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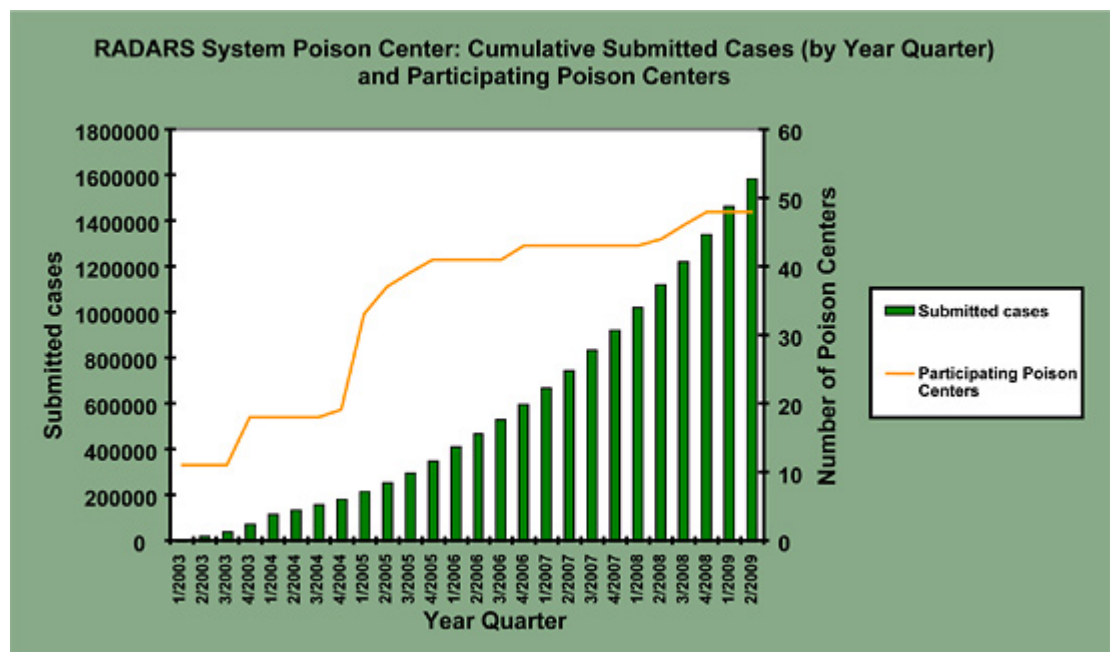
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RADARS[®] System Poison Center Program Reviews 1.5 Million Cases To Date

As of second quarter 2009, the RADARS System Poison Center Program has reviewed nearly 1.5 million cases submitted from participating poison centers and the number submitted each quarter has increased to over 120,000.



Regulatory News

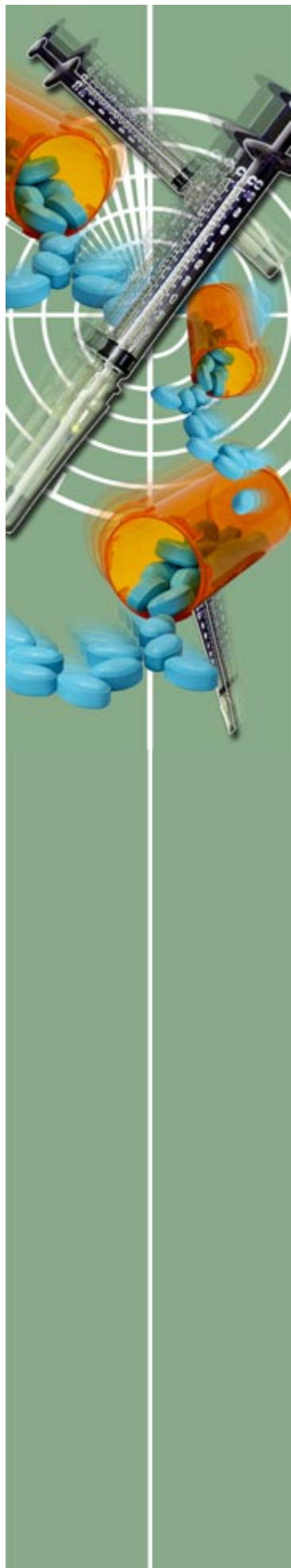
FDA Launches *Safe Use Initiative* aimed at reducing preventable harms and identifies abuse and misuse of prescription drugs as preventable harms to be addressed.

The RADARS System Poison Center Program has collected data on a panel of opioid products as well as stimulants and muscle relaxants since first quarter 2003. The number of participating poison centers continues to increase, ensuring that the Poison Center Program provides a geographically and quantitatively robust sampling of prescription drug exposures reported by the US population.

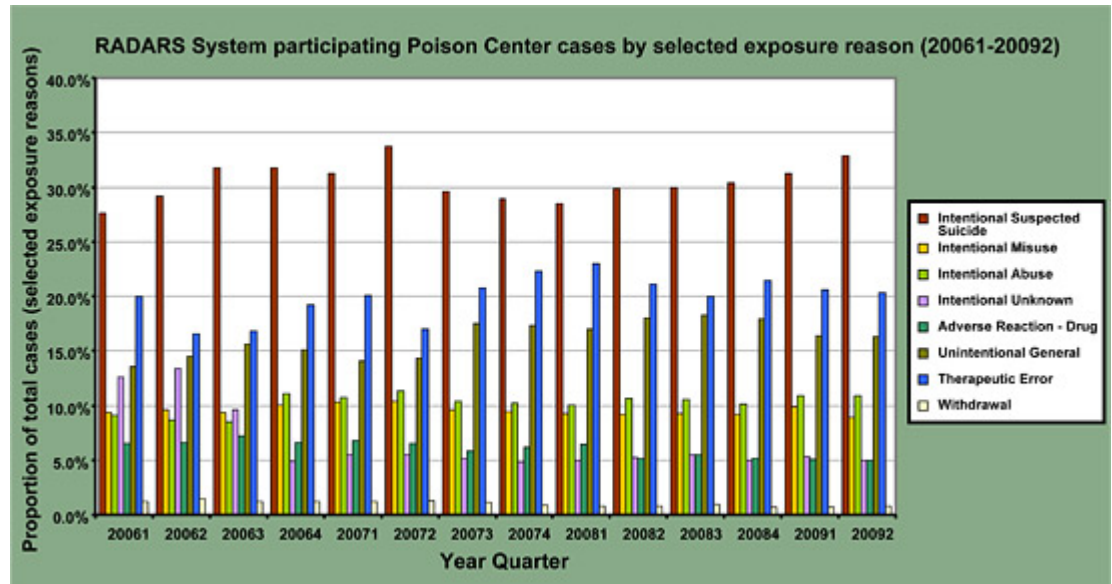
These data provide a rich data set which RADARS System subscribers use to monitor abuse and misuse of prescription drugs. Additionally, Poison Center Program data have been used in numerous publications addressing public health concerns, including:

- Bailey JE, Campagna E, Dart RC. Reporting for the RADARS[®] System Poison Center Group. The Underrecognized Toll of Prescription Drug Abuse on Young Children. *Annals of Emergency Medicine*. 53:419-424, 2009.
- Smith M, Irish W, Wang J, Haddox J, Dart R. Detecting Signals of Opioid Analgesic Abuse: Application of a Spatial Mixed Effect Poisson Regression Model Using Data from a Network of Poison Control Centers. *Pharmacoepidemiology and Drug Safety*. 17:1050-1059, 2008.
- Kirtland MN, Bailey JE, Dart RC. Suicide and Gender: Characterization Using RADARS[®] System Poison Center Data. American Psychiatric Association Conference. Washington, DC. May, 2008.





Further, data submitted to the Poison Center Program provide the opportunity for numerous special analyses including the graph below showing a breakdown of the most commonly reported exposure reasons. Intentional Suspected Suicide is the most prevalent exposure reason each quarter followed by Therapeutic Error, Unintentional General, Intentional Abuse and Intentional Misuse. The proportion of cases per exposure reason remains consistent across quarters.



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FDA Reopens Docket On Opioid Risk Evaluation and Mitigations Strategies (REMS)

The US Food and Drug Administration (FDA) has decided to reopen the docket on Opioid REMS for comments until October 19, 2010. This follows months of hearings, more than 2000 comments from individuals and stakeholders submitting to the REMS docket, and the release of the draft guidance for REMS in October,

Several components of the REMS for certain opioid drugs have created controversy among stakeholder groups. These include the Agency's decisions to focus solely on the extended-release opioid products, to require generic manufacturers to provide a REMS, to mandate the evaluation of REMS by drug sponsors, and on the metrics involved in the evaluation.

This extended time for comments will allow FDA to solicit additional feedback from stakeholders prior to finalizing the *Guidance for Industry: Format and Content of REMS, REMS Assessment, and REMS Modifications*.



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FDA and Interim REMS

The approval of King Pharmaceutical's EMBEDA™ is an indication that the FDA is continuing to approve new opioid products despite the lack of a finalized guidance document for REMS. This demonstrates the FDA wants to maintain accessibility of opioids for patients with pain. According to John Jenkins, director of the FDA's Office of New Drugs, the FDA's required class-wide REMS for extended-release (ER) opioids and methadone will not be in place until next year; however, in the interim, "We have products coming through the pipeline. We have to decide what to do with them while we are working on this class REMS program."¹

New opioids that are being considered may be required to submit an "interim REMS" for approval. Exalgo™, developed by Neuromed Pharmaceuticals and licensed to Covidien, is one such product. If approved, Exalgo, an ER hydromorphone product will need an approved REMS prior to product launch.

Manufacturers of other ER opioid products like Exalgo that are currently seeking an approval are moving forward on how to prepare their REMS with the newly released draft guidance from the FDA.



¹ <http://www.allbusiness.com/legal/health-care-law-drug-medical-devices-approval/13041717-1.html> | Neuromed, Covidien Drug 'Unique' No-Vote Panel: Exalgo Approval Needs Tight Abuse Safeguards

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New Formulation of OxyContin®

On September 9, 2009, an FDA panel recommended a reformulated version of OxyContin that is designed to make tampering more difficult. A majority vote was tallied in favor of an inquiry that questioned whether the FDA should approve the application of the reformulated OxyContin.

If this reformulated version is ultimately approved, Purdue Pharma L.P. will replace the current OxyContin formulation with the new one. The reformulated version is harder to crush and more difficult to dissolve, both common methods used by abusers to defeat the extended-release mechanism and access the entire dose immediately. In the case of those attempting to dissolve the pills, the new formulation is designed to form a gel which also slows the release of the drug and will, once dissolved, make it difficult to inject or inhale.

Richard Dart, M.D., Ph.D., Executive Director of the RADARS System commented, "It is widely believed that many individuals who abuse prescription drugs prefer OxyContin. If approved, it will be interesting to see what the impact on abuse rates this will have for all tamper resistant or abuse deterrent formulations."

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Recent RADARS System Publications and Presentations

- Inciardi JA, Surratt HL, Cicero TJ, Kurtz SP, Martin SS, Parrino MW. The 'Black Box' of Prescription Drug Diversion. *Journal of Addictive Diseases*. 28(4) : 332-347, 2009.
- Schneider, MF, Bailey, JE, Cicero TJ, Dart RC, Inciardi JA, Parrino M, Munoz A. Integrating Nine Prescription Opioid Analgesics and/or Four Signal Detection Systems to Summarize Statewide Prescription Drug Abuse in the United States in 2007. *Pharmacoepidemiology and Drug Safety*. (9):778-90, September, 2009.
- Sweet LE, Zolot L, Bailey JE, Dart RC. Where Do Calls Come From? Analysis of RADARS® System Opioid and Stimulant Poison Center (PC) Mentions by Caller Site and Intent. North American Congress of Clinical Toxicology Conference San Antonio, TX. September, 2009.

[Complete Publication List](#)

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Save the Date!

2010 RADARS System Annual Scientific Meeting

April 14, 2010
Bethesda, MD

Upcoming Meetings of Interest

- Academy of Addiction Psychiatry, December 3-6, 2009. Los Angeles, California
- Food and Drug Law Institute, December 4-5, 2009. Washington, District of Columbia
- Academy of Addiction Psychiatry, December 3-6, 2009. Los Angeles, California
- American College of Neuropsychopharmacology, December 6-10, 2009. Hollywood, Florida

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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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