

RADARS[®] SYSTEM

News

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

First Quarter 2009

Volume 4, Issue 1

In This Issue

[RADARS System 3rd Annual Scientific Meeting](#)

[RADARS System Launches College Signal Detection Survey](#)

[FDA Requires REMS for Certain Opioid Drugs](#)

[Recent RADARS System Publications and Presentations](#)

[Upcoming Meetings of Interest](#)

[Contact Information](#)

[Mission Statement](#)

[RMPDC and DHHA](#)

RADARS System Hosts Third Annual Scientific Meeting: *Risk Management of Scheduled Drugs- Where Are We Now? Where Are We Headed?*

The Third Annual RADARS System Scientific Meeting, *Risk Management of Scheduled Drugs – Where Are We Now? Where Are We Headed?* took place on April 23, 2009, in Bethesda, MD., marking the seventh anniversary of the RADARS System. Ninety six attendees, including researchers and representatives from the pharmaceutical industry and regulatory agencies, participated in the meeting.

“This meeting was an opportunity to stimulate discussions on some of the current challenges facing stakeholders today including development of a class-wide REMS and effective intervention strategies,” said Richard C. Dart, M.D., Ph.D., Executive Director of the RADARS System. “Guest speakers presented various stakeholder perspectives on REMS, as well as the industry perspective on interventions and the unintended consequences of past interventions.”

Dr. Dart provided an overview of 2008 RADARS System data on prescription drug abuse, misuse and diversion as well as data supporting the use of the RADARS System to evaluate the effectiveness of interventions using Kentucky’s Operation UNITE as an example.

Leading authorities in REMS and experts in public health interventions served as speakers at the meeting. The following describes the guest speakers and their presentation topics.

- Nabarun Dasgupta from the University of North Carolina presented *Community-Oriented Interventions and Roles of the Pharmaceutical Industry*. Dasgupta presented findings from an overdose intervention program called, “The Chronic Pain Initiative & Project Lazarus” which was designed and implemented to prevent overdose deaths in Wilkes County, North Carolina, where the poisoning mortality rate is five times higher than the national average.
- Karen Simone and Jennifer Bubar from the Northern New England Poison Center presented *Maine Attempts to Treat Pain and Addiction – Is Treatment Part of the Problem?* Simone and Bubar presented data from the Northern New England Poison Center evaluating the effects of a 2001 change to the state’s methadone policy which allowed methadone maintenance programs to provide take home methadone doses.
- Dr. Juergen Schmider from Cephalon presented *New Developments and Challenges in Risk Management of CII Opioids*. Dr. Schmider described the current struggle facing pharmaceutical companies in trying to maintain adequate pain management for patients while protecting public health. These struggles have been brought on by the perception of prescription opioid abuse and diversion.
- Josephine Torrente of Hyman, Phelps and McNamara, P.C. presented *FDA’s “Class-Wide” Risk Evaluation and Mitigation Strategies for Opiates: A Legal Perspective*. Torrente discussed the use of REMS by the FDA to ensure the benefits of a drug continue to outweigh the risks which may not be discovered until

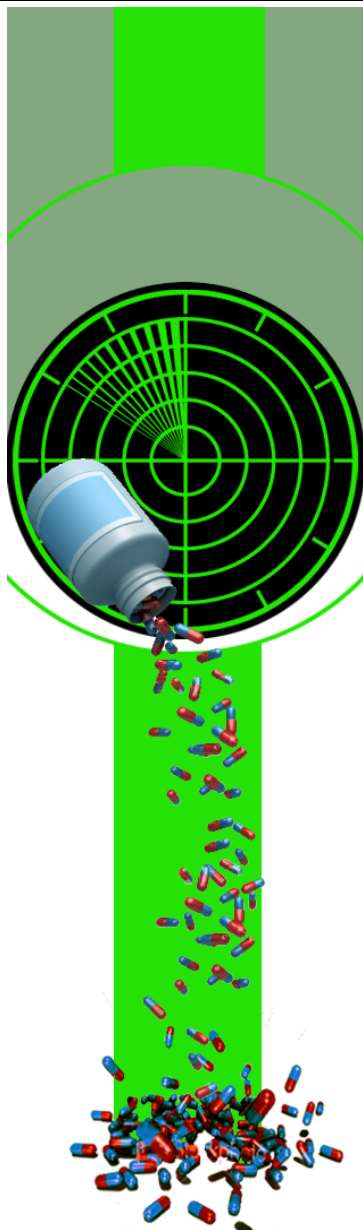
Regulatory News

For complete information on the REMS requirements for certain opioid drugs, please visit [FDA REMS Questions and Answers](#)

Did You Know?

The RADARS System is a member of the Pain Care Forum.





well after a product is launched. Suggested components of REMS such as the certification of doctors and pharmacists could prove burdensome for patient access.

- Dr. Ernest Boyd of the Ohio Pharmacists Association presented *Compliance Issues with Class-Wide Risk Evaluation and Mitigation Strategies: A Pharmacist's Perspective*. Boyd stated that pharmacists are a prominent source of information for pharmaceutical companies due to their front line experiences with patients. Further, considerations for REMS must include; registries are cumbersome for pharmacists, patchwork REMS instead of uniform REMS will be confusing, certain pharmacies may have to close their doors if REMS solutions are not cost effective.
- Will Rowe of the American Pain Foundation presented *Balanced Policy and Practice in Risk Management: The Pain Patient Perspective*. Rowe discussed that the misuse and abuse of opioids is a well known issue. However, what may be less well known is the issue of under treatment of pain. Seeking the balance between these issues is difficult but must be a consideration in REMS if this policy is to be successful.

Please visit www.RADARS.org for a summary of the meeting.

[TOP](#)

RADARS System Launches its Seventh Signal Detection System: College Survey

After three successful pilot studies, the RADARS System launched the College Survey Signal Detection System in December 2008. The College Survey is an online, national survey completed by college students each semester and after the summer. Each administration of the survey collects data from 2000 respondents sampled equally from the four regions of the U.S. and captures data on respondents endorsing non-medical use of prescription drugs. Data provided by the College Survey are product specific, geographically precise and provide details including source of the drug and route of administration.

"College students using prescription drugs for non-medical purposes represent an important group to understand" said Richard C. Dart, M.D., Ph.D., RADARS System Executive Director. "For many people, college represents the first opportunity to experiment with drugs, both illicit and prescription. Our hope is that by understanding more about this group, more effective, targeted education efforts can be developed."

The RADARS System has already begun analyzing data from the College Survey Signal Detection System, and these data are available by subscription.



[TOP](#)

FDA Requires REMS for Certain Opioid Drugs

On February 6, 2009 the Food and Drug Administration (FDA) sent letters to 16 pharmaceutical manufacturers of select extended-release opioid drugs informing the manufacturers that a risk evaluation and mitigation strategy (REMS) will be required to ensure that the benefits of the drugs continue to outweigh the risks. Both branded and generic manufacturers were sent letters indicating that a REMS will be required.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) has provided the FDA with increased authorities to enforce compliance with REMS requirements. Over the past decade, attempts to curb the abuse, misuse, diversion of prescription opioids have been largely ineffective as rates for these events have increased.

According to the FDA, REMS is an evolution of the Risk Minimization Action Plan (RiskMAP) previously used to assess the risk of drugs and biological products on a voluntary basis. FDAAA of 2007 provides the FDA with an arsenal of enforcement tools to ensure compliance with REMS requirements including monetary penalties and ultimately removing a product from the market if a REMS is not provided.

This mandate by the FDA is the largest of its kind and poses many challenges for drug companies, patients and other key stakeholders. As a result, the FDA announced a series of meetings with stakeholders to discuss key FDA initiatives for the class-wide REMS and to solicit input on items to be included in the REMS. On February 10, 2009 the FDA held the first of these meetings, *FDA Regulatory Processes and Standards for Review and Approval of Opioid Analgesics: An Education Primer*. The next meeting held exclusively with the pharmaceutical manufacturers took place on March 3rd. On May 4th and 5th the FDA held a meeting to gain perspective on the class-wide REMS from researchers, prescribers, pharmacists, insurers, risk managers and patient advocates. Finally, public meetings were held on May 27th and 28th. The RADARS System was in attendance at the February 10th and May 4th meetings and had two presentations at the May 27th and 28th meeting.



[TOP](#)

Recent RADARS System Publications and Presentations

- Varney SM, Buchanan JA, Lavonas EJ, Campagna EJ, Bailey JE, Dart RC. How Acetaminophen-Opioid Patients Die. North American Congress of Clinical Toxicology Conference. Toronto, ON. September, 2008.
- Spiller HA, Lorenz DJ, Bailey JE, Dart RC. Epidemiological Trends in Abuse and Misuse of Prescription Opioids. *Journal of Addictive Diseases*. 28:30-136, 2009.

[Complete Publication List](#)

[TOP](#)

Upcoming Meetings of Interest

Did You Know

RADARS System data can be used to evaluate the effectiveness of interventions.

- European Association of Poison Centres and Clinical Toxicologists, May 12-15, 2009. Stockholm, Sweden
- Society for Academic Emergency Medicine, May 14-17, 2009. New Orleans, Louisiana
- American Psychiatric Association, May 16-21, 2009. San Francisco, California
- American College Health Association, May 26-30, 2009. San Francisco, California
- Council of State and Territorial Epidemiologists, June 7-11, 2009. Buffalo, New York
- College on Problems of Drug Dependence, June 20-25, 2009. Reno, Nevada
- Drug Information Association, June 21-25, 2009. San Diego, California

[TOP](#)

Contact Information

Account or Subscription

Inquiries:

[Matt Jachetta](#)

Account Manager

303-739-1229

Signal Detection System or

Data Inquiries:

[Elise Bailey](#)

Business Manager

303-739-1297

Media Inquiries:

[Public Relations](#)



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.

[TOP](#)

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.



RADARS® System ▪ 777 Bannock Street ▪ Mail Code 0180 ▪ Denver, CO 80204

To unsubscribe, please reply to this email with "unsubscribe"

Questions or comments? Email the RADARS System at radars@rmpdc.org