DEA to provide the most recent internal inspection report available from each field division. The inspection reports DEA provided in response to this request varied in date from fiscal year 2005 to 2010.

to demonstrate program results.[10] We also interviewed DEA officials within the Office of Diversion Control and the Office of Resource Management to determine how they use these measures, and what plans, among other things, they had to evaluate the usefulness of the measures as indicators to track results towards the program's overall performance goal of reducing the diversion of licit drugs.

We conducted this performance audit from May 2010 through August 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[10] GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1996); GAO, *Agencies Annual Performance Plans Under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking* GAO/GGD/AIMD-10.1.18 (Washington, D.C.: February 1998); and GAO, *Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures,* GAO-03-143 (Washington, D.C.: November 2002).

Background

The CSA and DEA's Office of Diversion Control

Schedules of controlled substances

Controlled substances are classified into five schedules on the basis of their currently accepted medical use and potential for abuse and dependence:

- Schedule I substances have no currently accepted medical uses and have a high potential for abuse. Examples: heroin and marijuana.
- Schedule II substances have currently accepted medical uses but also have high potential for abuse that may lead to severe psychological or physical dependence. Examples: oxycodone and (methylphenidate) Ritalin.
- Schedule III substances have currently accepted medical uses and a potential for abuse which may lead to moderate or low physical dependence or high psychological dependence. Examples: anabolic steroids, codeine, and hydrocodone in combination with aspirin or acetaminophen.
- Schedule IV substances have currently accepted medical uses and a low potential for abuse which may lead to limited physical or psychological dependence. Examples: anti-anxiety medications diazepam (Valium) and alprazolam (Xanax).
- Schedule V substances have currently accepted medical uses and a low potential for abuse which may lead to limited physical or psychological dependence. Example: cough syrup preparations with codeine.

All drugs but those in Schedule I are legally available with a prescription.

Sources: 21 U.S.C. § 812; GAO.

The CSA places various plants, drugs, and chemicals such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids, into one of five schedules based on the substance's medical use or lack thereof, potential for abuse, and safety or potential for dependence.[11] The act requires persons who handle controlled substances and/or listed chemicals (such as manufacturers, wholesale distributors, physicians who dispense controlled substances, hospitals, pharmacies, importers/exporters, and scientific researchers) to register with the DEA. This agency, by delegation from the U.S. Attorney General, is responsible for administering and enforcing the CSA and its implementing regulations. Through its Office of Diversion Control, DEA administers the Diversion Control Program whose mission is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals into the illicit market, while ensuring an adequate and uninterrupted supply for legitimate needs. In addition to conducting investigations, the office conducts a variety of activities such as the establishment of production quotas, drafting and promulgating regulations for handling controlled substances, regulating handlers of controlled substances, and monitoring and tracking the production and distribution of certain controlled substances, among other things. To carry out this mission, the Office of Diversion Control is authorized approximately 1,300 full-time equivalent positions and a budget of approximately $292 million. The program is funded through the Diversion Control Fee Account, which consists of registration fees paid by registrants.

[11] 21 U.S.C. § 812. The act also authorizes the Attorney General to promulgate regulations adding, moving, or removing a drug or substance to, among, or from the five schedules established by the act after making certain findings specified by statute.

DEA Registers Entities Authorized to Handle Controlled Substances

As required by the CSA, businesses, individuals, or entities that import, export, manufacture, distribute, dispense, conduct research with respect to controlled substances and/or listed chemicals must register with the DEA. DEA has more than 1.3 million individuals and companies that are registered to handle controlled substances or regulated chemicals. These registrants include manufacturers, distributors, and importers/exporters of controlled substances or medications; pharmacies, hospitals, narcotic treatment programs, and clinics that dispense controlled medications; practitioners who prescribe and administer or dispense controlled medications; and researchers who use controlled substances or medications in their research or analyses (see table 1.)

Table 1: DEA Registrants, by Type, as of May 2011

Registrant type	Number of registrant type	Percent of total registrant population
Practitioner	1,103,159	79.46%
Mid-Level Practitioner	188,577	13.58%
Retail Pharmacy	66,829	4.81%
Hospital/Clinic	15,735	1.13%
Researcher	9,036	0.65%
Analytical Labs	1,483	0.11%
Narcotic Treatment Program	1,259	0.09%
Distributor	793	0.06%
Manufacturer	526	0.04%
Teaching Institute	348	0.03%
Exporter	228	0.02%
Importer	206	0.01%
Reverse Distributor[a]	59	<0.01%
Total	**1,388,238**	**100.00%**

Source: DEA.

Notes:

[a]A reverse distributor is a registrant who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or processes such substances or arranges for processing such substances for disposal.

In order to maintain their registration, DEA registrants must comply with a variety of regulatory requirements imposed by the CSA and its implementing regulations. Examples of these regulatory requirements include:

- *Recordkeeping:* A registrant must keep accurate records and maintain detailed inventories of controlled substances in compliance with applicable federal and state laws. For example, the registrant must maintain accurate records of each substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant.
- *Reporting:* Manufacturers and distributors must report acquisition or distribution transactions of certain controlled substances, such as Schedule I and II drugs and Schedule III narcotics, to DEA through the Automated Reports and Consolidated Orders System (ARCOS). ARCOS is an automated reporting system to monitor the flow of controlled substances from their point of manufacture to the point of sale or distribution at the dispensing/retail level such as hospitals, retail pharmacies, practitioners, midlevel practitioners, and teaching institutions. Manufacturing transactions of Schedule I and II controlled substances, as well as Schedule III and IV narcotics, among others are also covered by the ARCOS reporting requirements.
- *Dispensing of controlled substances:* The CSA provides special requirements for licensed practitioners and pharmacists who dispense controlled substances in Schedules II-V to patients. For example, a prescription for a controlled substance must be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Accordingly, practitioners also have a responsibility to ensure that the controlled substance is properly prescribed and dispensed while a corresponding responsibility exists with the pharmacist filling the prescription.
- *Security of controlled substances:* For the purposes of ensuring the secure storage and distribution of controlled substances, all registrants must "provide effective controls and procedures to guard against theft and diversion of controlled substances." Among other things, DEA regulations also detail specific security requirements for the different types of applicants and registrants. For example, nonpractitioners (i.e., manufacturers, distributors, and narcotic treatment programs) are required to store Schedule I and II substances in electronically monitored safes, steel cabinets, or vaults that meet or exceed certain specifications. Licensed practitioners must store controlled substances in a "securely locked, substantially constructed cabinet" and must notify DEA of the theft or significant loss of any controlled substances.

DEA investigations to monitor and enforce CSA compliance

To achieve its mission, DEA monitors and enforces compliance with the CSA through three types of investigations—regulatory, complaint, and criminal:

Penalties for diversion of controlled substances

DEA can initiate a variety of actions for violations of the CSA or its implementing regulations. The type(s) of action taken is typically driven by the severity of the offense(s) and whether or not a registrant was the subject of any previous actions. The following is a partial listing of potential actions DEA can take against a registrant or diverter:

- Administrative actions are handled primarily by DEA and can include (1) a letter of admonition to advise the registrant of any violations; (2) an order to show cause which initiates revocation or suspension of a DEA registration; and (3) an immediate suspension order against the registrant if there is a finding of imminent threat to public health or safety.
- Civil penalties are typically coordinated with an Assistant United States Attorney or in some instances the local district attorney. Civil violations are typically recordkeeping violations involving controlled substances or listed chemicals. Penalties for civil actions generally include monetary fines.
- Criminal prosecutions are coordinated with an Assistant United States Attorney or local district attorney. Criminal violations include offenses such as the illegal distribution of controlled substances and other related offenses such as health care fraud, tax evasion, and money laundering. Criminal penalties generally include incarceration and fines.

Source: DEA.

- **Regulatory Investigations:** DEA conducts scheduled investigations or inspections (depending on the registrants, the frequency of the scheduled investigations can range from every 3 years to every 5 years) of wholesale registrants who include manufacturers, distributors, importer/exporters, and narcotic treatment programs as well as other registrants such as researchers, analytical labs, and teaching institutions, among others. Retail level registrants such as pharmacies and physicians—with the exception of physicians permitted to treat narcotic dependence—do not receive regulatory investigations by the DEA. These registrants are regularly investigated by the states in which they conduct business. According to DEA officials, they focus their efforts related to regulatory investigations on the wholesale registrants because such registrants are the sources of supply to criminal schemes such as rogue pharmacies and pill mills. To conduct these investigations, DEA Diversion Investigators arrive at the registrant unannounced and inspect and verify the registrant's records, take a physical inventory of the registrant's controlled substances, and inspect any other items necessary to verify the registrant's compliance with the CSA and its implementing regulations. If deficiencies are found during the investigation, DEA may work with the registrant to correct the deficiencies. DEA may also take administrative, civil, or criminal action against the registrant depending on the type, severity, and frequency of the deficiencies found.
- **Complaint Investigations:** Complaint investigations are investigations that are started on the basis of information or a tip provided to DEA or state regulators, or other information DEA has regarding purchases or losses of controlled substances. The origin of the information could be from any number of sources, such as a state or local official or citizen that saw something suspicious, employees of a registrant, the identification of unusual purchasing trends by a registrant such as a pharmacy tracked by DEA through its ARCOS, or a report of a loss of controlled substances by a registrant. Diversion Investigators conduct preliminary investigative work to determine whether the information is valid and warrants a full investigation. Depending on the outcome of the preliminary complaint investigation, DEA determines whether the investigation will be handled as a regulatory noncompliance issue, a criminal case, or a dismissal.
- **Criminal Investigations**: DEA also conducts investigations into criminal activities involving diversion of controlled substances. Criminal diversion may involve DEA registrants such as pharmacies and practitioners and nonregistrants such as pharmacy burglars or doctor shoppers, among others.

Within its 21 field divisions, DEA utilizes a variety of personnel to carry out these investigative responsibilities:

- *Diversion Investigators* conduct investigations of regulatory, civil, and criminal issues pertaining to DEA registrants. The investigators do not have law enforcement authority and cannot perform law enforcement functions such as making arrests and conducting surveillance.
- *Special Agents* conduct diversion investigations and assist Diversion Investigators by performing law enforcement functions such as serving search warrants and making arrests.
- *Diversion Program Managers* oversee diversion control activities in their field division.
- *Special Agents-in-Charge* manage the activities of the DEA field division including diversion control activities.
- *Assistant Special Agents-in-Charge* assist the Special Agents-in-Charge in managing activities of the field division including diversion control activities.

DEA Has Expanded Its Resources and Targeted Its Investigation Strategies to Respond to Rising Criminal Diversion and Growing Registrant Population

To respond to the increasing rate of criminal diversion and a growing registrant population, DEA has expanded its resources and targeted investigation strategies in ways to collaborate with state and local entities and enhance the effectiveness of its Diversion Control Program. Specifically, DEA has expanded its use of Tactical Diversion Squads, which work with DEA's state, local, and other federal partners, to maximize resources and improve efforts to investigate, disrupt, and dismantle individuals or organizations involved in diversion schemes related to controlled substances and listed chemicals. DEA has also renewed its focus on regulatory oversight of the more than 1.3 million DEA registrants to ensure registrants comply with the CSA and implementing regulations. DEA accomplished this by increasing the frequency of scheduled investigations of DEA registrants that are registered to handle controlled prescription drugs.

Tactical Diversion Squad Expansion Provides Additional Resources and Facilitates Coordination and Information Sharing for Criminal Investigations

To help respond to the ever-changing methods of criminal diversion such as rogue pain clinics and rogue Internet pharmacy schemes, in October 2008 the DEA acting Administrator authorized the expansion of squads devoted to addressing criminal diversion of controlled substances and listed chemicals across the United States. DEA has historically utilized these squads, called Tactical Diversion Squads (squads), as a collaborative mechanism to address the criminal diversion of controlled substances. The squads are teams of DEA diversion personnel (such as Special Agents and Diversion Investigators), as well as state and local

law enforcement personnel (task force officers) whose mission is to detect, investigate, and refer for prosecution, violators of federal and state statutes pertaining to diversion. They also develop investigative leads from information and intelligence obtained from participating agencies, undercover operations, and the use of informants. This multiagency effort helps coordinate the investigative activities of the participating agencies. According to DEA, the squads also allow DEA to provide manpower for diversion investigations at reduced costs to DEA because task force officer positions are less expensive than Special Agents or Diversion Investigators. For example, DEA compensates state and local Tactical Diversion Squad task force officers for overtime, use of a vehicle, equipment, and diversion training, while the parent agencies are responsible for their task force officers' salary and benefits.

This expansion resulted in a significant increase in the number of Special Agents and task force officers for criminal diversion investigations. At the time the expansion was authorized, DEA had 5 squads in operation which, according to DEA officials, were authorized 5 Special Agents, 12 Diversion Investigators, and 27 task force officers. With existing positions and funding previously authorized and agreements with state and local law enforcement partners in place, DEA has since established 35 additional squads across the United States (see fig. 1) increasing the total number of Special Agents, Diversion Investigators, and task force officers working on all the squads to a total of 141, 54, and 301, respectively.[12] With the increase in squads, DEA has been able to perform more criminal investigations each year. For example, DEA was able to increase the number of criminal investigations initiated from 1,571 in fiscal year 2009 to 1,904 in fiscal year 2010, an increase of 21 percent. According to the Executive Assistant to the Deputy Assistant Administrator for Diversion Control, they plan to add 16 more squads between fiscal years 2011 and 2013 and eventually have at least 63 squads across the country, depending on the need for the squads and availability of resources. With the further expansion of these squads, DEA officials stated that they expect to continue to be able to conduct more criminal diversion investigations each year. To staff these additional squads, DEA

[12] According to DEA officials, the locations for the additional squads were based on proximity to major cities, availability of office space within the DEA field divisions, the reported needs of local areas for a task force focused on diversion investigations, and the interest and ability of state and local law enforcement agencies to provide task force officers.

Coordination with state partners: Prescription Drug Monitoring Programs

State Prescription Drug Monitoring Programs (PDMPs) provide data and analysis to state law enforcement and regulatory agencies to assist in identifying activities potentially related to the illegal prescribing, dispensing, and procuring of controlled substances. The PDMP can be designed to identify possible abusers or diverters by tracking the volume and frequency of prescriptions. As of June 2011, 35 states have operational PDMPs that have the capability to receive and distribute controlled substance prescription information to authorized users. As the PDMP is a state program, DEA does not have a role in its implementation or operation. However, DEA can access PDMP data for use in squad investigations. In 2002, we reported that states with PDMPs experienced considerable reductions in the time and effort required to investigate drug diversion cases (see GAO-02-634).

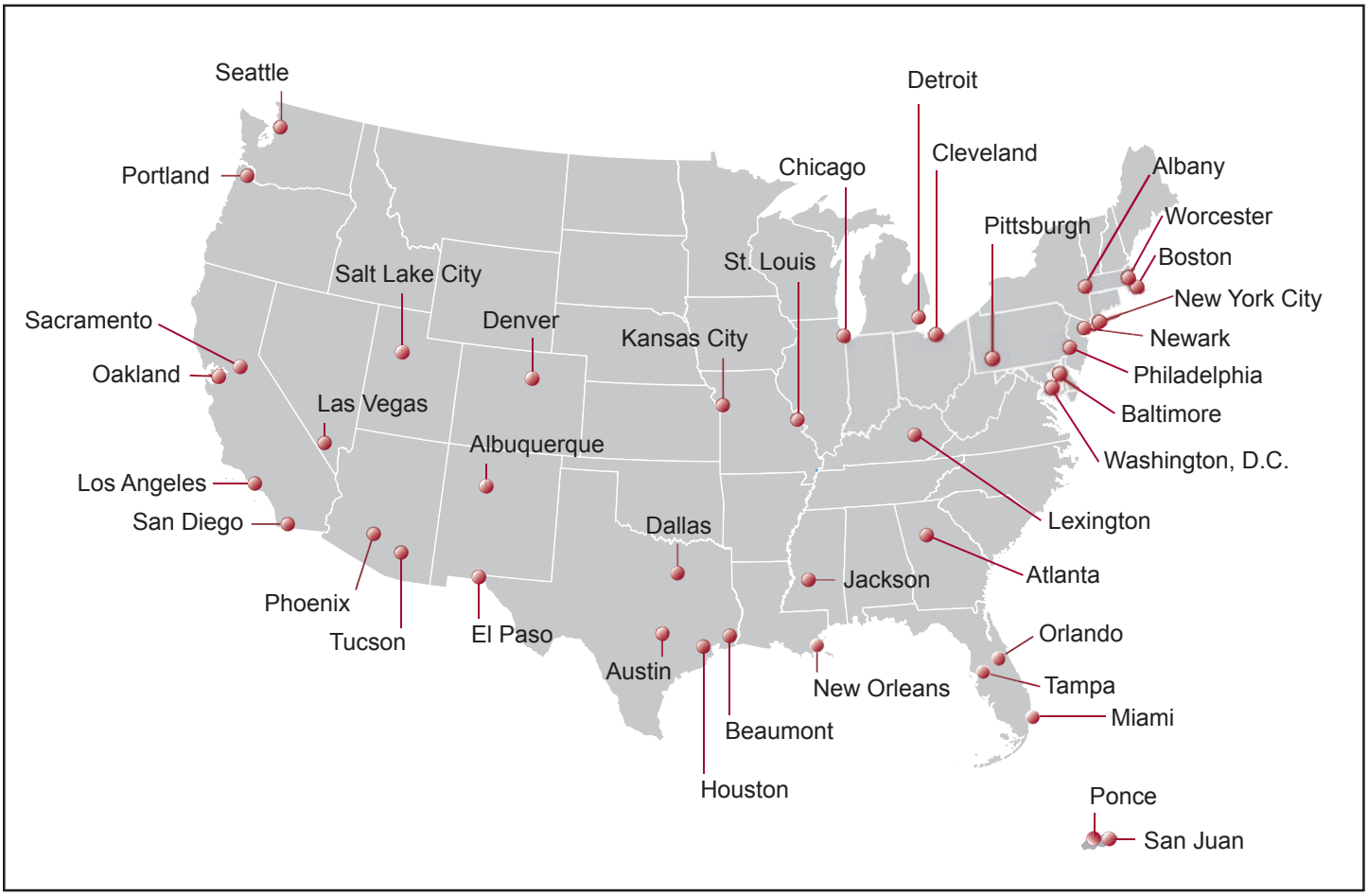
Sources: GAO; DEA.

requested an additional 60 Special Agent, 37 Diversion Investigator, and 64 task force officer positions for fiscal year 2011, and an additional 50 Special Agent, 16 Diversion Investigator, and 64 task force officer positions for fiscal year 2012. Because the Diversion Control program is funded through its fee account, DEA officials noted that such increases in personnel are contingent on the revision of the schedule of fees charged registrants, which is currently underway.[13] They anticipate beginning to collect fees under the revised fee schedule in fiscal year 2012. DEA's current annual registrant fees range from $184 to $2,293.[14] The last time DEA revised its fees was in 2006.

[13] In October 1992, Congress passed the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act of 1993 which changed the source of funding for DEA's Diversion Control Program from being part of DEA's congressional appropriation to full funding by registration and reregistration fees. The act required that the fees charged by DEA under its diversion control program be set at a level to recover the costs of operating the program.

[14] DEA registrants (practitioner, hospital/clinic, retail pharmacy, and teaching institution) that fall under the business activity category "Dispensing or Instructing" pay a registration fee once every 3 years.

Figure 1: Location of the 40 Tactical Diversion Squads



Source: GAO analysis of DEA data; Copyright © Corel Corp. All rights reserved (map).

Coordinating with state and local law enforcement has been beneficial to the squads in investigating diversion. According to squad participants in 6 of the 10 squads we contacted, state and local law enforcement's participation is critical because they are familiar with the local communities they patrol and are able to bring information from their communities to the investigations.[15] At the same time, participating in the

[15] These participants volunteered this information. Because these officials volunteered this information, we do not know the extent to which other squad officials share this view.

Example of diversion of controlled substances—Illegal pain clinics

States such as Florida have experienced significant diversion problems through illegal pain clinics. According to DEA officials, Florida physicians order the majority of oxycodone compared to the rest of the country. In 2010, Florida dispensing physicians ordered over 41 million dosage units of oxycodone, while the rest of the country ordered a total of 4 million dosage units. Some of these physicians are reported to have links to illegal pain clinics where they either dispensed or wrote prescriptions that were not for legitimate medical purposes. Individuals from other states would come to Florida to visit the clinics to obtain controlled substances for abuse or resale. Florida recently enacted legislation to address these clinics. Similarly, Texas and Louisiana have experienced problems with illegal pain clinics and also enacted legislation to address this roblem. Among other things, the legislation for these states requires pain clinics to be owned and operated by licensed physicians with no previous medical board action, and to register with state regulators.

Sources: DEA, Federation of State Medical Boards, and National Drug Intelligence Center (data); Edward Linsmier/St. Petersburg Times (image).

The picture shows a line up of individuals detained after a law enforcement raid of a Florida pain clinic.

squad has enabled local law enforcement agencies to carry out more complex investigations into diversion within their localities. For example, although some local law enforcement agencies had conducted investigations of lower level diverters such as doctor shoppers prior to the establishment of squads, they did not have the resources on their own to carry out the longer, more complex investigations required for targeting higher level diverters such as physicians and their clinics. DEA officials noted that state and local agencies also lack the administrative authorities DEA has to take action against a DEA registrant when necessary. The squad provided a means for state and local law enforcement to collectively pool their resources with DEA to investigate higher level diverters.

Based on feedback from squad participants and DEA officials we interviewed, coordination and information sharing within the squads were reported as excellent and an improvement over presquad times. According to DEA and local officials we interviewed, the establishment of the squads has been a means to improve communication, coordination, and simplify information sharing as the squads have become the clearinghouse for diversion-related investigative information. As a result, information is now shared more rapidly and broadly between law enforcement agencies, according to these officials we interviewed. These squads have also become an important deconfliction mechanism for law enforcement agencies regarding the diversion cases they are working or information they receive from other sources. For example, one local law enforcement official with a task force officer on a squad stated that all leads his department receives for potential diversion investigations are first referred to the squad to determine whether there are any links to ongoing squad investigations or if the lead would be an appropriate target for it to take on as a new investigation.

Federal agencies such as the Federal Bureau of Investigation (FBI), the U.S. Department of Health and Human Services (HHS), and the Internal Revenue Service (IRS) may also be involved in the squads' criminal investigations depending on the case and if their expertise is needed. For example, FBI agents will generally join a squad's investigation if fraud is involved; HHS investigators may become involved in investigations related to health care fraud; and IRS agents may assist in investigations involving tax evasion and money laundering. In March 2011, for example, the DEA in conjunction with the FBI and HHS, among other agencies, concluded an investigation into a Detroit physician for unlawfully distributing controlled substances, including the Schedule II controlled substance OxyContin (oxycodone), and fraudulently billing Medicare.

According to DEA, a conviction of this offense carries a maximum of 20 years in prison, a fine of $1 million, or both. In another example, according to DEA squad officials, DEA, FBI, and IRS, among others, conducted a joint criminal investigation into a Texas business owner's rogue Internet pharmacy scheme. The investigation resulted in a guilty plea to several offenses including unlawfully distributing controlled substances, money laundering, and fraudulently billing healthcare providers, among other offenses. According to DEA officials, joint investigations with other federal agencies are very helpful for the squad in advancing the investigation because the other federal agencies bring specific subject matter expertise in areas that DEA staff do not have.

Tactical Diversion Squad investigation: Operation Pill Nation

To deal with criminal diversion, DEA through its Tactical Diversion Squads worked with federal, state, and local law enforcement partners to conduct criminal investigations. As an example of collaborative actions to address criminal diversion, the Miami Tactical Diversion Squad and its law enforcement partners are conducting an investigative effort called Operation Pill Nation. This operation involved the mobilization of 11 squads from across the United States to coordinate with the Miami Tactical Diversion Squad in investigating illegal pain clinics. As of April 2011, DEA reported that the investigation resulted in the closure of 38 clinics, the arrest of 32 individuals including 12 physicians, the seizure of more than $16.4 million in assets, and the surrender of 83 DEA registrations.

Source: DEA.

Exotic cars seized during Operation Pill Nation.

DEA Has Significantly Increased the Number of Regulatory Investigations to Help Ensure Growing Registrant Population Complies with CSA

In addition to the expansion of the squads in October 2008, the DEA acting Administrator also called for an enhanced focus on DEA's regulatory oversight aimed at ensuring that the more than 1.3 million DEA registrants comply with the CSA and its implementing regulations. According to DEA, the overall registrant population tends to grow at a rate of 2 to 2.5 percent annually; however, registrants such as Drug Addiction Treatment Act[16] waived physicians (DWPs) have grown faster. For example, from fiscal year 2002 to fiscal year 2010 the number of DEA registered DWPs increased from 1,451 to 19,211, an increase of about 1,300 percent. DWPs are physicians who dispense or prescribe Federal Food and Drug Administration approved buprenorphine products for treatment of narcotic addiction/dependence on an outpatient basis. In an effort to help meet the demand for this specialty, the Drug Addiction Treatment Act of 2000 waived the requirement for qualified physicians to obtain a separate DEA registration as a Narcotic Treatment Program in order to provide medication-assisted chemical substance therapy.[17] With the enactment of the act, the Substance Abuse and Mental Health Services Administration within HHS aggressively pursued training for interested physicians to help meet this demand. As a result, there was a significant increase in the number of physicians who registered with DEA as DWPs. In response to this growing registrant population, DEA increased the frequency of scheduled investigations of DWPs as part of the enhanced regulatory oversight called for by the acting Administrator. For example, in October 2008, DEA decided to move towards conducting regulatory investigations of all DWPs every 5 years to monitor for compliance. Previously DEA was conducting regulatory investigations of only one DWP in each of its 21 Field Divisions annually, a rate that, given the growth of that registrant type, would have taken decades for DEA to investigate all registered DWPs, according to the Executive Assistant to the Deputy Assistant Administrator for the Diversion Control Program. According to DEA's Chief of the Regulatory Section, the decision to increase the rate for conducting regulatory investigations of DWPs was also due, in part, to some DWPs not complying with regulatory requirements relating to recordkeeping and the loss of controlled substances used to treat patients.

[16] Pub. L. No. 106-310, tit. XXXV, 114 Stat. 1101, 1222-27 (2000).

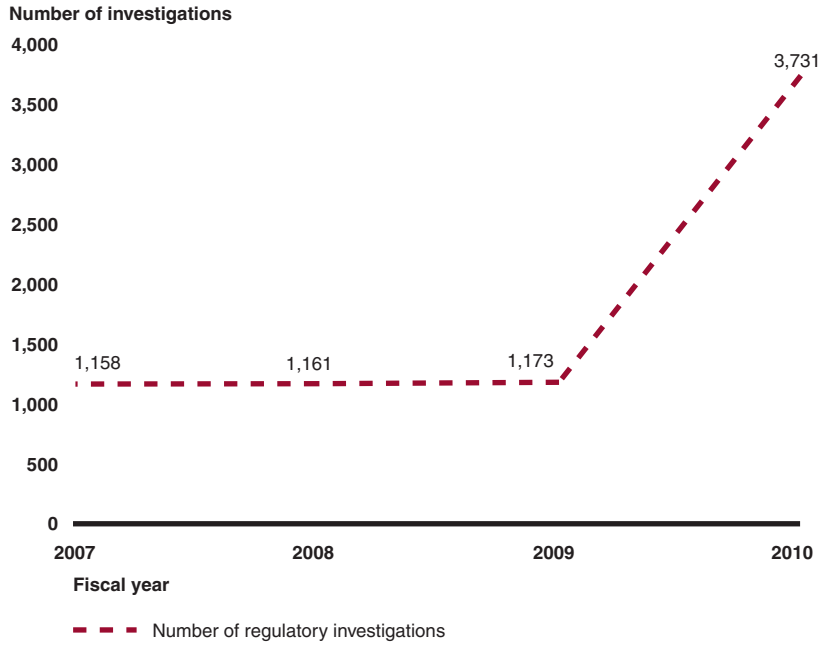
[17] 21 U.S.C. § 823(g).

DEA also increased the frequency of regulatory investigations for other registrant types as well, such as registrants involved in the manufacture and distribution of drugs (from once every 5 years to once every 3 years), and chemicals (from once every 3 years to once every 2 years).[18] For some registrant types that had not previously been subject to regulatory investigation, such as researchers, analytical labs, and teaching institutions, DEA required that regulatory investigations be conducted once every 5 years. According to DEA's Chief of the Regulatory Section, the increase in the frequency of regulatory investigations for some registrant types was also due to the registrants' noncompliance with the CSA and DEA's implementing regulations. For example, some distributors did not report suspicious orders for controlled substances to DEA, as required by regulation.[19] Reflecting the changes in requirements for regulatory investigations, DEA more than tripled the number of regulatory investigations from 1,173 in fiscal year 2009 to 3,731 in fiscal year 2010 (see fig. 2 below).

[18] These registrant types include manufacturers, bulk manufacturers, distributors, importers/exporters, and bulk importers.

[19] 21 C.F.R. § 1301.74(b).

Figure 2: Number of Regulatory Investigations Initiated by DEA Diversion Control, by Fiscal Year



Source: GAO analysis of DEA data.

According to the Executive Assistant to the Deputy Assistant Administrator for Diversion Control, DEA was able to increase its regulatory investigations primarily by using the squads to free up Diversion Investigator resources that had previously been working both criminal and regulatory cases and DEA plans to hire additional diversion staff in the future to conduct investigations. To keep up with the level of regulatory investigations to be completed in the future, DEA plans to hire additional staff. For example, for fiscal year 2011 DEA requested 60 Diversion Investigator positions and for fiscal year 2012 requested an additional 50 Diversion Investigator positions, pending completion of the revision of the schedule of fees charged registrants, which must provide the funding necessary to fill those positions.[20] According to DEA officials, of the 60 Diversion Investigator positions requested for fiscal year 2011, 23 were requested to support regulatory activities while 37 were to

[20] According to DEA officials, of the 60 Diversion Investigator positions requested for fiscal year 2011, as of May 2011, 34 positions have been allocated.

support the squads; for fiscal year 2012, of the 50 Diversion Investigator positions requested, 34 were for regulatory activities and 16 for support of the squads.

In addition to conducting regulatory investigations, DEA has also actively engaged registrants and their industry associations to help the registrants understand current trends in diversion and the regulatory obligations they must demonstrate that they have fulfilled during regulatory investigations. For example, DEA periodically hosts conferences for the chemical and pharmaceutical industries to share information on current trends, issues, federal laws, and regulations, and to discuss practices to prevent diversion. Industry associations reported that DEA also attends industry-sponsored conferences and shares useful information and guidance. In addition, regulated industry reported that DEA provides information to registrants on DEA's Web site as well as through policy letters and correspondence. According to DEA officials, they also speak at conferences such as the National Association of Boards of Pharmacy, the American Society of Interventional Pain Physicians, pharmacy schools, and other industry venues.

Furthermore, DEA has conducted other targeted outreach efforts to specific registrant types to inform them of specific regulatory responsibilities or help them prepare for regulatory investigations:

- In 2005 DEA established an initiative to better inform wholesale distributors of controlled substances of their responsibilities under the CSA to report suspicious orders from pharmacies that are possibly filling invalid prescriptions. As part of this initiative, DEA created a presentation explaining the laws, regulations, and DEA policies. The presentation provided examples of Internet pharmacies and rogue pain clinics as well as their purchase patterns and methods of operation. The presentation was designed to emphasize the need for wholesalers to utilize due diligence, and when appropriate, stop supplying retail outlets with controlled substances where diversion is occurring. From August 2005 through March 2011, DEA reported briefing 74 corporations concerning illegal Internet pharmacy operations and rogue pain clinics. Since the launch of the program, DEA reports that distributors have voluntarily stopped selling or restricted sales of controlled substances to approximately 1,390 customers believed to be placing suspicious orders for such substances.
- During 2009 and 2010, DEA's Office of Diversion Control officials met with a number of DWPs and industry associations that represent

DWPs to inform them about the regulatory investigation process and regulatory requirements. They discussed recordkeeping and the security of controlled substances, among other items, that DWPs must meet to comply with the CSA and its implementing regulations.

DEA's Internal Controls Help to Ensure the Quality of Investigations, but DEA Could Enhance Efforts to Measure Program Results

DEA helps to ensure the quality of its diversion control investigations through the use of internal controls, but could enhance its efforts to measure the results of its Diversion Control Program. To ensure that Diversion Investigators and Special Agents have the necessary skills to carry out their responsibilities and that DEA monitors the results of its employee guidance and training, DEA has established internal control activities, which are consistent with *Standards for Internal Control in the Federal Government*. DEA has established performance measures to assess and report on its progress toward meeting its performance goal of reducing the diversion of licit drugs, but could reassess the measures to identify ways to better capture and report on the results of DEA's investigations.

DEA's Efforts to Ensure Its Staff Have the Necessary Guidance, Training, and Oversight Are Consistent with Internal Control Standards

Diversion investigations are the primary means DEA uses to monitor registrant compliance with the CSA and to identify diversion activities. As such, it is important that the employees responsible for conducting investigations—Diversion Investigators and Special Agents—have the necessary skills to carry out their responsibilities and that DEA management monitors the results of its investigative efforts. To accomplish this, DEA has established internal control activities related to guidance, training, and monitoring. Given DEA's increased focus on regulatory and criminal investigations in response to growing and evolving diversion, these internal controls help to provide reasonable assurance that investigators and agents have the necessary skill levels to meet existing program requirements for diversion investigations and changing organizational priorities as new trends in diversion emerge.

DEA guidance and training provide investigators tools needed for investigations

DEA has established internal control activities related to guidance and training such as program policy and procedures manuals and diversion investigation courses. These efforts are consistent with *Standards for Internal Control in the Federal Government*, which state that agency management should help to ensure it has a workforce that has the required skills that match those necessary to achieve organizational goals. Specifically, DEA provides guidance in the form of manuals to its Diversion Investigators and Special Agents on the policies and procedures they are to follow in conducting diversion investigations. DEA

officials told us that they use this guidance for conducting diversion investigations and reviewing employee work products. The Diversion Investigator Manual describes and explains the policies and procedures for Diversion Investigators in carrying out their regulatory and investigative responsibilities, the processes for conducting diversion investigations, and the procedures for developing investigative reports. The Special Agent Manual describes and explains the responsibilities of Special Agents in diversion investigations.[21]

In order to familiarize employees with the process for conducting diversion investigations and related policies and procedures, DEA requires basic training for new employees and offers advanced and supplemental training courses to existing personnel within the Diversion Control Program to help them maintain the knowledge and skills necessary to conduct diversion investigations. Specifically, DEA's Office of Training provides a 12-week basic course to newly hired Diversion Investigator personnel, which includes techniques for diversion investigations among other relevant subjects, to help ensure that they have the required skills for performing investigator responsibilities.[22] The training is provided through a combination of in-classroom lessons and practical application; direct observation; and instructor-to-trainee feedback. Course trainees must maintain an 80 percent average on exams and simulated on-site investigations in order to pass the course and be certified as a Diversion Investigator. After the completion of basic training, the investigators enter into duty under a 1-year probationary period with a midpoint review provided after 6 months of duty. In addition, according to DEA officials we spoke with, group supervisors may go on-site with newly hired employees to help ensure that they are familiar with the requirements of investigations.

[21] DEA headquarters officials told us that they are in the process of revising the Diversion Investigator and Special Agent manuals to address new laws, regulations, and policies concerning the Diversion Control Program and that they anticipate completing revisions to the manuals by fall 2011.

[22] The Basic Diversion Investigator course is divided into five segments covering the following subject areas including: (1) an overview of diversion control, (2) techniques for diversion investigations, (3) the laws and regulations governing the Diversion Control Program, (4) an overview of chemical diversion control, and (5) criminal investigations. Within these segments, the training covers issues such as the policies and procedures for conducting different types of diversion investigations, documenting investigations, determining the appropriate sanctions to apply in cases of noncompliance, and processes for supervisory review of the work.

DEA also requires its Diversion Investigators to complete an advanced (or in-service refresher) training course every 2 years to help ensure their investigative skills and knowledge remain current. The advanced training course is a 1-week course that focuses on current legal issues in diversion, recent updates to DEA program policies and technology, investigative techniques, and any other new initiatives or programs that DEA has incorporated as part of the diversion control program within the previous 2 years. Officials in DEA's Office of Training told us that the topics that are covered during the advanced training course are identified through a biannual survey of Diversion Investigators and group supervisors to find out what issues they are facing in their work or what additional guidance is needed. DEA's efforts to help ensure Diversion Investigators maintain their investigative skills and are informed of new program initiatives and program policy changes are consistent with federal internal controls standards which state that training should be aimed at developing and retaining employee skill levels to meet changing organizational needs.

Beyond the required basic and advanced training courses, Diversion Investigators and supervisors may take additional courses in other relevant subject matter areas as time, resources, and needs permit. For example, officials in DEA's Office of Training told us that they offer specialized courses on specific issues related to diversion control investigations such as interviewing techniques, chemical investigations, techniques for financial investigations, and asset forfeiture, among others. Furthermore, the Diversion Control Program's field divisions may occasionally sponsor supplemental training for personnel that they determine would be beneficial. Typically, such training is shorter in duration and narrowly focused on topics such as report writing, interviewing techniques, or legal or investigative issues specific to that division.

Group supervisors of Diversion Investigators also receive supervisory training to help ensure that they have the requisite knowledge to perform their supervisory responsibilities, including those responsibilities related to reviewing the work of Diversion Investigators. Specifically, when first promoted, supervisors attend a supervisory institute to learn their new roles and responsibilities as supervisors as well as receive training in management and leadership techniques. Group supervisors also have electronic access to PowerPoint presentations, handouts, and administrative manuals to help guide them in carrying out these responsibilities once they return to duty. As with the Diversion

Investigators, supervisors also receive a 1-week advanced supervisor refresher course every 2 years.

Special Agents assigned to the Diversion Control Program are also provided training related to conducting criminal diversion investigations. The training for Special Agents includes a 1-week course to provide them with an in-depth understanding of criminal diversion investigations and includes instruction on methods of diversion, Internet investigations, and the investigative techniques to develop criminal investigations, among other issue areas related to diversion control.

Furthermore, DEA's Office of Diversion Control recently developed and implemented a new training curriculum designed to retrain and retool all Diversion Investigators. According to DEA officials, as the reorganization of the diversion program required Diversion Investigators to conduct more regulatory investigations than previously, the retraining was developed to refresh the investigators' skills and abilities for conducting the investigations. DEA officials reported that as of December 2010, all Diversion Investigators completed this training. These efforts are consistent with federal internal control standards which provide that training should help to retain employee skill levels in order to meet changes in organizational needs.

To assess the effectiveness of its training courses, officials in DEA's Office of Training stated that they obtain student feedback on a training course evaluation form at the conclusion of each training course. Additionally, DEA training officials review the curriculum for basic Diversion Investigator training every 3 years using feedback from students and input from a training working group comprised of Diversion Investigators and group supervisors to ensure that the material being presented is relevant and up to date. DEA officials also reported that the Office of Training is in constant communication with diversion management staff at headquarters and in the field to ensure that the training curriculums include updated policies relating to diversion operations.

DEA's monitoring process did not identify widespread or systematic problems with the quality of investigations

As DEA continues to enhance its diversion control efforts, it is important that it has controls in place to review the quality of its diversion investigations and to test the effectiveness of its review process in order to readily identify and resolve deficiencies related to its key compliance activity. Standards for internal control in the federal government provide that internal control monitoring should assess the quality of performance over time and ensure that findings of audits and other reviews are

promptly resolved. DEA's internal control monitoring activities collectively are consistent with these standards, which also state that internal controls should generally be designed to assure that ongoing monitoring occurs in the normal course of operations. Internal control monitoring includes regular management and supervisory activities among other activities and is performed continually. DEA has implemented a multilayered approach to monitor the work of its Diversion Control Program personnel to help ensure that they are following policies and procedures for diversion investigations. The monitoring process includes direct supervisory review, self-inspection/peer review, and on-site internal inspection. Additionally, DEA assesses the effectiveness of its monitoring process by reviewing the results of inspections conducted as a part of the overall program evaluation responsibilities of DEA's Office of Inspections (IN) and determining actions necessary for improvement and additional employee training needs. Furthermore, DEA's 2009-2014 Strategic Plan reflects that the agency plans to use the Office of Inspections to help ensure effective and efficient program oversight through its on-site inspections.

DEA field division supervisory officials reported that they directly review employee work products to assess the extent to which employees are following required policies and procedures for diversion investigations. Specifically, these supervisory officials review reports and active case files submitted by their employees for completeness, accuracy, and adherence to reporting procedures. If any discrepancies are found that need to be corrected, feedback is provided to employees as appropriate detailing what needs to be revised or clarified. Additionally, supervisory officials in three of the five field divisions we spoke with reported that they maintain regular communication to help ensure that employees are completing investigations in an accurate and timely manner. DEA officials also reported that group supervisors work with Diversion Investigators on-site when necessary to help advise them on the appropriate steps to take during an investigation. Whenever a case is being elevated for disciplinary action (civil or criminal), Division management presents a summary of the case to the program manager detailing the facts and rationale for the disciplinary action. Division management reviews the case summary and determines approval for further action (e.g., prosecution).

In addition to direct supervisory review of work products, DEA's Office of Inspections also has a Self-Inspection Program (SIP) in which DEA field divisions are required to conduct annual self-inspections of five major program areas: enforcement management; enforcement effectiveness; financial management; confidential source management; and evidence.

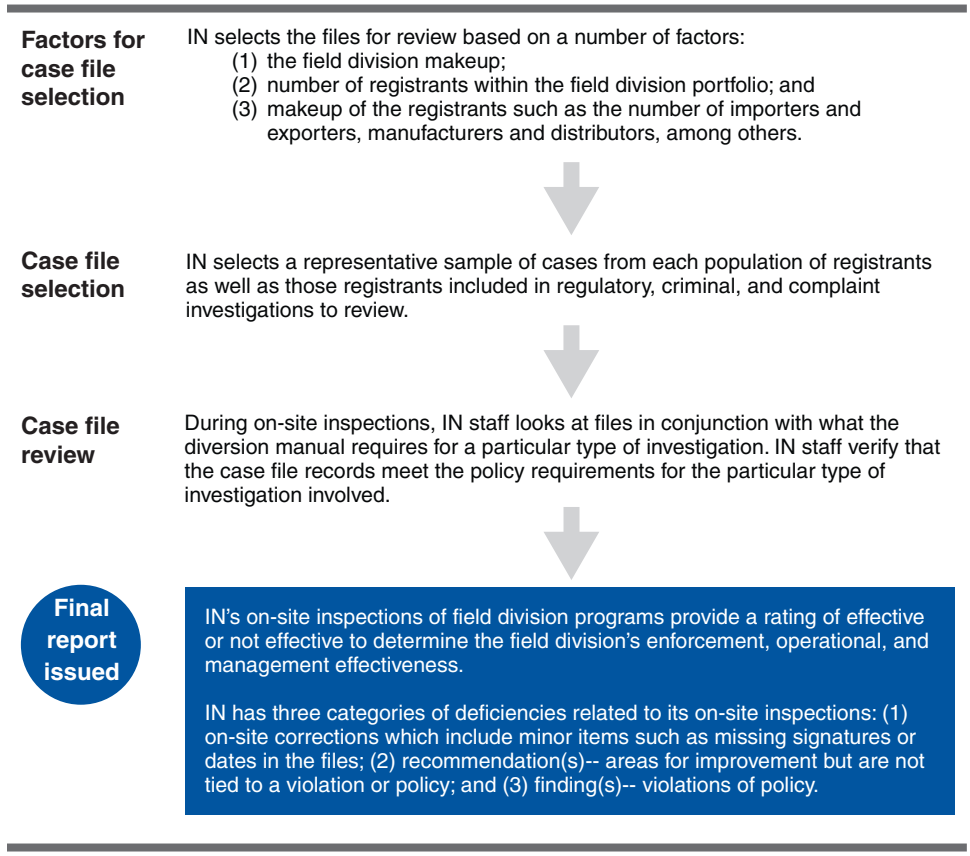
According to the DEA officials we spoke with, during the on-site inspection process, field division group supervisors inspect each others' group case files to determine if investigations were conducted in accordance with required policies and procedures. Supervisory officials in all five field divisions we spoke with stated that they conduct the self-inspections on an annual basis. The results of the self-inspection reports are reviewed by the Office of Inspections. According to DEA's 2009-2014 Strategic Plan, information related to the SIP is used as the starting point for the Office of Inspection's cyclic, on-site inspections.

The Chief of the Diversion Control Program's Regulatory Section reported that field division officials submit to headquarters for review a copy of the investigative reports for every regulatory investigation that has been conducted.[23] DEA officials then conduct a quality review of these reports which assists them in identifying deficiencies and determine the training needs of diversion personnel as they relate to completing regulatory investigations. The chief of the Diversion Control Program's Regulatory Section stated that if report errors are identified during the review process, officials in the Regulatory Section follow up with the respective field division to address the issue and submit supplemental report information.

The Office of Inspections also conducts on-site internal inspections of DEA's 21 field divisions to ensure that employees are following required program policies and procedures—in accordance with the Diversion Investigator manual. The office's primary objective for on-site inspections of the diversion control program is to determine how the diversion control work is being conducted by the field divisions and identify and address any problems. According to the Chief Inspector the Office of Inspections, it is the Office of Inspection's goal to conduct on-site inspections every 3 years as resources allow. See figure 3 for a description of the steps involved in the internal inspection report process:

[23] DEA's Regulatory Section (ODG) has oversight of regulatory matters under the Diversion Control Program (DCP) such as administrative or civil action taken against a registrant pursuant to the CSA and promulgated regulations. ODG also monitors field regulatory investigative activities such as periodic scheduled cyclic investigations, preregistration investigations, Order to Show Cause investigations, and drug theft/loss investigations, among other investigations.

Figure 3: Description of On-Site Internal Inspection Process



Source: DEA's Office of Inspections.

According to DEA officials, the Office of Inspections briefs headquarters-level management about the issues identified, and sends the report to the field division. For findings, the field division then has 60 days to provide a written response about the corrective actions that the field division has taken or plans to take. DEA officials also reported that they use internal inspections as an internal management tool to review their areas of responsibility. We reviewed DEA's most recent inspection reports available for each of its 21 field divisions which summarized the results of interviews with management and staff, reviews of program operations,

and case files reviews for policy compliance, among other items.[24] We found that the inspections did not identify widespread findings or issues related to the timeliness and overall quality of the diversion investigations.

DEA Could Better Identify and Report on the Results of Its Diversion Control Efforts

Given DEA's increased focus on regulatory and criminal investigations in response to growing prescription drug diversion, it is critical for DEA to determine and report on the extent to which these additional efforts are helping to reduce diversion. In this regard, DEA has established performance measures to assess and report on its progress towards meeting its performance goal of reducing the diversion of licit drugs, but could enhance its set of performance measures to better capture and report on investigative outcomes and their results on diversion. We have previously reported that performance information can be used to help decide among competing priorities and allocate resources in a results-oriented management system.[25] Such performance information allows program managers to compare their programs' results with goals and thus help determine where to target resources to improve performance. In addition, one of the key characteristics of successful hierarchies of performance measures is the ability of the measures to demonstrate how well a program is achieving its goals.[26] As shown in table 2, DEA has developed five measures to track and publicly report the progress and results of its efforts in reducing the diversion of licit drugs.

[24] The most recent reports available ranged in issue date from fiscal year 2005 to 2010.

[25] GAO/GGD-96-118; GAO, *Results-Oriented Government: Using GPRA to Address 21st Century Challenges,* GAO-03-1166T (Washington, D.C.: Sept. 18, 2003); GAO*, Results-Oriented Budget Practices in Federal Agencies,* GAO-01-1084SP (Washington, D.C.: August 2001); and GAO*, Human Capital: Key Principles for Effective Strategic Workforce Planning,* GAO-04-39 (Washington, D.C.: December 2003).

[26] As we discussed in our June 1996 guide on implementing the Government Performance and Results Act, we studied a number of leading public sector organizations that were pursuing management reform initiatives and becoming more results-oriented. As part of these initiatives we found leading organizations seek to establish clear hierarchies of performance goals and measures, linking the goals and performance measures for each organizational level to successive levels and ultimately to the organization's strategic goals. Based on this study of leading public sector organizations, we found that at least four characteristics are common to successful hierarchies of performance measures: (1) Demonstrate results; (2) Limited to the vital few; (3) Respond to multiple priorities; and (4) Link to responsible programs. As our focus of this review was on how DEA determines the results of its efforts against the diversion problem, we limited our analysis of DEA's performance measures to the characteristic of "Demonstrate results."

Table 2: Performance Measures for DEA's Diversion Control Program

Milestones for development, implementation, and maintenance of the Rapid Targeting Online Reports Tool (RapTOR)
Number of Diversion Priority Target Organizations (PTOs) [a] not linked to Consolidated Priority Organization Target (CPOT)[b] targets disrupted/dismantled [c]
Number of Diversion PTOs linked to CPOT targets disrupted/dismantled
Number of planned scheduled regulatory investigations completed
Number of Administrative/Civil/Criminal Sanctions

Source: DEA.

Notes:

[a] Priority Target Organizations are defined as drug trafficking organizations with an identified hierarchy engaged in the highest levels of drug trafficking and/or drug money laundering operations, having a significant international, national, regional, or local impact upon drug availability. According to DEA, the disruption or dismantlement of the organization will have a significant impact upon drug trafficking and/or money laundering activities and warrant the dedication of significant resources to achieve this end.

[b] Consolidated Priority Organization Targets (CPOTs) are defined as the command and control element of a major international drug trafficking organization and/or money laundering enterprise that significantly impacts the U.S. drug supply as identified by Organized Crime Drug Enforcement Task Forces member agencies. An organization is considered "linked" to a CPOT, if credible evidence exists of a nexus between the primary target of the investigation and a CPOT target. With the nature of the Diversion program, linkages to these international drug trafficking and money laundering organizations are a rare event.

[c] According to DEA, a disruption is defined as significantly impeding the normal and effective operation of a targeted organization, as indicated by changes in organizational leadership, trafficking patterns, drug production methods, etc. Examples of this may be seen in changes in price/purity of the drug or changes in methods of operation; increases in fees paid to couriers or transporters; movement of the organization to a neighboring district; and/or a reduction in availability of a drug on the streets, even if only temporarily. Dismantlement is defined as destroying the organization's leadership, financial base, and drug supply network such that the organization is incapable of operating and/or reconstituting itself.

According to DEA program officials, these measures were selected as a result of a performance measure review by the Department of Justice (DOJ) in 2009. For this review, DOJ asked all of its components to reexamine their performance measures to identify and discontinue performance measures that were confusing or did not adequately reflect the core mission. In place of such measures, DOJ asked the components to develop five core measures that are easy to understand and explain what is being accomplished with the resources expended. Our analysis of the measures found that while some indicate results, such as the number of organizations disrupted or dismantled that were involved in diverting prescription drugs, when taken together, the set of measures does not clearly demonstrate to what extent the additional efforts DEA has made in investigations in recent years are having an effect on the diversion problem. As a result, the set of measures do not clearly explain how they demonstrate progress towards the overall program performance goal of

reducing diversion. DEA program officials acknowledged that these measures do not fully reflect the results of the program towards the reduction of diversion and as a result, they do not rely on them exclusively for managing the program or determining where best to allocate program resources. They stated that for the purposes of internal program planning and management, they have access to and utilize other data and measures not reported, or can pull up additional information on investigative results that provide more detail on what the program is achieving towards the reduction of diversion.

Overall outcome measure does not demonstrate program results

DEA has designated an overall outcome measure to track the results of the diversion control program as a whole; however, this measure does not demonstrate program results.[27] This measure—Milestones for Development, Implementation, and Maintenance of Data Warehouse to Monitor Closed Distribution System—tracks the development of an information warehouse system DEA is developing for use in diversion investigations. According to DEA officials, when completed, this warehouse—known as the Rapid Targeting Online Reports Tool (RapTOR)—will facilitate data and trends analysis as part of diversion investigations. DEA officials explained that RapTOR is intended to streamline the investigation process by providing a comprehensive data warehouse tool that is linked to other DEA databases such as ARCOS, the drug theft/loss reporting system, and a system that tracks the number of asset forfeitures, arrests, and other enforcement data.

While the RapTOR appears to hold promise as a useful tool in diversion investigations, tracking the milestones of its development as the outcome measure for the overall diversion program does not demonstrate results or capture outcomes from the program as a whole as it is only one project within the program. According to OMB guidance to agencies on preparing strategic plans and performance reports, outcome measures are to describe the intended result of carrying out a program and define an event or condition that is external to the program and is of direct importance to the intended beneficiaries or the public.[28] While tracking milestones for the RapTOR's deployment may be useful as project-

[27] Performance measures may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). See GAO-11-646SP.

[28] OMB Circular A-11 PART 6 Section 200.4, July 2010.

specific outcome measures, due to their focused nature they do not provide information on results of the diversion control program as a whole. For instance, reporting on RapTOR's testing and deployment status does not provide program management or other decision makers such as Congress information to indicate the results of DEA's regulatory and criminal investigations are having towards the reduction of diversion of licit drugs, the program's performance goal. Development of an outcome measure that more directly demonstrates the external results of the overall program could provide better information to DEA program managers and other decision makers such as Congress about program successes which could also help determine how to most effectively use resources. According to DEA's fiscal year 2012 budget submission, the RapTOR will allow for the development of an outcome measure. When asked if they planned to develop an outcome measure to replace the RapTOR, DEA officials indicated that until RapTOR is fully developed and implemented, it would be too soon to tell when a replacement outcome measure would be necessary. Furthermore, DEA officials could not explain how they use the RapTOR measure to show overall program results or outcomes or how it will be used to develop a measure that reports such results or outcomes.

Performance measures tracking investigations of priority targets demonstrate results

Two of DEA's performance measures track results DEA has achieved through criminal investigations of priority targets. In April 2001, DEA implemented the Priority Target Organization (PTO) program as a strategic initiative to identify, target, investigate, and disrupt or dismantle drug trafficking and/or money laundering organizations having a significant impact on drug availability within the United States. Although the Diversion Control Program was not officially part of the DEA's Priority Targeting Program prior to fiscal year 2010, with the creation of Tactical Diversion Squads in every domestic DEA field division, the Diversion Control Program has since begun focusing on the identification of PTOs and their eventual disruption and dismantlement.

DEA has two separate measures to track the number of PTOs disrupted and dismantled—one for those with identified links to Consolidated Priority Organization Targets (CPOTs) and another for those without links to CPOTs. As a participant in the PTO program, the Diversion Control Program is required to report on these performance measures. Whereas PTOs are organizations with an identified hierarchy engaged in drug trafficking or drug money laundering operations, CPOTs are the command and control elements of a major international drug trafficking organization and/or money laundering enterprise that significantly impacts the U.S. drug supply. An example of a diversion PTO cited by DEA

officials was a practitioner who prescribed large quantities of controlled substance pharmaceuticals for nonmedical purposes to "patients" from at least five different states. DEA officials stated examples of CPOTs involved in diversion include international chemical distributors that traffic in chemicals used to manufacture methamphetamine while other CPOTs traffic in pharmaceuticals or counterfeit pharmaceuticals.

Specifically, these measures report the extent to which DEA disrupted (disrupt) or stopped (dismantle) the operations of PTOs and these organizations' ability to divert controlled substances, which helps to reduce the diversion of licit drugs, the program's overall performance goal.[29] For example in fiscal year 2010, DEA reported that it disrupted one PTO with linkages to a CPOT and dismantled one PTO with CPOT linkages. For PTOs without linkages to a CPOT, DEA reported disrupting 96 and dismantling 65 in fiscal year 2010. According to DEA officials, the PTO-related measures are useful in helping the program to focus criminal investigations on those priority targets against which they are likely to have the greatest impact on the diversion of licit drugs.

Other performance measures do not clearly demonstrate results of regulatory investigations

While DEA has some performance measures to demonstrate the results of its criminal investigations, it lacks measures that clearly track resulting outcomes DEA has achieved through its additional regulatory investigations. For example, DEA has a measure that provides a numerical count of the scheduled or regulatory investigations completed. According to DEA's Fiscal Year 2009-2014 Strategic Plan, one of the objectives for the diversion control program is to ensure 98 percent compliance of all registrants by fiscal year 2014. However, while the performance measure is focused on the regulatory investigations and provides a count of the number of investigations completed, this measure does not demonstrate the results of those completed investigations or give a sense as to the extent to which registrants were found to comply with the CSA and thereby the extent to which DEA is achieving its stated objective. According to DEA officials, while they previously reported on the compliance rate of a subset of wholesale registrants as the program's outcome measure, the reexamination of program performance measures

[29] Under disruptions, registrants usually retain the DEA Registration with restrictions and/or financial penalty. Registrants may also be temporarily denied access to controlled substances/chemicals. Under dismantlements, registrants lose or forfeit their DEA Registration or are convicted of a drug felony. Registrants are permanently denied access to controlled substances/chemicals pending a reversal of circumstances.

in 2009 resulted in discontinuing use of the measure. DEA officials stated that because the compliance level among registrants tends to be very high in general, the values of the measure did not significantly change from year to year. Consequently, they stated, the measure did not provide a meaningful gauge of the results regulatory investigations were having. However, DEA data reported before it discontinued use of this measure showed that the compliance rate, while always relatively high, fluctuated between 88.5 percent to as high as 97.7 percent between fiscal years 2003 and 2008. Further, as stated in DEA's strategic plan, one of the key objectives of the program is to ensure a certain level of compliance among registrants.[30] Without the reporting of a measure that directly tracks a level of compliance among registrants, the public and other external stakeholders such as Congress will not be able to determine the extent to which DEA is achieving that specific objective. In addition, given that DEA more than tripled the number of regulatory investigations conducted from fiscal year 2009 to fiscal year 2010 including investigations of previously excluded registrant groups as well as increasing the frequency of investigations for a rapidly growing DWP registrant group—it will be important for DEA to be able to assess and report on the potential results these additional investigations are having on regulatory compliance.

In addition, the other performance measure reports on the number of sanctions DEA has taken against diverters or noncompliant registrants over the past year. As such, it is one indicator of the results of DEA investigations. However, as it is a count of the sanctions, it only demonstrates the number of sanctions taken, but does not provide context as to the severity of the sanctions or the reason for the sanctions. For example, administrative sanctions resulting from deficiencies in a registrant's recordkeeping found during regulatory inspections may reflect a lack of compliance with the CSA but not necessarily instances of actual diversion. In contrast, criminal sanctions, such as prison time given to an individual or registrant for diversion of controlled substances, reflect sanctions taken against actual diversion that has occurred and identified during a criminal investigation. Because the sanctions are tallied together for the performance measure, it is difficult to determine to what extent

[30] DEA's Fiscal Year 2009-2014 Strategic Plan states that a 6-year objective for the program is to "ensure CSA compliance among 98 percent of all registrants by the end of fiscal year 2014."

they have resulted from regulatory noncompliance issues or instances of criminal diversion.

Another difficulty with combining the total number of administrative, civil, and criminal sanctions in one total is that changes in the number of the respective type of penalties mean different things in terms of what they indicate about the potential risk for diversion. For example, an increase in the number of criminal sanctions resulting from DEA's criminal investigations indicates that individuals or PTOs involved in diversion have been disrupted or dismantled, reducing the potential risk for future diversionary activities, and is therefore a desirable change. However, an increase in the number of administrative sanctions resulting from regulatory investigations could indicate a trend of rising noncompliance among registrants, which is an undesirable change as it implies that DEA's outreach efforts with industry may not have been effective and the potential risk for diversion is higher as a result of registrants' noncompliance. As a result, this measure does not provide a clear indication as to the effect DEA's investigative efforts are having on the problem of diversion. By tracking sanctions resulting from regulatory noncompliance combined with sanctions resulting from criminal diversion, program managers and other decision makers may lack information on what type of noncompliance is increasing and be able to determine what adjustments to the program's efforts, if any, might be necessary to address the root causes of increases in the number of sanctions.

DEA officials acknowledged that this measure by itself is not detailed enough to provide that information. However, they stated they supplement the measure for internal program planning and management functions by conducting analyses that separate out the different types of sanctions and provide more meaningful data on the sanctions to identify diversion trends, determine the results of their efforts, and inform future program plans and policy decisions. Officials also noted that providing a single count of sanctions without breaking them out helped simplify the measure and meet DOJ's goal of limiting the number of overall performance measures to five. While this may be more manageable for the purpose of providing performance information, the measure does not clearly tie to outcomes and demonstrate program performance—a key goal of DOJ's performance measure reexamination effort—and does not provide sufficiently meaningful information and data to external stakeholders and policy makers such as Congress about the types of sanctions DEA has taken as a result of both regulatory and criminal investigations.

Conclusions

The growing problem of controlled substance diversion presents a serious and constantly evolving threat to public health and safety. In responding to this threat, DEA faces a unique challenge in being proactive to investigate and stop the diversion of controlled prescription drugs and substances, while at the same time, ensure that individuals with legitimate needs and uses for such substances can obtain them. In recent years, DEA has taken steps to adjust its approach to increase its efforts in conducting regulatory and criminal investigations to facilitate registrant compliance with the CSA and enhance coordination and leverage the resources and abilities of other federal, state, and local partners when conducting investigations into criminal diversion. Given the steps DEA has taken, it is important for DEA management to track the results its efforts are having against diversion in order to determine what benefits are being realized and what, if any, adjustments need to be made to make them more effective.

DEA has established a set of performance measures for the program, but the link between most of the measures and how they demonstrate the progress DEA is making towards the overall goal of reducing diversion is unclear. Making more meaningful information available externally about the program's results would enable program managers and external stakeholders to better understand what the program is accomplishing and provide more effective oversight. By developing an outcome measure that demonstrates programwide results of benefit to the public and revising other performance measures to better track and report on the results of investigations and their results on reducing diversion of prescription drugs, DEA could make the measures more effective for demonstrating results. Doing so could also provide DEA program managers and other decision makers such as Congress better information to target program approaches accordingly to further optimize results against diversion.

Recommendation for Executive Action

In order for DEA to better determine to what extent its efforts are decreasing diversions and to inform future program decisions, we recommend that the Administrator of DEA strengthen the agency's performance measurement for the Diversion Control Program by reassessing its set of performance measures for the program to identify ways to enhance the measures and their link to the program outcome goal of reducing diversion.

Agency Comments and Our Evaluation

We requested comments on a draft of this report from DOJ. DEA provided written comments, which are summarized below and reprinted in full in appendix I. In its comments, DEA stated it would take action to address the recommendation to strengthen its set of performance measures for the Diversion Control Program but that it disagreed with the finding that its performance measures do not adequately measure how its efforts reduce diversion or that such deficiencies impede resource allocation decisions. In an e-mail received on August 4, 2011, the Acting Assistant Director of DOJ's Audit Liaison Group clarified DEA's position stating that DEA did not concur with the recommendation.

In its comment letter and attachment, DEA stated that the report demonstrated that its management is appropriately directing its resources towards key points of diversion and confirms that DEA has been successful in accomplishing its objectives. DEA reiterated that performance measures must be viewed within the context of other information to assess the results that DEA efforts have on public health and safety as well as the reduction of diversion. To this end, DEA stated that its leadership provides policy makers and legislators information though a variety of other sources such as budget requests, intelligence reports, briefings, and testimonies. They also noted that the majority of such information presented to policy makers is based on investigative data and intelligence which is broader in scope than performance measures. In regards to developing or implementing measures to track regulatory performance, DEA stated that further strengthening the current performance measures to include regulatory performance measures would not provide any additional benefit in assisting the agency or other decision makers in the allocation of resources or targeting of program approaches to further optimize results. DEA stated that it would be extremely difficult to do so because the vast majority of registrant inspections do not uncover serious violations of the CSA and thus a very small number of registrants are subject to sanctions during the annual inspection cycle. Further, DEA stated that the deterrent effect of regulatory investigations cannot be quantified making it impossible to measure the lack of diversion resulting from DEA's efforts.

As the report indicates, we recognize that DEA has taken steps to allocate resources and position the program to respond to emerging diversion trends. However, the report does not state that DEA management has appropriately directed its resources or confirm that DEA has been successful in accomplishing its objectives. The review on which this report is based describes how DEA manages its investigations to address the growing and evolving nature of diversion and did not evaluate

those actions for their efficiency or effectiveness as implied by DEA. At the same time, as our evidence did not suggest that DEA's use of current performance measures has directly impeded its resource allocation decisions to date, we made changes to the report to minimize any inference of such a finding. Moreover, the fact that a program may appear well managed on the basis of anecdotal and qualitative evidence does not negate the need or obligation for an agency to develop and use performance measures that hold it accountable for determining, articulating, and reporting what a program is accomplishing.

As performance measurement is a key part of an agency being results-oriented, that is, tracking and being held accountable for the results or outcomes an agency produces through its programs, our recommendation is intended to ensure that the program's performance measures meet the standards for performance measures established by DOJ and OMB and are the best measures possible to demonstrate and report the program's results to program management, other external decision makers such as Congress, as well as the public. We agree that program managers and decision makers can and should use other relevant program information in addition to performance measures when allocating resources and making program decisions. However, this also does not negate the need or obligation for an agency to develop and use performance measures that meet the standards established by DOJ and OMB. On the basis of our evaluation of the program's performance measures against the guidance and criteria for performance measures provided by DOJ and OMB, as well as our previous work on performance measurement, we believe that further refinements to the program's performance measures are merited and have the potential to help make the measures provide more useful information on the achievements of the program.

Because many outside parties, such as industry members and the American public, may not have access to other contextual information DEA may provide policy makers and legislators, refinement of the current set of program performance measures could enable DEA to better assess and externally report on the results of the program in a more meaningful and understandable way. As DOJ guidance to component agencies suggests, performance measures should clearly articulate what an agency is accomplishing with the resources used in language outsiders can understand. Some of the key measures DEA is using do not meet this standard. For example, according to DEA, tracking the milestones for the development, implementation, and maintenance of the program's Rapid Targeting Online Reports Tool (RapTOR) was chosen as the

program's outcome measure so that managers could monitor the development and implementation of the system to ensure it was done in a timely and cost-efficient manner. While we agree that project schedule and cost should be closely monitored, this measure does not articulate to outsiders what the program is accomplishing as called for by DOJ's guidance for performance measures. Further, given that the RapTOR is an internal data warehouse tool DEA is developing, the reporting of milestones for the development, implementation, and maintenance of the tool does not provide an overall indicator of success for DEA's diversion program or its stated goal of reducing the diversion of licit drugs. As a result, it also does not meet OMB's criteria that requires outcome measures to describe or capture an event or condition external to the program that is of importance to the public. Indeed, DEA program officials could not describe how they use this measure more broadly beyond tracking the progress of the project itself.

In regards to developing or implementing a performance measure to track the impact of the regulatory inspection process, we disagree with DEA that including a regulatory performance measure would not provide any additional benefit. DEA stated that it would be extremely difficult to develop such a measure because the vast majority of registrant inspections do not uncover serious violations and thus sanctions are taken against a very small number of registrants. While this may be the case, reporting the number of administrative, civil, and criminal sanctions taken as a single count as DEA currently does, does not provide perspective as to how many sanctions are a result of regulatory infractions and how many are a result of criminal infractions. Also, as DEA points out, the severity of sanctions and their impacts can vary greatly ranging from requiring on-site corrections by a registrant for minor infractions to DEA pursuing legal sanctions against a registrant which could have a profound effect on the wider registrant population as a whole. Given the differences between regulatory sanctions and criminal sanctions and the potential severity of different sanction types, we continue to believe it would be useful for DEA to develop a measure that separately tracks the results of regulatory investigations or the number and severity of regulatory sanctions taken for identified infractions. With such a measurement, more information would be available to program managers, other decision makers, and the public on what type of noncompliance, if any, is increasing and thereby decision makers would be better able to determine what adjustments to the program's efforts, if any, might be necessary to address the causes of increases in the number of sanctions.

In terms of tracking the lack of diversion or similarly, the reduction in diversion resulting from DEA's efforts, DEA stated that it would be impossible to measure. However, given that one of the key program objectives DEA identified in its strategic plan is ensuring a level of compliance with the CSA among DEA registrants, whose compliance in turn directly maintains the closed system of distribution established by the CSA, it is important that DEA have a performance measure that directly links to this objective. We and OMB have acknowledged the difficulty in developing measures for programs that aim to deter or prevent specific behaviors, and have reported that in such instances proxy measures should be designed to assess the effectiveness of program functions. Proxy measures can be used to assess the effectiveness of program functions rather than directly assess the effectiveness of the program. In this regard, one possible approach DEA could use is to develop a proxy measure that tracks the compliance rate of wholesale registrants based on the results of regulatory investigations completed that year. Also, OMB has pointed out, it may be necessary to have a number of proxy measures to help ensure sufficient safeguards are in place to account for performance results.

Given the significant and growing problem of the diversion and abuse of pharmaceutical-controlled substances in the United States, having a set of performance measures that clearly conveys the accomplishments of the Diversion Control program is perhaps even more important now. By reassessing the program's current performance measures and making changes where necessary to the measures, DEA will be in a better position to provide enhanced information to program managers, other decision makers such as Congress, and the public on the extent to which the program is achieving its stated longer range performance goal of reducing diversion.

DEA also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from its issue date. At that time, we will send copies of this report to interested congressional committees, the Attorney General, the Administrator of the DEA, and other interested parties. In addition, the report will be made available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions concerning this report or wish to discuss the matter further, please contact me at (202) 512-8777, or larencee@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix II.

Eileen Regen Larence
Director, Homeland Security and Justice Issues

Appendix I: Comments from the Drug Enforcement Administration

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov Springfield, Virginia 22152

JUL 2 8 2011

Eileen Larence, Director
Homeland Security and Justice Issues
441 G Street, N.W.
Washington, D.C. 20548

Subject: GAO Draft Report *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, But Could Better Assess Efforts* (GAO-11-744)

Dear Ms. Larence:

On July 1, 2011, the Government Accountability Office (GAO) provided the draft report *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, But Could Better Assess Efforts* (GAO-11-744) to the Department of Justice (DOJ) and the Drug Enforcement Administration (DEA) for official agency review and comment.

DEA is pleased with GAO's overall positive review of the Diversion Control Program and its acknowledgement of the many efforts the agency has taken on both the criminal and regulatory aspects of controlling the diversion of pharmaceuticals and listed chemicals. The GAO report describes many of the extensive actions DEA has taken to address the escalating problem of the diversion of prescription drugs. The GAO report highlights some of DEA's recent accomplishments such as *Operation Pill Nation* which is designed to address the plethora of rogue pain clinics in south Florida.

The report contains one Recommendation for Executive Action:

> In order for DEA to better determine to what extent its efforts are decreasing diversions and to inform future program and investments decisions, we recommend that the Administrator of DEA strengthen the agency's performance measurement for the Diversion Control Program by reassessing its set of performance measures for the program to identify ways to enhance the measures and their link to the program outcome goal of reducing diversion.

DEA disagrees with the assertion that DEA does not adequately measure how its efforts reduce diversion, or that such deficiencies impede resource allocation decisions.

Reducing prescription drug abuse requires a multi-faceted approach which includes education, treatment, and enforcement. With respect to the latter, the performance measures used by DEA to track disruptions and dismantlements of Diversion PTO investigations and administrative, civil, and criminal sanctions represent more than just numbers.

As outlined in the attached detailed response, the specter of increased scheduled regulatory investigations and proactive educational efforts have a deterrent effect that cannot be measured by raw data; it is impossible to measure the *lack* of diversion. These actions help prevent future diversion as well as maintain the closed system of distribution established by Congress through the Controlled Substances Act.

In addition, our investigations expose or identify new and evolving trends in diversion which demand tailored, multi-faceted responses. Diversion trends may require new or innovative investigative methods or the re-allocation of resources. For example, a reorganization of the Office of Diversion Control expanded the use of Tactical Diversion Squads in order to raise the stakes for criminal activities at all levels of diversion, and increased administrative oversight in order to emphasize compliance, educate registrants, and reinforce the deterrent effect of regulatory investigations. This reorganization was prompted by the rising tide of prescription drug abuse. Other diversion trends may identify the need for new legislation to keep pace with emerging technologies such as the Ryan Haight Act, or regulations that authorize electronic prescribing for controlled substances and disposal opportunities for members of the public. Yet other trends may call for new training or equipment as was the case with rogue Internet pharmacies.

The GAO report clearly demonstrates that management is appropriately directing its resources towards key points of diversion and towards those individuals or organizations directly responsible for large-scale diversion. Consequently, the direct and indirect outcomes from our performance measures are very apparent. They are a means by which the Agency sets priorities, directs resources, identifies new trends, formulates budgets, works with other agencies to develop national strategies, educates the public and industry, develops training curriculum, and provides Congress with technical assistance towards new legislation. The investigations conducted by DEA help reduce the supply of drugs diverted and the ways in which drug seekers/addicts acquire their drugs that might not otherwise occur in the absence of such investigations. But more importantly, these investigations and administrative actions help reduce diversion and the negative impact drug diversion has on families, the local community, the medical community, the economy, and overall public health and safety.

DEA will follow up with GAO on a course of action to address the recommendation included in the report. DEA will continue to work closely with DOJ and the Office of National Drug Control Policy to improve its performance measures consistent with the National Drug Control Strategy. DEA is also committed to providing Members of Congress with information on the agency's efforts or information on diversion as needed.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

DEA's Response to GAO's Report (GAO-11-744):
Prescription Drug Control DEA Has Enhanced Efforts to Combat Diversion, But Could Better Assess Results to Inform Investments

The Drug Enforcement Administration (DEA) appreciates the opportunity to respond to GAO's report cited above.

Performance measures provide a structure for an agency to become results-oriented. This is done through a process of identifying and eliminating fragmentation, improving the strategic planning process and ensuring sound fiscal responsibility. This is precisely what the GAO found after their 14-month long investigation of the DEA Diversion Control Program.

GAO stated in their report that in addressing the increase in illegal diversion of controlled substance pharmaceuticals, DEA has expanded its resources by combining separate and sometimes disparate Federal, state and local information, authorities, and enforcement programs. GAO noted in their report that in doing so, DEA has maximized resources, improved investigative efforts, improved communication and coordination, and simplified information sharing. The GAO report also documented how DEA has increased the frequency of regulatory investigations by more than three-fold between fiscal years 2009 and 2010. GAO also pointed to the fact that DEA has established internal controls that ensure investigators follow policies and procedures when conducting diversion investigations. Furthermore, "[t]hese efforts are consistent with *Standards for Control in the Federal Government,* which states that agency management should help to ensure it has a workforce that has the required skills that match those necessary to achieve organizational goals."[1] GAO investigators also reviewed DEA's internal inspection reports and stated that they did not find any systemic issues relating "to the timeliness and overall quality of diversion investigations."[2]

From their extensive investigation, GAO determined that DEA's use and expansion of Tactical Diversion Squads, "…has been a means to improve communication and coordination and simplify information sharing as the squads have become the clearinghouse for diversion-related investigative information."[3] GAO acknowledged that the Tactical Diversion Squads have vastly improved law enforcement's ability to investigate diversion cases. Specifically, GAO stated, "…participating in the squad has enabled local law enforcement agencies to carry out more complex investigations into diversion within their localities" and "…prior to the establishment of squads, they did not have the resources on their own to carry out the longer, more complex investigations required for targeting higher level diverters such as physicians and their clinics."[4] "The squads provided a means for state and local law enforcement to collectively pool their resources together with DEA to investigate higher level diverters."[5] "As a result, information is now shared more rapidly and broadly between law enforcement agencies."[6] These

[1] GAO report p. 24.
[2] GAO report p. 30.
[3] GAO report p. 16,
[4] GAO report p. 16.
[5] GAO report pp. 15 & 16.
[6] GAO report p. 16

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investigations are designed to ensure that registrants comply with all aspects of the Controlled Substances Act (CSA) and its accompanying regulations thereby reducing diversion.

The GAO report, however, represents a dichotomy. The report is replete with details explaining how DEA's Office of Diversion Control has set priorities, improved the allocation of its resources in an efficient and effective manner, and joined together fragmented systems. Their report further provides examples that clearly demonstrate successful results from these actions. But after laying out all of this information, GAO contradicts itself by stating "performance information can be used to help decide among competing priorities and allocate resources in a results-oriented management system." They further state that, "DEA could better identify and report on the results of its diversion control efforts." However, DEA's performance measures are used effectively by the agency to set priorities, direct limited resources, identify new trends, formulate budgets, work efficiently and effectively with other agencies, help develop national strategies, educate the public and industry, develop training curriculum, and provide Congress with technical assistance towards new legislation.

DEA representatives advised GAO investigators that DEA's performance measures are not myopically focused solely on raw statistics. Diversion investigations are aimed at reducing and stopping the flow of controlled substances and listed chemicals into the illicit market. These investigations do not benefit from purely numerical performance measures. Accordingly, DEA's performance measures align themselves with the goals and objectives of the Administration's National Drug Control Strategy, DEA's Strategic Plan, and DEA's statutory obligations. More importantly, these performance measures must be viewed in their entirety to assess the full impact or results they have on public health and safety as well as the reduction in the diversion of controlled substances and listed chemicals. In fact, decision-makers, members of Congress and the general public do not use performance measures in isolation. Statistical performance measures are but one component in the decision-making process. They are linked to budget requests, strategic plans, investigative reports, and other types of information that help make educated decisions and improve performance.

DEA representatives explained to the GAO investigators that the effect its investigations and regulatory oversight has on the diversion problem is attained through a variety of information that is a direct result of its performance measures. DEA investigations stop those who are diverting controlled substance pharmaceuticals and prevent them from future diversion of these substances.

- To illustrate this point, in 2007, the Office of Diversion Control initiated *Operation Lightning Strike* which resulted in the service of Immediate Suspension Orders (ISOs) on eight rogue pharmacies that were illegally distributing controlled pharmaceuticals via the Internet. This operation resulted in the seizure of 907,328 dosage units of hydrocodone and enough bulk hydrocodone to yield an additional 600,000 dosage units. Two other pharmacies voluntarily terminated their DEA registrations. In 2006, these ten pharmacies had collectively purchased 45 million dosage units of hydrocodone which was 64 times the amount ten legitimate pharmacies would normally dispense during a one-year period.

As traffickers adapt to new laws or exploit advancements in technology, DEA must also adapt. Today, the problem of rogue domestic Internet pharmacies has virtually disappeared due to the passage of the Ryan Haight Act, which placed severe restrictions on how DEA registrants can prescribe and dispense controlled substances via the Internet. Traffickers immediately adapted, and rogue pain clinics (RPLs) began to flourish throughout Florida, Texas and California. RPLs operate under the guise of providing "pain management" or "medical treatment" but in reality are just storefronts for drug trafficking. The prescriptions issued and pharmaceuticals dispensed are not prescribed for a legitimate medical purpose and the physicians, health practitioners and clinic owners are feeding the addictions of thousands of drug seekers by diverting millions of dosage units of controlled substances that inevitably enter the illicit marketplace.

The damage caused by these operations is staggering. The Florida Medical Examiner's Office has reported a 248% increase between 2005 and 2009 in the number of overdose deaths associated with oxycodone, the primary drug distributed via the pill mills. This data further shows an average of 3.2 persons dying every day in Florida from an oxycodone overdose.

DEA and state and local law enforcement have taken action through priority target initiatives such as *Operation Pill Nation*, a series of investigations targeting rogue pain clinics in Florida. As of July 1, 2011, this operation resulted in the closure of 40 rogue clinics, the arrest of 36 individuals, the seizure of approximately $18.9 million in assets, and the surrender of 95 DEA registrations. Closing these clinics and causing the surrender of these registrations will clearly reduce diversion. DEA has identified and reported on the results of these and other diversion control efforts through Congressional briefings and testimony, budget requests, and media reports/releases.

Priority Target Organizations (PTOs) Disrupted or Dismantled as a Performance Measure:

DEA uses PTO investigations as a performance measure to ensure that the resources and investigative efforts of the agency are focused on the highest level of trafficker. From their investigation, GAO concluded that "[p]erformance measures tracking investigations of priority targets demonstrate results."[7]

PTO investigations are established when investigators identify organizations that are engaged in high levels of drug trafficking and/or money laundering or are causing significant problems on the local, regional, national or international level. The disruption or dismantlement of such organizations will impact their ability to divert controlled substance pharmaceuticals or listed chemicals.

PTO investigations often involve multiple jurisdictions; the outcome can therefore be wide-ranging and substantial, and can include positive results in several ways. The criminal acts committed by these organizations negatively affect the quality of life within a given community. Drug trafficking organizations and drug abusers are often linked to other criminal activities such

[7] GAO report, p. 34.

as robberies, burglaries, drugged driving, and even deaths in their communities. These criminal organizations cause significant economic burdens within their communities such as loss of productivity, and strains on judicial systems and social and health care services. This was demonstrated by a study conducted by the University of Washington which reported that the economic costs in the United States from the non-medical use of prescription opioids for 2006 were estimated at $53.4 billion ($42 billion due to loss of productivity; $8.2 billion in criminal justice costs; $2.2 billion in treatment costs and $944 million in medical complications).[8] Removing or reducing sources of diversion drastically eliminates drug addicts'/drug seekers' ability to sustain any such activity and thereby reduces their burden on society.

Scheduled regulatory investigations and Administrative/Civil/Criminal Sanctions:

GAO reported that while DEA's performance measures for its criminal investigations demonstrate results, its performance measures for regulatory investigations do not. GAO stated that "[w]ithout the reporting of a measure that directly tracks a level of compliance among registrants, the public and other external stakeholders such as Congress will not be able to determine the extent to which DEA is achieving that specific objective."[9] DEA believes that the totality of the facts and circumstances must be taken into account to discern the outcome of any performance measurement.

Congress intended for DEA to enforce all aspects of the Controlled Substances Act (CSA) and its implementing regulations. DEA conducts regulatory inspections/investigations on certain registrants to ensure that they are in compliance with the CSA. If the inspection reveals violations of the CSA, the registrant can be held accountable through administrative, civil, or criminal sanctions. Registrants subject to routine cyclical inspections include, but are not limited to, certain practitioners, importers, wholesalers, distributors, or manufacturers.

On-site inspections are an important component of the DEA regulatory program and its oversight of the registrant population. However, criminal, civil and administrative sanctions are taken against a very small number of registrants during the annual regulatory inspection cycle. In fact, the vast majority of controlled substance registrants do not want to jeopardize their controlled substance registrations and potentially their businesses by violating provisions of the CSA. Generally speaking, the registrant population complies with the CSA and its implementing regulations. In many cases, cyclical inspections of facilities are utilized to point out potential weaknesses in security, recordkeeping or inventory practices and provide the regulatory oversight to bring the registrant into compliance. In many cases, the violations found are nothing more than minor infractions that can be corrected on-site. However, when DEA does pursue legal sanctions against a registrant, that action has a profound effect on the registrant population as a whole, resulting in better industry compliance while also identifying potential weaknesses in the closed system of distribution. It is extremely difficult to develop or implement a performance measure to track the impact of the regulatory inspection process, especially when the vast majority of registrant inspections do not uncover serious violations of the CSA.

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[8] Clinical Journal of Pain, December 2010, University of Washington, Hansen RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD

[9] GAO report p. 36.

However, there are other regulatory programs that can illustrate a dramatic impact on controlled substance diversion. For example, as part of the regulatory oversight process, DEA developed and implemented a Distributor Initiative Program to help controlled substance wholesalers/distributors understand their regulatory and statutory obligations concerning controlled substance transactions. This was done initially to cut off the flow of controlled substances to rogue Internet pharmacies but was expanded to address the increase and proliferation of rogue pain clinics that dispensed medications as well as pharmacies that serviced these clinics. This program has resulted in the registrants developing improved due diligence processes to assist in their ability to identify suspicious orders. This regulatory education program resulted in the discontinuation of controlled substance sales to approximately 1,300 suspicious customers, proactively preventing the diversion of controlled substances into the illicit market.

Still, within the last two years, it was necessary for DEA to take administrative and civil action against several wholesaler/distributors who continued to disregard their obligations under the CSA and supply large quantities of controlled substances to rogue pain clinics operating in Florida. Legal action against these distributors resulted in a significant decline in oxycodone sales in Florida, thus reducing diversion.

In summary, the specter of scheduled regulatory investigations and the above-mentioned proactive educational efforts have a deterrent effect that cannot be measured by raw data; it is impossible to measure the *lack* of diversion. These actions help prevent future diversion as well as maintain the closed system of distribution established by Congress through the Controlled Substances Act. It should be noted that our entire regulatory workforce was provided with the most up-to-date training concerning the regulatory investigative process during the last two years. This course was developed to enhance the performance of our diversion investigators as they take on a more focused role in regulatory oversight of DEA registrants.

Rapid Targeting Online Reports Tools Performance Outcome Measurement

As stated above, performance measurements are used as a tool to improve an agency's overall performance. This can be done in a variety of ways, such as improving work productivity, eliminating fragmentation, and employing cost-cutting measures. This is the reason that the Diversion Control Program developed the Rapid Targeting Online Reports tool (RapTOR). By leveraging technology, the agency will utilize RapTOR to link together fragmented database systems thereby streamlining and improving the investigative process. This performance measure was selected so that managers could monitor the development and implementation of this system to ensure that it was done in a timely and cost-efficient manner.

Conclusion:

GAO recommends that DEA strengthen the agency's performance measurement for the Diversion Control Program that would link to the program outcome goal of reducing diversion. GAO states that developing better performance measures "could also provide DEA program

managers and other decision-makers such as Congress better information to allocate resources or target program approaches accordingly to further optimize results against diversion."[10]

Over the last several years, the Diversion Control Program has evolved to address the ever changing face of pharmaceutical controlled substance diversion. These changes were made by well-informed managers and decision-makers who authorized the allocation of resources and altered the face of the program to adapt to changing trends and trafficking patterns of pharmaceutical controlled substance distribution. While we understand the importance of performance measures, we respectfully believe further strengthening the current performance measures to include regulatory performance measures would not provide any additional benefit in assisting the agency or other decision makers in the allocation of resources or target program approaches to further optimize results against diversion. The programmatic changes to the Diversion Control Program in the last several years and highlighted in the GAO report, were made, in part, due to the previous and current performance measures.

DEA provides Congress with detailed budget requests and supporting information to justify such requests. The justification for resource allocation is not limited to performance measures. For example, DEA's decision to expand its use of the Tactical Diversion Squads was predicated on the need for a job series which had full law enforcement authorities (Special Agents and Task Force Officers as opposed to Diversion Investigators) and the need to combine disparate agencies for a more effective and efficient means of addressing drug diversion. GAO's 14-month investigation confirms that DEA has been successful in accomplishing these objectives.

DEA leadership provides policy makers and legislators with requisite information though a variety of means including intelligence reports, congressional briefings, testimony, and briefings to executive staff within the Administration. The information presented during these briefings may include performance measures. However, fixed performance measures tend to be narrow in scope and could reflect trends that have already changed. The vast majority of information presented to policy makers is based on the collection and analysis of a wide range of investigative data and intelligence. This broader scope of information is far more beneficial in providing insight to leadership concerning decisions in the direction of resource allocations and programmatic changes.

Reducing prescription controlled substance abuse requires a multi-faceted approach which includes education, treatment, and enforcement. With respect to the latter, the performance measures used by DEA to track disruptions and dismantlements of Diversion PTO investigations and administrative, civil, and criminal sanctions represent more than just numbers.

The intricacies of our investigations expose or identify new or evolving trends which produce various outcomes. These trends may require the need for new or innovative responses or the allocation of resources such as the need to expand the use of Tactical Diversion Squads and the need to focus on enhanced regulatory oversight. The trends may identify the need for new legislation to keep pace with emerging technologies such as the Ryan Haight Act or

[10] GAO report p. 39.

regulations that authorize electronic prescribing for controlled substances. These trends may require new training or equipment as was the case with rogue Internet pharmacies.

The GAO report clearly demonstrates that management is appropriately directing its resources towards key points of diversion and towards those individuals or organizations directly responsible for large-scale diversion. Consequently, the direct and indirect outcomes from our current performance measures are very apparent. They are a means by which the agency sets priorities, directs resources, identifies new trends, formulates budgets, works with other agencies to develop national strategies, educates the public and industry, develops training curriculum, and provides Congress with technical assistance towards new legislation. The investigations conducted by DEA help reduce the supply of drugs diverted and the ways in which drug seekers/addicts acquire their drugs that might not otherwise occur in the absence of such investigations. But more importantly, these investigations and administrative actions help reduce diversion and the negative impact drug diversion has on families, the local community, the medical community, the economy, and overall public health and safety.

DEA will continue to review its performance measures for the Diversion Control Program and make any necessary adjustments to ensure that these measures are appropriate and that they are designed to provide the public, stakeholders, policy makers and members of Congress with the requisite knowledge to make informed decisions.

7

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

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Acknowledgments

In addition to the contact named above, Kirk Kiester, Assistant Director, and Christopher Hatscher, Analyst-in-Charge, managed this assignment. Frances Cook, Vanessa Dillard, Sally Gilley, Jessica Orr, and Alechia Smith made significant contributions to the report.

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