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RADARS[®] System Data for Evaluation of REMS

On December 4, 2009, drug manufacturers participating in the Industry Working Group (IWG) presented their recommendations for curbing the abuse, misuse, and overdose associated with extended-release prescription opioids to the Food and Drug Administration (FDA). The recommendations are intended to assist the FDA in developing a class wide REMS for certain extended-release opioid products.

Many of the recommendations focused on the evaluation of REMS, a mandatory component, and the metrics involved in the evaluation. This topic is of particular interest to the RADARS System as many of the metrics currently being discussed for REMS evaluation are metrics that can be assessed using RADARS System data.

Important metrics to be assessed by REMS evaluation include:

- Monitoring of abuse, misuse and diversion trends as a surrogate for appropriate use – The RADARS System monitors rates of abuse, misuse and diversion over time. Monitoring the changes in these rates can provide insight into the effectiveness of REMS initiatives or if REMS initiatives need to be reevaluated.
- Monitoring overdose in unintended populations – Arguably a visible outcome of prescription drug exposure is overdose, whether accidental or intentional. The RADARS System can provide data on overdose in unintended populations to assist drug manufacturers in evaluating their efforts at reducing overdose in these populations.
- Monitoring of patient and non-patient populations – Prescription drug abuse as a public health concern impacts patients as well as non-patient populations. The RADARS System has the ability to distinguish patients from non-patients in some of its Programs.

Richard Dart, M.D., Ph.D, Executive Director of the RADARS System stated, “We have been surprised to find that some subscribers to the RADARS System do not realize that they can use our data for REMS evaluation without additional expense.”

Regulatory News

The presentations and webcast of the FDA meeting on December 4th can be found at:

<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm193499.htm>



Additional information on how the RADARS System can be used in evaluation of REMS can be found in the RADARS System docket submission to the FDA at

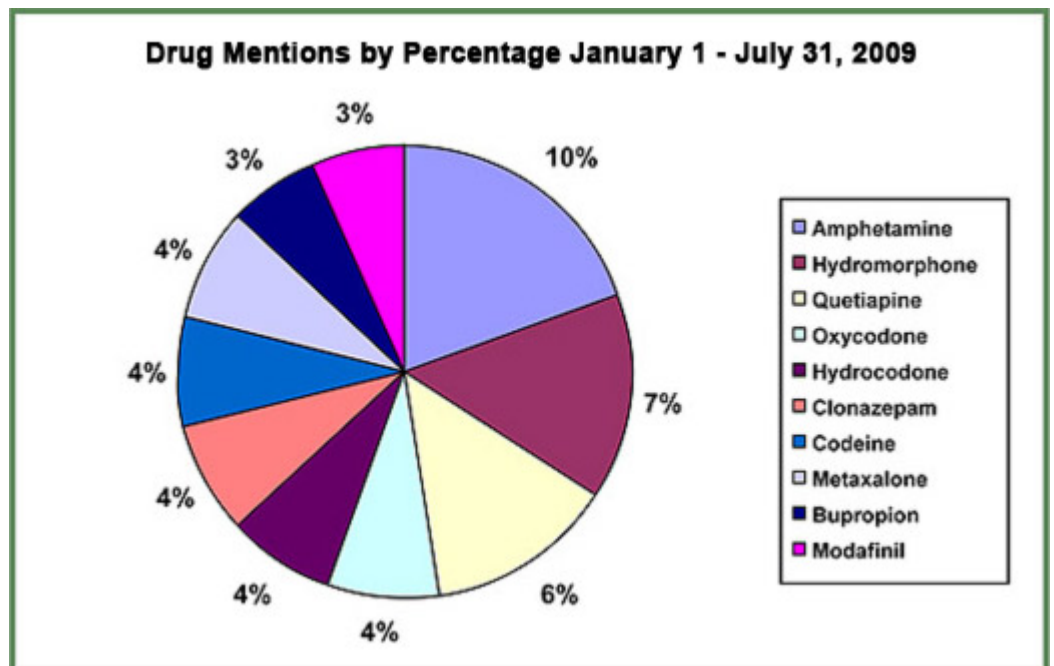
http://www.radars.org/Portals/1/FDA_REMS_Evaluation_062809.pdf

RADARS® System Reports on Current Trends In Prescription Drug Abuse as Observed on Erowid

The RADARS System works ardently to stay abreast of current trends in prescription drug abuse. While the RADARS System currently monitors a panel of several opioid and stimulant products, there are a number of other products including muscle relaxants, anti-psychotics and sleep aids that are concerns for abuse, misuse and diversion.

One tool employed by the RADARS System to evaluate current abuse trends is Erowid (www.erowid.org). Erowid is an online, member-supported organization where individuals can anonymously post their experiences with various psychoactive substances whether illicit, over-the-counter or prescription. The “vaults” of Erowid provide a detailed account of individual experiences with psychoactive substances. While some accounts or “postings” are more telling than others, most contain the drug substance(s) involved, date, route of administration, dose, gender, weight and outcome of the individual’s experience with the substance(s).

Using the Erowid postings from the first seven months of 2009, the RADARS System reviewed each experience report related to prescription drugs to determine which prescription drugs are most mentioned and if there are significant changes in the drugs mentioned from year-to-year. The chart below demonstrates the ten most frequently mentioned prescription drugs (by percentage) on Erowid for the first seven months of 2009.



Dr. Richard Dart, Executive Director of the RADARS System commented, “While we understand the limitations of Erowid, we certainly find the postings to be useful in determining which prescription products are of current or continued interest and how the specific products are being discussed.”



In Memoriam: Dr. James A. Inciardi



The RADARS System was greatly saddened at the passing of our respected colleague, Dr. James A. Inciardi. Dr. Inciardi passed away on November 23.

In addition to serving as Principal Investigator of the RADARS System's Drug Diversion Program, Dr. Inciardi was co-director of the Center for Drug and Alcohol Studies at the University of Delaware and professor of sociology and criminal justice.

Born on Nov. 28, 1939 in Brooklyn, Dr. Inciardi spent his young adulthood in New York City where he graduated from Fordham University. He received his Ph.D. in 1973 from NYU, and then relocated to Miami, where he held several positions in academics and research at the University of Miami. During the early 1970s, he continued to work in the Division of Addiction Sciences in the Department of Psychiatry at the University of Miami, including director of the National Center for the Study of Acute Drug Reactions at the University of Miami School of Medicine.

Dr. Inciardi became a professor at the University of Delaware in 1976, and the institution became his academic home for the remainder of his career. He was the director of Criminal Justice in the Department of Sociology and Criminal Justice at Delaware, from 1976 to 1991, and became well-known as a teacher of criminal justice. Dr. Inciardi was a member of the College on Problems of Drug Dependence, and was an associate of the Internal Advisory Committee, Executive Office of the President, Office of National Drug Control Policy. In 1994, he received the Outstanding Scholar Award from the University of Delaware and was awarded a Merit Grant from the National Institute on Drug Abuse, and in 1995 he was named a fellow of the American Society of Criminology. In 1991, Dr. Inciardi founded the Center for Drug and Alcohol Studies (CDAS) at the University of Delaware within the Department of Sociology and Criminal Justice in the College of Arts and Sciences and continued as an exceedingly active co-director of the center until his death.

As a lasting memorial, Dr. Inciardi published more than 500 articles, chapters, books and monographs in the areas of substance abuse, criminology, criminal justice, public policy, AIDS, medicine and law. In the course of his distinguished career, he amassed a wealth of friends in a range of organizations such as NIDA, SAMHSA, CDC and ONDCP and here at the RADARS System.

Personally, Dr. Inciardi loved jazz, scuba diving, traveling and collecting art from Latin America. While his battle with cancer curtailed many of these activities in recent years, he remained remarkably positive and upbeat, and never gave up hope in his fight.

He is survived by his wife, partner and collaborator, Hilary Surratt, and by his three children, Craig, Brooks and Kristin.

Recent RADARS System Publications and Presentations

The RADARS System has submitted three abstracts to the College on Problems of Drug Dependence (CPDD) for their 72nd Annual Meeting from July 12th to 17th, 2010 in Scottsdale, Arizona.

- Buchholtz C, Reifler L, Bailey JE, Dart R. Chewing Then Swallowing In Self Reported Non-Medical Opioid Use by College Students as Reported by the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) System.
- Cleland C, Rosenblum A, Fong C, Parrino M. Prescription Opioid Abuse Predicts First Admission into Methadone Treatment.
- Zosel A, Dart R. Fatal Methadone Exposures From Liquid, Tablet and Diskette Preparations as Reported by the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS[®]) System.

[Complete Publication List](#)

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Save the Date!

2010 RADARS System Annual Scientific Meeting

Wednesday, April 14, 2010
Bethesda, MD

Upcoming Meetings of Interest

- Food and Drug Law Institute Conferences, January 25-26, 2010. Washington, District of Columbia
- American Academy of Pain Medicine, February 3-6, 2010. San Antonio, Texas
- Drug Information Association Euro Meeting, March 3-10, 2010. Monaco, France

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RADARS System Mission Statement

The RADARS System provides timely, product specific and geographically-precise data to the pharmaceutical industry, regulatory agencies, policymakers and medical/public health officials to aid in understanding trends in the abuse, misuse, and diversion of prescription drugs in the United States.

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Rocky Mountain Poison and Drug Center and Denver Health

The RADARS System is a governmental nonprofit operation of the [Rocky Mountain Poison and Drug Center](#) (RMPDC), an agency of [Denver Health](#) (DH). The RMPDC has been in operation for more than 50 years, making it one of the oldest poison control centers in the nation. DH is the safety net hospital for the City and County of Denver and is the Rocky Mountain region's academic Level I trauma center and includes Denver Public Health, Denver's 911 emergency medical response system, nine family health centers, 12 school-based clinics, NurseLine, correctional care, Denver CARES, the Denver Health Medical Plan, and the Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics.



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