Department of Justice

STATEMENT OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, FEDERAL SERVICES, AND
INTERNATIONAL SECURITY
COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

ENTITLED

"A PRESCRIPTION FOR WASTE: CONTROLLED SUBSTANCE ABUSE IN MEDICAID"

PRESENTED

SEPTEMBER 30, 2009

Written Statement of
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
U.S. Drug Enforcement Administration

"A Prescription for Waste: Controlled Substance Abuse in Medicaid"

September 30, 2009

Senate Homeland Security and Governmental Affairs Committee
Subcommittee on Federal Financial Management, Government Information, Federal Services and International Security

Introduction

Chairman Carper, Ranking Member McCain, and distinguished Members of the Subcommittee on Federal Financial Management, Government Information, Federal Services and International Security, on behalf of the Acting Administrator and the more than 9,300 men and women of the Drug Enforcement Administration, I want to thank you for the opportunity to discuss the problem of prescription drug abuse and the illegal distribution of controlled substance pharmaceuticals and associated health care fraud.

Abuse of Controlled Substance Pharmaceuticals

The level of control mandated by Congress for pharmaceutical controlled substances far exceeds that for other prescription drugs. This level of control is commensurate with the potential for physical and psychological dependence and abuse properties that have historically been associated with controlled substances. Several studies of drug abuse patterns indicate that nonmedical use of pharmaceutical controlled substances is an increasing problem.

According to the 2008 National Survey on Drug Use and Health, 6.2 million Americans indicated that during the past month they had used psychotherapeutic drugs non-medically (4.7 million reporting abusing pain relievers). Nationally, the misuse of prescription drugs is second only to marijuana. Part of this increase in abuse is fueled by the fact that there is relatively little stigma associated with prescription drug use compared to other commonly abused drugs such as cocaine, heroin, and methamphetamine. Because they are manufactured for a legitimate medical purpose, many teenagers and young adults have the mistaken belief that they are safer than traditional illicit drugs such as cocaine or heroin.

Results of a separate study of seventh through twelfth grade students were released May 15, 2006, by the Partnership for a Drug-Free America. The Partnership Attitude Tracking Study tracks consumers' exposure to and attitudes about drugs. The study found that teenagers are more likely to have abused a prescription pain medication to get high than they are to have experimented with a variety of illicit drugs including Ecstasy, cocaine, crack and LSD. The study reported that nearly one in five (19 percent, or 4.5 million) teens has tried pharmaceutical

controlled substances (pain relievers such as the schedule II substance OxyContin® and the schedule III substance Vicodin®, or stimulants such as the schedule II substances Adderall® or Ritalin®) to get high. Abuse of these medications is equivalent to or higher than abuse of illegal drugs such as Ecstasy (8 percent), cocaine/crack (10 percent), and methamphetamine (8 percent). The 2005 survey indicated that 50 percent of the teenagers surveyed indicated that pharmaceutical controlled substances are widely available; a third indicated that they were easy to purchase over the Internet.

The Partnership Attitude Tracking Study also focused on perceived risk and social attitudes. Some of their Key Findings are most alarming:

- Two in five teens (40 percent or 9.4 million) agree that prescription medicines, even if they are not prescribed by a doctor, are much safer to use than illegal drugs;
- Nearly one third of teens (31 percent or 7.3 million) believe there's "nothing wrong" with using prescription medicines without a prescription "once in a while;"
- Nearly three out of 10 teens (29 percent or 6.8 million) believe prescription pain relievers – even if not prescribed by a doctor – are not addictive.

Means by Which Controlled Substances Are Diverted

According to the Kaiser Family Foundation, there were more than 3,450,000,000 total prescriptions dispensed in calendar year 2007. Of these, approximately 11 percent are for pharmaceutical controlled substances. With approximately 380,000,000 prescriptions being written for pharmaceutical controlled substances, and 6.2 million Americans abusing pharmaceutical controlled substances, the potential for diversion and health care fraud is considerable.

Understanding the means by which controlled substances are diverted is critical in determining appropriate regulatory controls. One of the factors that contribute to the abuse of pharmaceutical controlled substances is the perception by some members of the public that it is safer to abuse prescription substances than to abuse illicit substances. This could not be farther from the truth. Additionally, black-market sales for prescription controlled substances are typically five to ten times their retail value. Profits generated from these street sales provide a strong incentive for continued diversion.

Diversion of pharmaceutical controlled substances can occur in a number of ways, including, but not limited to, the following:

- Prescription pads are stolen from practitioners' offices by patients, staff, or others and illegitimate prescriptions are written and forged.
- Legitimate prescriptions are altered to obtain additional amounts of legitimately prescribed controlled substances.

- Drug-seeking patients may falsify symptoms and/or obtain multiple prescriptions from different practitioners for their own use or for resale. In some cases, organized groups visit practitioners with fake symptoms to obtain prescriptions, which are filled and resold. Some patients resell their legitimately obtained drugs to earn extra money.
- Prescription pads containing legitimate practitioner information (e.g., name, address, DEA registration number) are printed with a different call-back number that is answered by an accomplice to verify the prescription.
- Computers and scanning or copying equipment are used to create prescriptions for nonexistent practitioners or to copy legitimate practitioners' prescriptions.
- Pharmacies and other locations where pharmaceutical controlled substances are stored are robbed or burglarized.

Diversion from within the practitioner's practice or pharmacy may also occur, such as in the following situations:

- Prescriptions are written for other than a legitimate medical purpose. Some practitioners knowingly write prescriptions for nonmedical purposes. Criminal organizations commonly referred to as "rogue Internet pharmacies" often employ practitioners to issue prescriptions based on on-line questionnaires from patients with whom the practitioner has no legitimate medical relationship.
- Pharmaceutical controlled substances are stolen from pharmacies by pharmacy personnel. Legitimately dispensed prescriptions may be altered to make the thefts less detectable.

Registration

As part of the closed-system of distribution and to ensure proper oversight and accountability, the following individuals and entities are required to apply for registration with DEA: any business that imports or exports a controlled substance, or that manufactures or distributes a controlled substance; pharmacies that dispense controlled substances; practitioners that prescribe, administer, or dispense controlled substances; or any person that conducts research or chemical analysis with a controlled substance. Currently, there are more than 1.3 million registrants registered with the DEA with the vast majority of them being practitioners. Once registered, each individual or business location is issued a unique DEA registration number. DEA maintains these numbers in a database that includes historical or current action(s) taken against a registrant.

DEA provides an electronic means by which registrants can check the validity of another registrant's DEA registration number. DEA also provides access to state agencies that have a responsibility to investigate health care fraud. DEA provides access to the registrant database to 28 states that have requested the data. DEA provides this data to agencies such as the New York State Medicaid Inspector General's Office; the Illinois Office of Inspector General Health and Family Services; the Illinois Department of Human Services Bureau of Pharmacy and Clinical Support Services; the North Carolina Medical Board; and the Texas Department of Public Safety,

Controlled Substances Registration section. Additionally, DEA provides a listing of current DEA registration numbers to the National Technical Information Service (NTIS), an agency of the U.S. Department of Commerce, on a weekly basis. NTIS collects and disseminates technical information produced by and for Federal agencies. It operates on a self-sustaining basis and makes this information widely available to those who need it on a subscription basis at no cost to the Treasury.

DEA is working to acquire Social Security death records electronically from NTIS. DEA will then cross check that information against DEA registration records to better reconcile these two databases and thereby curb potential avenues of healthcare fraud.

The CSA and DEA Regulations Pertaining to Prescriptions for Controlled Substances

In enacting the CSA, Congress sought to control the diversion of pharmaceutical controlled substances into illicit markets by establishing a "closed system" of drug distribution governing the legitimate handlers of controlled substances. The CSA and implementing regulations build in checks and balances to help maintain the integrity of this closed-system. When used correctly, these checks and balances help reduce waste, fraud, and abuse.

The CSA requires that a prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe by the state in which he or she is licensed to practice and is registered, or exempted from registration, with DEA. Additionally, to be valid, a prescription must be written for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice; a corresponding responsibility also rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of the CSA, and the person knowingly filling such a purported prescription, as well as the person issuing it, is subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A prescription may be filled only by a pharmacist acting in the usual course of professional practice who is employed in a registered pharmacy. Except under limited circumstances, a pharmacist may dispense a schedule II controlled substance only upon receipt of the original written prescription manually signed by the practitioner. A pharmacist may dispense a schedule III or IV controlled substance only pursuant to a written and manually signed prescription from an individual practitioner, which is presented directly or transmitted via facsimile to the pharmacist, or an oral prescription, which the pharmacist promptly reduces to writing containing all of the information required to be in a prescription, except the signature of the practitioner.

Every prescription must be initialed and dated by the pharmacist filling the prescription. Under many circumstances, pharmacists are required to note certain specific information regarding dispensing on the prescription or recorded in a separate document referencing the prescription before the prescription is placed in the pharmacy's prescription records.

DEA requires the registered pharmacy to maintain records of each dispensing for two years from the date of dispensing of the controlled substance. However, some states require that these records be maintained for longer periods of time. These records must be made available for inspection and copying by authorized employees of DEA. This system of records is unique in that the prescribing practitioner creates the prescription, but the dispensing pharmacy retains the record.

The elements of the prescription that identify the practitioner (the practitioner's name, address, DEA registration number, and signature) also serve to enable the pharmacy to authenticate the prescription. If a pharmacy is unfamiliar with the practitioner, it can use the registration number to verify the identity of the practitioner through publicly-available records. Those same records would indicate to the pharmacy whether the practitioner has the authority to prescribe the schedule of the controlled substance in question.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are typically electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMP programs and encourages the use of these programs by medical professionals in detecting and preventing doctor shopping and other forms of diversion. Currently, 40 states have enacted some type of legislation to establish a PDMP and of those 33 are operational. Additionally, DEA makes its registrant database available to any state, free of charge, for use in their PDMP or other state agency whose mission is to prevent health care fraud or diversion. These programs, however, are only as good as the data that is in each system and the willingness of practitioners and pharmacists to use such systems on a consistent basis.

Medicare – Medicaid Fraud

Medicare and Medicaid are administered by the Department of Health and Human Services (HHS). Federal investigations of health care fraud and misuse are investigated by investigators from HHS and the FBI, under Title 18 U.S.C. §§ 287 and 1001, and Title 42 U.S.C. § 1320a-7b. State agencies also have a responsibility to investigate Medicaid health care fraud within their jurisdiction. When conducting investigations into violations of the Controlled Substances Act, DEA agents and investigators may also uncover violations involving health care fraud. This information is typically turned over to investigators from HHS, the FBI, or state authorities within their area of responsibility. DEA does not have any databases that have information regarding the dispensation by a pharmacy to individual patients. Records at this granular level are acquired through investigations of a pharmacy on a case-by-case basis.

DEA's Regulatory and Enforcement Strategy

As previously stated, DEA maintains a registrant population of more than 1.3 million registrants under a variety of business activities. DEA is currently restructuring its Diversion

Control Program to establish approximately 57 new Tactical Diversion Squads (TDS). These TDS groups will include Diversion Investigators, Special Agents, and state and local Task Force Officers and will focus efforts on criminal investigations related to the diversion of controlled substances. Where a TDS group uncovers evidence of health care fraud, the TDS group will partner with additional investigative agencies to fully utilize all investigative tools and expertise. Currently, DEA is working with HHS to integrate investigators from HHS into these TDS groups to help combat health care fraud. The restructuring plan will also include strengthening DEA's efforts to provide the necessary regulatory oversight of the registrants by ensuring that registrants are adhering to their responsibilities under the Controlled Substances Act and its implementing regulations.

The vast majority of the more than 800,000 medical doctors and doctors of osteopathy medicine are law-abiding professionals. During any given year, DEA arrests only approximately 75 medical doctors or doctors of osteopathy for violations of the Controlled Substances Act. Additionally, DEA has taken the following actions against registrants:

- FY-2007 DEA issued 31 Orders to Show Cause/Immediate Suspensions
- FY-2008 DEA issued 40 Orders to Show Cause/Immediate Suspensions
- FY-2009 (as of August) DEA issued 48 Orders to Show Cause/Immediate Suspensions

Conclusion

Individuals and organized groups, regardless of their professional status, continue to circumvent both state and federal laws and regulations which threaten the health and safety of Americans. Nevertheless, the DEA continues to refine its methods of identifying, pursuing, and ultimately dismantling these criminal entrepreneurs. DEA remains committed to bringing to bear all of the resources at its disposal to fight this growing problem while simultaneously ensuring an uninterrupted supply of pharmaceutical controlled substances for legitimate demands. DEA's core mission is to disrupt and dismantle drug trafficking organizations, including those who seek to illegally distribute or divert pharmaceutical controlled substances.

Chairman Carper, Ranking Member McCain, and members of the Subcommittee, I thank you for the opportunity to discuss this vital issue and welcome any questions you may have.