

**Statement of  
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*Before the*

**U.S. House of Representatives  
Committee on Government Reform  
Subcommittee on Criminal Justice, Drug Policy  
and Human Resources  
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*“To Do No Harm: Strategies For Preventing Prescription Drug Abuse”*

***Executive Summary***

*The rapid rise and widespread abuse of new generation high potency prescription drugs like OxyContin® presents new strategic challenges in controlling the longstanding problem of prescription abuse. In addition to traditional methods of diversion such as forged and fraudulent prescriptions, pharmacy theft, and doctor shopping, new technology has facilitated increased diversion of drugs through “rogue” Internet pharmacies. In response, DEA is creating a sophisticated infrastructure that will use an encryption system known as Public Key Infrastructure (PKI) to protect against fraudulent prescriptions as well as an advanced system that will search the online public domain for illicit drug activity. In addition, the 2001 DEA OxyContin® Action Plan has spurred a flurry of joint enforcement operations with state and local agencies to combat traditional methods of diversion. We also continue to work with state officials on Prescription Monitoring Programs (PMP) to prevent diversion at the point of sale and participate in numerous Joint Task Forces nationwide to combat the abuse of pharmaceutical controlled substances and health care fraud. Our approach to illicit diversion of prescription drugs is reasonable and ensures adequate supplies of pain medications are available for those with legitimate needs while protecting the public from the consequences of abuse.*

Chairman Souder and distinguished members of the Subcommittee, it is a pleasure to appear before you today to discuss the challenge of prescription drug abuse and the efforts of the Drug Enforcement Administration to combat it. My name is Thomas Raffanello, and I am the Special Agent In Charge of the Miami Division. Mr. Chairman, on behalf of Administrator Karen P. Tandy, I would like to thank this subcommittee for its unwavering support of the men and women of the DEA and its mission.

## **Introduction**

DEA has primary authority to prevent and prohibit the diversion and improper use of controlled substances under the Controlled Substances Act (CSA), as well as the duty to ensure their availability for legitimate medical and scientific needs. While the problem of prescription drug abuse unfortunately is not a new one, its urgency has been heightened by a new generation of high dose, extended release, opioid pain medications. Along with greatly increased effectiveness to treat pain, these drugs also offer equally increased risk of abuse and diversion that force a delicate balance for medical and health professionals and law enforcement personnel. OxyContin®, Duragesic® and Actiq® are examples of this type of licit drug. The potency, purity and quantity of their active ingredients are stronger and more dangerous than ever before, tempting addiction by legitimate patients and offering a high potential for deliberate abuse by those seeking narcotic drugs. In addition, these powerful drugs provide strong incentives for diversion by both new means such as “rogue” Internet pharmacies and older challenges such as improper prescriptions written for profit. The DEA is committed to aggressively address and counter the risks posed solely by this new generation of prescription drugs and their abuse.

## **Personifying a Different Type of Drug Abuser**

Prescription drugs can be an easy and insidious form of abuse for a variety of reasons. Abusers know that prescription drugs are not adulterated and have standardized, precise dosages. Abusers believe that “If my doctor can prescribe it for me, it can’t be bad.” Many think that if the user does not inject the drug, he or she is not truly a drug abuser. Controlled substances obtained via prescriptions are frequently covered by health insurance or Medicaid. Finally, prescription drugs are readily available through open commercial markets.

Opiates in pill form have historically been among the most abused prescription drugs, especially hydrocodone, hydromorphone, and oxycodone. Diverted from legitimate channels, these drugs can substitute for illicit narcotics and are frequently trafficked on the street by individuals or structured organizations. As far back as the 1970s, hydromorphone-based Dilaudid® was known on the street as “drug store heroin.”

## **Increasing Abuse of Controlled Release and Sustained Release Opiates**

Prescription drug abuse has recently escalated to a new level of concern with the development of opiate-based pain killers designed for controlled or sustained release. These products pose special challenges to law enforcement. It is easy to see why when you consider that OxyContin® contains two to sixteen times the dosage of oxycodone as its well known predecessor Percodan®.

OxyContin® is also the most widely known example of an abused prescription drug, and its diversion has increased dramatically since its introduction to the market. OxyContin® is a valuable and efficient pain management drug when properly prescribed and used. At the same time, however, its popularity for abuse skyrocketed when word made its way to the street that manipulating this powerful drug can bring heroin-like effects. DEA has never witnessed such a rapid increase in the abuse and diversion of a pharmaceutical drug product.

Problems with OxyContin® diversion occurred relatively soon after its initial marketing. By 2000, DEA had noted a dramatic increase in its illicit availability and abuse. Available data for the following year indicated that OxyContin® reached record levels of diversion and abuse never before seen. In 2001, the DEA's National Forensic Laboratory Information System (NFLIS) reported double the amount of drug exhibits analyzed by state and local forensic laboratories contained oxycodone in comparison to 2000. OxyContin® diversion first emerged as an issue in rural areas of the eastern United States, particularly in parts of Appalachia and New England, and became so prevalent it is known as "hillbilly heroin." Its popularity among prescription drug abusers spread quickly, and it was not long before OxyContin® abuse and diversion widened to other parts of the country, including Florida.

OxyContin® abuse has been so prevalent in the Florida Panhandle and the Jacksonville area that DEA, the Federal Bureau of Investigation (FBI), the Defense Criminal Investigative Service, the Florida Attorney General's Medicaid Fraud Control Unit, the Florida Department of Financial Services and the Bay County Sheriff's Office formed the North Florida Health Care Task Force (HCTF) in 2001. The Task Force combats abuse of pharmaceutical controlled substances and health care fraud. HCTF recently created an OxyContin® focus group to concentrate on the diversion of OxyContin® in the Florida Panhandle area.

Investigative successes are having an impact, but also highlight the extent of the problem of prescription drug abuse. In September 2002, the Citrus County Sheriff's Office arrested the owner and pharmacist of an Inverness, Florida pharmacy for diverting several hundred OxyContin® pills from his pharmacy each week. A subsequent DEA investigation and audit revealed shortages of approximately 90,000 pills of diverted drugs in just ten months, including approximately 36,000 tablets of oxycodone products and 54,000 tablets of hydrocodone products. The pharmacist was recently sentenced to five years imprisonment. More recently, the HCTF apprehended a Panama City, Florida physician on several counts of illegal distribution of controlled substances, including distribution resulting in death. Our enforcement operations have also had a positive effect on public awareness. The DEA Tallahassee Resident Office has responded to numerous telephone calls, ranging from inquiries as to where to obtain substance abuse treatment to physicians asking how to handle the influx of patients requesting OxyContin® prescriptions.

## **Methods of Diversion**

The popularity of OxyContin® and other drugs of abuse have also inspired a wide range of diversion methods, some new and some old. Practitioners and pharmacists illegally or indiscriminately prescribe or dispense OxyContin® for a profit. Addicts and dealers steal drugs through pharmacy thefts and in-transit hijackings. Forged or fraudulent prescriptions are common occurrences, as are patients who claim false medical needs. “Doctor Shopping” abusers travel from doctor to doctor to find an easy mark who will readily write prescriptions or who can be duped. Foreign diversion and smuggling of contraband drugs into the United States contributes to the problem. And perhaps of the greatest concern, the Internet has become a virtual wild west bazaar for “spam” emails and website advertisements that sell controlled substances with little or no oversight that the drugs are sold for legitimate medical reasons. At times, multiple methods of diversion occur simultaneously. In Sarasota, Florida, a physician recently was arrested for writing prescriptions for controlled substances to known drug dealers and abusers including Dilaudid® and OxyContin®. The doctor saw as many as 80 patients daily and charged \$250.00 for an initial office visit and \$150.00 for follow-up appointments. During the search of the physician’s office, DEA and local law enforcement seized approximately 25,000 doses of controlled substances including large quantities of oxycodone, methadone and hydrocodone.

## **Preventing Diversion**

### **The OxyContin® Action Plan**

In response to growing concern among federal, state and local officials about the dramatic increase in the illicit availability and abuse of OxyContin®, the DEA initiated an OxyContin® Action Plan in May 2001 as a comprehensive effort to prevent diversion and abuse of the drug. The initiative is not intended to impact the availability of OxyContin® for legitimate medical use.

The OxyContin® Action Plan has four main goals: First, enhance coordination of enforcement and intelligence programs with other federal, state, and local agencies to target individuals and organizations involved in the illegal sale and abuse of OxyContin®. Second, use the full range of regulatory and administrative authorities to make it more difficult for abusers to obtain OxyContin®. The DEA does this by closely monitoring the quota of oxycodone available to manufacturers, continuing to work closely with the Department of Health and Human Services to reduce the abuse of reformulated OxyContin® by injection, and continuing our efforts to improve physician education on treatment of pain and recognition of addiction. Third, increase cooperative efforts with the pharmaceutical industry. Fourth, advance national outreach to educate the public, the healthcare industry, schools and state and local governments on the dangers related to the abuse and diversion of OxyContin®.

Since implementation of the OxyContin® Action Plan, DEA has initiated over 400 OxyContin® investigations, resulting in the arrest of approximately 600 individuals. Sixty percent of the cases initiated involved professionals such as doctors and pharmacists. Doctor shoppers, forgers, and individuals arrested for armed robberies and burglaries accounted for the remaining forty percent of the investigations.

The plan's impact locally is best illustrated by the recent arrest of a physician in Melbourne, Florida who was charged in state court with eleven counts related to trafficking large quantities of OxyContin® and other controlled substances. The investigation further revealed that office employees were operating a drug ring using the physician's prescriptions. To date, forty people have been arrested for illegal drug trafficking as a result of this investigation.

### Prescription Drug Monitoring

The DEA is also working with states on Prescription Monitoring Programs (PMP) to prevent diversion at the state level. PMPs capture information regarding prescriptions electronically at the "point of sale," usually the pharmacy. The information is transmitted to a state agency to identify doctor shoppers and/or other evidence of diversion. Sixteen states have active PMPs and another five states have partial or pending programs. The General Accounting Office concluded in a 2002 study that PMPs "... have aided investigators and helped to reduce doctor shopping ...". For the past two years, Congress has appropriated funds for states to initiate and expand PMPs. Florida has applied for an enhancement grant of \$350,000 to augment an initial grant beginning in January 2005. Use of these funds is contingent upon the passage of legislation during Florida's current legislative session.

### Internet Initiatives

Although the Internet has fostered the diversion of controlled substances and the inappropriate use of other drugs, it can also be used as a tool to reduce prescription fraud. As part of an overall modernization effort, DEA is developing regulations that will allow physicians to use the Internet to securely transmit prescriptions from their offices to the patient's pharmacy. These regulations will specify standards to electronically transmit prescriptions to foil prescriptions from being altered and prevent office staff from making fraudulent telephone authorizations on behalf of physicians. DEA anticipates that the regulations will be finalized this year with procedures being implemented in 2005.

DEA is also examining ways to deal with the recent rapid proliferation of "rogue" Internet pharmacies. During 2004, DEA intends to improve our capacity to identify illicit operations and better restrict internet sales of controlled substances through the use of a new and advanced system that will search the online public domain for illicit drug

activity. We anticipate receiving \$2.1 million and more than 60 diversion and support positions dedicated to the Internet diversion problem under DEA's Fiscal Year 2004 budget. We also plan to work with the Food and Drug Administration (FDA) and other agencies to better educate the public and work with those companies that facilitate the illegal sale of controlled substances including commercial freight carriers, credit card companies and Internet search engines.

### **Understanding Pain Management**

As I mentioned earlier, high-dose opiates can be an important and legitimate means of pain relief. In striking the delicate balance between preventing abuse and facilitating patient care, the DEA believes that physician education and cooperation with medical groups is essential. The DEA agrees with 21 health care organizations who endorsed a balanced approach to the use of pain medications like OxyContin®. We are continuing to work with organizations such as Last Acts and the University of Wisconsin Pain and Policy Studies Group to formulate Frequently Asked Questions (FAQs) for physicians and investigators alike to clarify appropriate prescribing issues. These FAQs will be made available to interested parties through DEA's website and other media. The DEA is also exploring continuing medical education opportunities for physicians that will become electronically available when a physician applies for, or renews, a DEA registration.

### **Conclusion**

The DEA is committed to protecting the American public's health and safety from the serious consequences of abuse of legal pain relief for life destroying illegal purposes. Initiatives like the OxyContin® Action Plan, PMPs, additional funding and positions for DEA diversion investigations, and our new Internet search system will enhance the DEA's enforcement efforts to stop the flow of prescription drugs from reaching our streets illegally.

I would be happy to answer any questions the Subcommittee may have.