IN THIS ISSUE

RADARS® SYSTEM News

Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System

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RADARS System Launches New Signal Detection System

The RADARS System has successfully launched its fifth signal detection system which reports prescription drug abuse and diversion cases involving health care workers in the United States. Currently a subset of the Drug Diversion and Key Informant Signal Detection Systems, the Impaired Health Care Worker Signal Detection System surveys criminal justice professionals regarding cases involving health care workers and surveys health care workers seeking treatment for dependence or addiction from a variety of treatment facilities throughout the nation. Future expansion of this signal detection system involves capturing data on impaired health care workers from both the Poison Center and Opioid Treatment Program Signal Detection Systems and reporting these data within the Impaired Health Care Worker Signal Detection System.

Prescription drug abuse affects a wide variety of populations in the United States, including health care professionals. The U.S. Drug Enforcement Agency notes that while a large majority of practitioners abide by controlled substances laws and regulations, impaired health professionals are one source of controlled substance diversion.[1]

"This signal detection system will provide information on a very unique population who has ready access to prescription medications," said Richard C. Dart, M.D., Ph.D., RADARS System Executive Director. "It will be interesting to see how this particular population of people is affected by prescription drug abuse and diversion."

The RADARS System has already analyzed first and second quarter 2007 data from this signal detection system.

1. U.S. Drug Enforcement Agency, Office of Diversion Control Informational Brochure. Drug Addiction in Health Care Professionals. Available at http://www.deadiversion.usdoj.gov/pubs/brochures/drug_hc.htm

RADARS System Adds Prescription Stimulants to Surveillance System

Effective July 2007, the RADARS System has added prescription stimulants to the list of drug classes monitored by the surveillance system.

"The addition of prescription stimulants to the RADARS System will increase current understanding of prescription drug abuse in the nation, provide a more clear idea of how these medications are being abused, misused and diverted and will provide information on what populations are affected," said Richard C. Dart, M.D., Ph.D. Executive Director of the RADARS System.

Prescription stimulants effectively treat and minimize the effects of certain neurological disorders including narcolepsy and attention deficit hyperactivity disorder (ADHD) which affects approximately 2 million children in the United States.[1,2]

"In recent years there have been reports of non-medical use of these medications, which should be closely monitored," said Dart. "But, we must remember that when used therapeutically, these prescription stimulants are effective and are helping many, many people across the nation today."

The RADARS System currently monitors nine drug substances; the addition of prescription stimulants will bring the total to 11 substances. These 11 substances include 77 specific products, each of which can be reported on. Third quarter 2007 prescription stimulant data will be evaluated by March 2008.

1. National Institute of Mental Health. Attention Deficit Hyperactivity Disorder. Available at http://www.nimh.nih.gov/health/publications/adhd/complete-publication.shtml
2. National Institute on Drug Abuse. Research Report Series - Prescription Drugs: Abuse and Addiction. Available at http://www.drugabuse.gov/ResearchReports/Prescription/prescription4.html#Stimulants

Food and Drug Administration Amendments Act Signed into Law

On September 27, 2007, the President signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007 (FDAAA) which provides the FDA with new authority and resources to more closely monitor drug safety.

Commissioner Dr. Andrew von Eschenbach said, "The act continues essential and successful programs that will enhance FDA's ability to more efficiently and effectively regulate drugs, biological products and medical devices. It will provide enormous benefit to the public health by allowing FDA to continue to deliver safe and effective medical products to Americans every day"[1]

The new provisions of the act include:

- *Prescription Drug User Fee Act (PDUFA)*— allows FDA to collect fees from drug companies to help fund reviews of new drugs. The act enables shorter review times and a more predictable review process, while still maintaining high-quality reviews.
- *Medical Device User Fee and Modernization Act (MDUFMA)*—allows for user fees, and will allow FDA to make significant improvements in the medical device review program.
- *Best Pharmaceuticals for Children Act (BPCA)*—encourages more studies in children and promotes the development of treatments for children.
- *Pediatric Research Equity Act (PREA)*—continues FDA's authority to require studies in children concerning certain medical products and under other specific circumstances.[2]

The new law also provides for:

- additional encouragement of specialized pediatric medical device development
- the creation of a foundation (Reagan-Udall) to modernize product development, accelerate innovation, and enhance product safety
- food safety provisions
- advisory committee provisions
- clinical trial registries
- provisions intended to enhance drug safety[2]

1. U.S. Department of Health and Human Services News Release. New Law Ensures Access to Medical Treatment and Information. Available at http://www.hhs.gov/news/press/2007pres/09/pr20070927e.html
2. FDA Consumer Update. Renewed Legislation Improves Safety of FDA-Regulated Products: Frequently Asked Questions. Available at http://www.fda.gov/consumer/updates/legislation092707.html

Food and Drug Administration Introduces New Drug Safety Newsletter

In response to the 2006 Institute of Medicine (IOM) report, the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) has introduced a new quarterly drug safety newsletter. The *Drug Safety Newsletter* launched on September 18, 2007 in response to the IOM recommendation that communication with health care professionals regarding potential drug safety concerns be increased.

FDA Commissioner, Andrew von Eschenbach, M.D. commented that "the role of this newsletter is to keep our medical community posted—including physicians, dentists, nurses, and pharmacists—about selected postmarketing drug safety reviews, important emerging drug safety issues, and recently approved pharmaceutical prioducts."[1]

Articles in the newsletter will primarily report any important safety findings, usually found following review of specific adverse drug events reported to the FDA and will provide information from clinical trials. Every issue will report on postmarket findings for newly approved pharmaceutical products.

The first issue of the newsletter is available on the web and subscription is free.

1. U.S. Food and Drug Administration Drug Safety Newsletter. Fall 2007; 1. Available at http://www.fda.gov/cder/dsn/default.htm

NDIC Releases 2008 National Drug Threat Assessment

The National Drug Intelligence Center (NDIC) has released the National Drug Threat Assessment for 2008. This assessment provides policymakers with a predictive report on potential threats involving drugs, gangs and violence.

Strategic findings for pharmaceutical drugs include:

- Pharmaceutical drug abusers in a growing number of states are having greater difficulty in acquiring drugs through prescription forgery, doctor-shopping, or indiscriminate prescribing.
- Criminal groups and abusers occasionally steal pharmaceutical drugs from delivery trucks that transport the drugs from manufacturers to wholesale or retail distributors.
- The number of Internet pharmacies selling controlled and noncontrolled pharmaceutical drugs has increased.
- Methadone-related deaths and overdoses have increased sharply since the 1990s.
- Parents are less likely to talk to their children about the dangers of prescription drug abuse than they are about heroin, cocaine, crack, MDMA, marijuana, or alcohol abuse.[1]

1. National Drug Threat Assessment 2008. U.S. Department of Justice-National Drug Intelligence Center. Available at http://www.usdoj.gov/ndic/topics/ndtas.htm

Recent Publications & Events

Using RADARS System Data

The RADARS System is committed to conducting research for the benefit of the scientific community and the general public. This research contributes to the body of scientific literature related to the abuse, misuse and diversion of prescription drugs. For a complete listing of current publications, please visit www.radars.org.

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Q&A

Q. How quickly are RADARS System data reported?

A. RADARS System subscribers receive information approximately four months after the end of a given quarter. By this time, the data will have gone through extensive quality control practices and two rates of abuse and diversion will have been calculated depicting prescription drug abuse and diversion from two unique perspectives. This timeframe is much more timely than other sources of data.

Did you know?

- The RADARS System newsletter will now be produced on a quarterly basis in 2008. The first quarter issue will be available in March 2008.
- The RADARS System has updated its website. Please visit www.radars.org for more information on the signal detection systems, services and benefits, and current research activities.

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RADARS System Mission Statement

The RADARS System provides timely and geographically-specific 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.

RMPDC 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. DH 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.

DENVER HEALTH
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