



NEWS

777 Bannock Street, MC 0278, Denver, CO 80204 Phone: 303-436-6606 Fax: 303-436-5131

RADARS[®] System Releases U.S. Data on Prescription Drug Abuse, Misuse and Diversion

May 22, 2007

Contact: Betty Rueda
303-436-6606

Prescription drug abuse affects every state in the nation, and is more prevalent in suburban and rural areas than inner cities. Researchers with Denver Health's Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) System recently reported a nationwide analysis of 2006 data on abuse, misuse and diversion of prescription opioids. RADARS System data found 93 percent of reporting three-digit ZIP codes had at least one case of prescription drug abuse, misuse or diversion to the black market in 2006. (See attached map.)

RADARS System researchers also found the highest pockets of abuse, misuse and diversion occurring in the Appalachian Region and the Northeast.

"Prescription drug abuse, including the use of opioids, is widespread," said Richard C. Dart, M.D., Ph.D., director, Rocky Mountain Poison and Drug Center, a division of Denver Health, and home of the RADARS System. "This is a public health problem that transcends socioeconomic classes and neighborhoods."

The RADARS System is a real-time prescription drug abuse monitoring system that measures rates of abuse, misuse and diversion, and quickly pinpoints geographic areas where abuse is prevalent. The RADARS System collects data from 854 of the 930 three-digit ZIP codes in the U.S.

Opioid prescription drugs can be found in many home medicine cabinets. Some commonly prescribed opioid-based medications include hydromorphone, morphine, methadone, hydrocodone, oxycodone, oxymorphone and fentanyl. RADARS System data indicate that all prescription opioid products are abused and diverted; however, the rate and extent is different for various products and formulations (extended release, etc.).

While products with higher sales tend to have more abuse because they are more widely available, abuse of every monitored opioid product was reported in 2006.

Recently, RADARS System subscribers, pharmaceutical industry representatives and federal regulatory agencies met in Washington, D.C., to evaluate and discuss the problem of prescription opioid abuse, misuse and diversion in the United States.

At the meeting, researchers with the RADARS System presented the 2006 data collected from the four signal detection systems which include poison centers, police and regulatory agencies, methadone clinics, and key informants (see attached Fact Sheet).

“The meeting and the presentation of 2006 data encouraged the group to collaboratively begin to develop risk management and surveillance strategies in response to these growing safety and societal concerns,” Dart said. “Understanding prescription drug abuse in its current state is the first step in developing effective interventions to decrease the abuse of these medicines. If we understand how these prescription drugs are being abused, what populations are being affected, and what drug safety and intervention measures are working, then we can reduce the misuse, abuse and diversion of prescription medications in the future.”

According to 2005 data, the most recent available from the Substance Abuse and Mental Health Services Administration, prescription drug abuse increased 42.5 percent nationwide between 2001 and 2005. In 2001, an annual average of eight million people had abused prescription pain relievers at least once during the previous 12 months. In 2005, this annual average jumped to 11.4 million people.

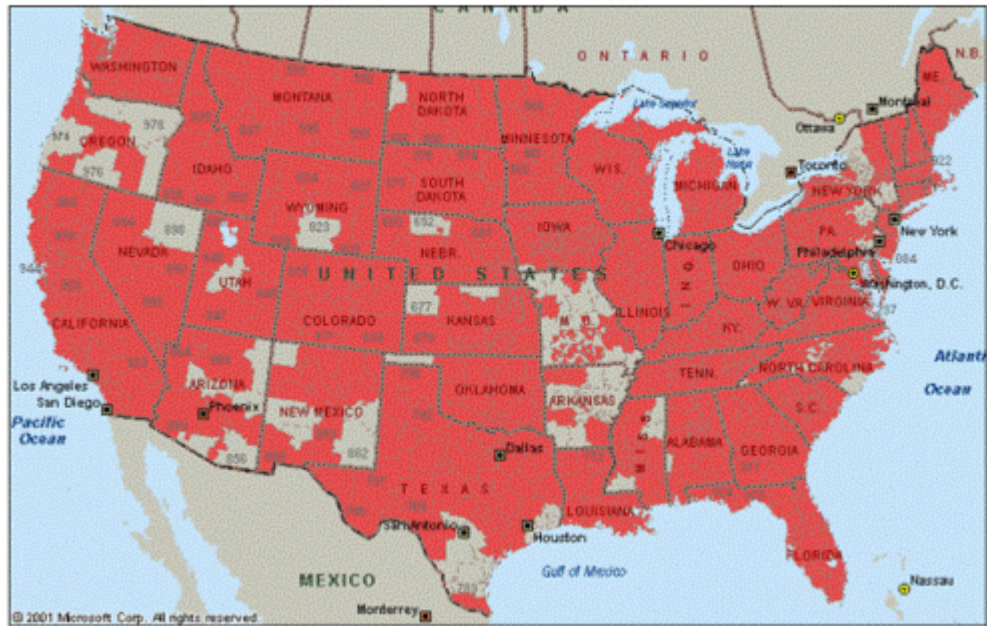
The RADARS System was initially created by Purdue Pharma L.P. in 2001 under the guidance of an external advisory board of medical and scientific experts in substance abuse and law enforcement. In 2006, the Rocky Mountain Poison and Drug Center, a division of Denver Health, acquired the RADARS System.

For more than 50 years, the Rocky Mountain Poison and Drug Center (RMPDC), a division of Denver Health, has provided an essential service to the citizens of Colorado and several other states. Highly trained nurses, pharmacists, physicians, pharmacologists and other medical professionals are available 24 hours a day, 365 days a year, responding each year to more than 200,000 callers who have questions about medical issues, such as accidental poisoning, drug overdose, chemical exposure, poisonous bites and stings, and drug interactions. In addition to its primary mission of assisting in the counseling of patients, RMPDC and other poison centers work closely with government agencies and industry to promote dissemination of safety information to the public.

Denver Health, formerly known as Denver General Hospital, is the Rocky Mountain Region's academic Level I trauma center, and the safety net hospital for the Denver area. The Denver Health system, which integrates acute and emergency care with public and community health, includes Denver Public Health, the Rocky Mountain Regional Trauma Center, Denver Health Paramedic Division, Denver's 911 emergency medical response system, eight family health centers, 12 school-based health clinics, the Rocky Mountain Poison and Drug Center, NurseLine, Correctional Care, Denver CARES, Denver Health Foundation, Denver Health Medical Plan and the Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics.

###

2006 Prescription Drug Abuse or Diversion Cases Reported to RADARS System (shaded red)



ADDITIONAL RESOURCES

For media inquiries or additional quotes, contact the following individuals.

1. Richard C. Dart, *Rocky Mountain Poison & Drug/RADARS System*, (303) 436-6606
2. J. David Haddox, *Purdue Pharma L.P.*, (203) 588-8069
3. Sidney Schnoll, *Pinney & Associates*, (301) 718-8440

For additional information on prescription drug abuse and addiction, please see the following documents.

1. *Misuse of Prescription Drugs: Data from the 2002, 2003 and 2004 National Surveys on Drug Use and Health (NSDUH)*. Substance Abuse and Mental Health Services Administration. April 6, 2007. Full report available at <http://www.oas.samhsa.gov/2k7/pain/pain.pdf>
2. *Media Guide: Drug Abuse and Addiction*. National Institute on Drug Abuse. Full document available at <http://www.nida.nih.gov/PDF/MediaGuide.pdf>
3. *Drugs, Brains, and Behavior: The Science of Addiction*. National Institute on Drug Abuse. Available at <http://www.drugabuse.gov/scienceofaddiction/>
4. *Substance Abuse or Dependence*. National Household Survey on Drug Abuse. Substance Abuse and Mental Health Services Administration. October 11, 2002. Full report available at <http://www.oas.samhsa.gov/2k2/dependence/dependence.pdf>

FACT SHEET

Prescription Drug Abuse

Addiction is defined as a psychological and physical craving for a certain drug's effects, which results in an increased tolerance to the drug, and, eventually, in a dependency on the drug.

Prescription drug abuse has been an on-going problem evolving over time. Drug abuse patterns change as drugs change, and the mechanisms of obtaining drugs also change. There have been ongoing efforts over the years to curb drug abuse and increase drug safety.

Drug abuse and addiction, including the abuse of legally prescribed pharmaceuticals, costs the U.S. nearly \$500 billion each year, according to the National Institute on Drug Abuse (NIDA).

In recent years, prescription drug abuse has continued to increase and the abuse and misuse of prescription drugs is reported as being more prevalent than heroin and sometimes even marijuana abuse by federal and international monitoring measures. Reports from the International Narcotics Board (INCB) and the Substance Abuse and Mental Health Services Administration (SAMHSA) report that nonmedical use of prescription drugs is expected to (or already does) exceed illegal drug use.

A recent report from the International Narcotics Board (INCB) said that with the exception of cannabis use, the abuse of prescription drugs has surpassed all illegal drugs. INCB President Philip O. Emafo stated in the report, "Most countries do not have any mechanism to systematically collect data to document this abuse, and are not aware to what extent drugs are being diverted or abused."

In a March 2007 report, the INCB stated that "in the United States, the abuse of prescription drugs, including pain killers, stimulants, sedatives and tranquilizers has gone beyond the abuse level of illicit drugs, with the exception of cannabis."

A SAMHSA report, *Misuse of Prescription Drugs: Data from the 2002, 2003 and 2004 National Surveys on Drug Use and Health*, noted that "misuse of prescription drugs is second only to marijuana as the nation's most prevalent drug problem."

Prescription drugs can produce the same addictive properties as illegal drugs.

"Among this emerging trend [the illegal use of prescription drugs] is its prevalence among teenagers and young adults, and the common misperception that because these medications are prescribed by physicians, they are safer even when used illicitly," according to NIDA's Monitoring the Future Survey of 2006.

"One in 10 high school seniors have used the painkiller Vicodin for non-medical purposes in the past year, with high rates for other prescription drugs as well," the NIDA survey stated.

Prescription pain medications are necessary treatments for patients who suffer from acute and chronic pain. These prescription painkillers are effective in treating pain, and when used as directed these medications typically do not result in abuse or addiction.

FACT SHEET

Opioid-Based Prescription Pain Medications

Opioid-based medications are used to treat acute and chronic pain.

Opioid-based pain medications are derived from the opium poppy plant, a natural pain-killer, which also supplies the base for the illegal drug, heroin.

When a person experiences pain, nerves send a pain message to brain receptors which in turn communicate with the brain. The brain sends a message that tells the person he is feeling pain. Opioid-based medications work by blocking the brain receptors, so that the pain message is not received by the brain. The pain still exists, but the message from the brain is never conveyed, therefore the sensation of pain is blocked.

Opioid-based medications are thoroughly tested by pharmaceutical manufacturers, and are extremely effective in treating pain. When these pain relievers are used properly, and taken as directed, addiction should not occur.

The elimination of prescription opioids would be ineffective in managing abuse because abusers will use whichever drug is available and cheap in an area. A balance must be achieved between making a prescription opioid available for pain control versus preventing the possibility of abuse.

Prescription drug abuse is a societal problem. No one industry can solve it. Some pharmaceutical companies are working with the FDA to reduce the risk of prescription drug abuse by addressing abuse liability in their Risk Minimization Action Plans (RiskMAP). Some of the ways to address this include abuse resistant formulations, improved packaging, labeling, and education.

Under the Controlled Substances Act, most (though, not all) opioid-based prescription medications are typically classified as either Schedule II or Schedule III drug substances. These classifications delineate rules for doctors on how these drugs can be prescribed, and how often.

The Harrison Narcotics Act of 1914 taxed the production, importation, distribution and use of [opioids](#). This act also forbade sale of substantial doses of opiates or cocaine except by licensed doctors and pharmacies. This act eventually led to a complete ban of illegal narcotics in 1924.

The FDA is working with pharmaceutical manufacturers, requiring RiskMAP for drugs with abuse liability to address potential abuse concerns of various drugs. The RADARS System provides timely and geographically specific data to pharmaceutical manufacturers, who utilize this data in meeting their obligations to the FDA.

<i>Drug Class</i>	<i>Brand Names*</i>	<i>CSA Schedule</i>
Buprenorphine	Subutex [®] , Suboxone [®] , Buprenex [®]	Schedule III
Fentanyl	Duragesic [®] , Actiq [®] , Fentora [®]	Schedule II
Hydrocodone	Vicodin [®] , Lortab, Lorcet [®] , Vicoprofen [®]	Schedule III
Hydromorphone	Dilaudid [®] , Palladone [®] (no longer on market)	Schedule II

Methadone	Methadose [®] , Dolophine [®]	Schedule II
Morphine	Kadian [®] , Avinza [®] , MS Contin [®]	Schedule II
Oxycodone	Endocet [®] , Endodan [®] , OxyContin [®] , Percocet [®] , Percodan [®]	Schedule II
Oxymorphone	Opana [®] , Numorphan [®]	Schedule II
Tramadol	Ultram [®] , Ultracet [®]	Non-scheduled drug
<i>*This is not an all inclusive list of trade name products.</i>		

Schedule II Drugs	
Requirements:	Description:
<p>A) <i>The drug or other substance has a high potential for abuse.</i></p> <p>B) <i>The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.</i></p> <p>C) <i>Abuse of the drug or other substances may lead to severe psychological or physical dependence.</i></p>	<p>These drugs are available only by prescription and distribution is carefully controlled and monitored by the DEA. Oral prescriptions are allowed, limiting the number of doses to 30, although exceptions are made for cancer patients, burn victims, etc. No refills are allowed. Also, Schedule II drugs are subject to production quotas set by the DEA.</p>
Schedule III Drugs	
Requirements:	Description:
<p>A) <i>The drug or other substance has a potential for abuse less than the drugs or other substances in Schedule II.</i></p> <p>B) <i>The drug or other substance has a currently accepted medical use in treatment in the United States.</i></p> <p>C) <i>Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.</i></p>	<p>These drugs are available only by prescription, though control of wholesale distribution is somewhat less stringent than Schedule II drugs. Prescriptions for Schedule III drugs may be refilled up to five times within a six month period.</p>

FACT SHEET
Rocky Mountain Poison and Drug Center—The RADARS® System

In 2006, the Rocky Mountain Poison and Drug Center at Denver Health and Hospital Authority acquired the Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS) System – a real-time prescription drug monitoring system – to study and track the prevalence of abuse, misuse and diversion prescription drugs.

The RADARS System provides timely and geographically-specific data to regulatory agencies, policymakers, medical/public health officials and the pharmaceutical industry, to aid in understanding trends in the abuse, misuse and diversion of prescription drugs in the United States. The RADARS System is a non-profit, government authority that provides data to pharmaceutical manufacturers via subscription.

RADARS actively detects, and obtains information on, reported events involving the illicit use of certain prescription drugs throughout the nation. The RADARS system collects data and distributes it to the subscribers, who, in turn, report the data to the FDA.

The RADARS System utilizes four signal detection systems to identify trends and incidences of abuse, each from a unique perspective. The signal detection systems serve as an early warning system, offer timely data collection and reporting, are sensitive to geographic location, and are useful for monitoring newly approved drugs.

The Drug Diversion Signal Detection System surveys more than 300 diversion investigators from jurisdictions in all 50 states, Puerto Rico and the Virgin Islands. It gives a sense of what drug dealers are selling, which reflects black market demand. James A. Inciardi, Ph.D., University of Delaware, is the principal investigator of this system.

The Key Informant Network Signal Detection System comprises leading professionals in the field of drug abuse such as clinicians, epidemiologists and treatment counselors from rural, urban and suburban areas across the nation. Theodore J. Cicero, Ph.D., Washington University in St. Louis, is the principal investigator of this system.

The Poison Center Signal Detection System includes 43 of 60 poison centers representing more than 200 million people in the U.S. The poison centers provide weekly data on cases of prescription-drug abuse and misuse and gather information for exposures at all ages. Richard C. Dart, M.D., Ph.D., Denver Health and University of Colorado, is the principal investigator of this system.

The Opioid Treatment Center Signal Detection System includes 75 methadone maintenance treatment programs across the USA that ask patients entering treatment to complete an anonymous questionnaire which inquires about the patient's drug use in the past month, lifetime drug abuse, the age when drug use first occurred, and the primary source of the abused drug(s). Results from more than 15,000 admissions have been collected and analyzed. Mark Parrino, M.P.A., American Association for the Treatment of Opioid Dependence, is the principal investigator of this system.