

# RADARS® SYSTEM



# News

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

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## Regulatory News

The FDA will be holding an Advisory Committee meeting on opioid REMS on July 22 – 23, 2010 - Please type the following into web browser.

[http://www.fda.gov/Advisory Committees/Calendar/ucm214816.htm](http://www.fda.gov/AdvisoryCommittees/Calendar/ucm214816.htm)

## The RADARS® System on the Discovery Channel

The RADARS System was recently highlighted on the Discovery Channel's *Discovery Health CME* cable program, an accredited Continuing Medical Education (CME) series for physicians and other health care professionals. Discovery Health CME, in partnership with Integrity CE, produced the episode titled "Critical Issues In Managing Pain With Opioid Therapy." Discovery Health CME focused a segment of the program on the RADARS System. In the segment, Richard C. Dart, M.D., Ph.D., RADARS System Executive Director, explains how the RADARS System collects prescription opioid data from its various programs (Poison Center, Drug Diversion, Opioid Treatment, Survey of Key Informants' Patients and College Survey), that RADARS System data demonstrate that prescription opioid abuse, misuse and diversion is widespread throughout the nation, and how RADARS System data can be used to monitor prescription drugs with abuse liability.

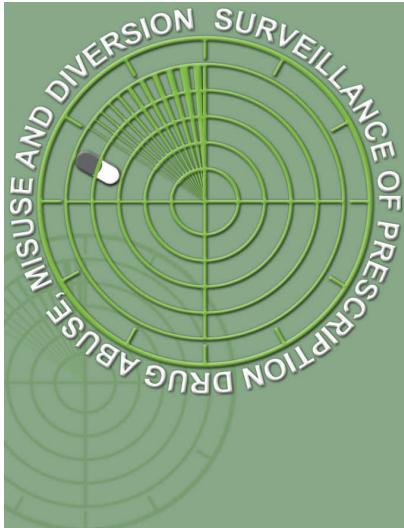
A separate segment of the program involved a roundtable discussion with a panel of esteemed experts including Gilbert Fanciullo, M.D., Director of the Pain Management Center, Dartmouth-Hitchcock Medical Center, Bill H. McCarberg, M.D., Founder of the Chronic Pain Management Program, Kaiser Permanente and Lynn R. Webster, M.D., Medical Director of Lifetree Clinical Research and Pain Clinic commented on RADARS System data. In particular, Dr. Fanciullo stated how RADARS System data are "extremely useful" in alerting the medical community as to where abuse, misuse and diversion of prescription opioids is taking place in the United States.

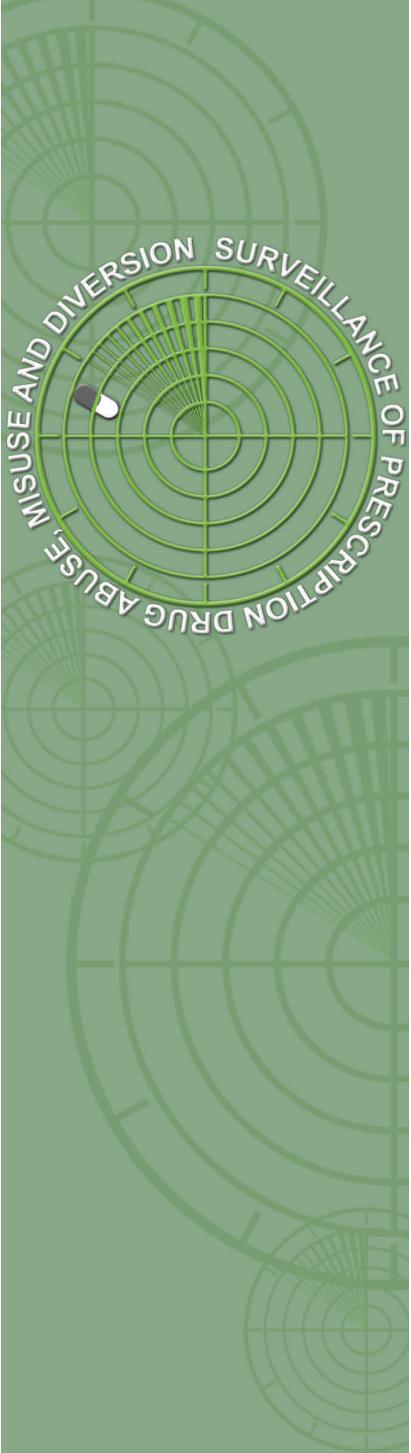
The broadcast aired on June 5, 2010 on the Discovery Channel at 8:00 a.m., Eastern Standard Time and can be viewed via webcast on Discover Health CME's website at

[Discovery Health CME – Critical Issues In Managing Pain With Opioid Therapy – Part 3](http://link.brightcove.com/services/player/bcpid90015301001?bclid=89784554001&bctid=90092387001)  
<http://link.brightcove.com/services/player/bcpid90015301001?bclid=89784554001&bctid=90092387001>



The Discovery Channel CME is an innovative approach to earn free CME credit. To learn about earning CME credits for this broadcast, please visit Discovery Health CME <http://discoveryhealthcme.discovery.com/risk/credit/credit.html>





## Status Update on DAWN Responses to Special Requests: A Response from Albert M. Woodward, M.D., Ph.D.

At the recent RADARS System Annual Meeting, Dr. Albert Woodward from the Drug Abuse Warning Network (DAWN) discussed the current state of DAWN responses to special data requests which have been impacted by recent developments.

DAWN is a public health surveillance system operated by the Substance Abuse and Mental Health Services Administration (SAMHSA) that monitors drug-related hospital emergency department (ED) visits and drug-related deaths to track the impact of drug use, misuse, and abuse in the U.S.

### Context/Background:

Over the last several years, DAWN staff in the Office of Applied Studies (OAS) have spent an increasing proportion of their time responding to special data requests. In the first 5 months of 2010, the number of these requests was well over 100. These have encompassed a wide variety of requests, with the overwhelming majority for adverse events of prescription/OTC drugs or supplements – requests from FDA, pharma, and contract research organizations working for pharma for Risk Evaluation and Mitigation Strategy (REMS) reporting requirements. The remaining requests include public health agencies (city, etc), researchers, hospital EDs, and law enforcement entities.

The recent designation of the OAS as a federal statistical unit requires the OAS to continually examine all analytic and dissemination activities emanating from outside investigators to ensure that the Office meets the requirements of the Confidential Information Protection and Statistical Efficiency Act (CIPSEA). OAS has provided access to de-identified, unweighted ED data through a secure online query system called DAWN Live! A recent review of the DAWN Live! Website protocols resulted in OAS closing access to Dawn Live! to individuals other than those who provide OAS with data. As a result, CIPSEA has in effect caused the shut down of DAWN-Live!, cutting off responses to all but contact persons at participating hospital EDs.

Special data requests are still coming in at the same rate as before and requestors are being notified of the limitations in responding to these special requests. At the same time, DAWN reporting has shifted away from responding to special requests to reporting on topics consistent with SAMHSA's mission as a public health agency focused on behavioral health prevention and treatment. Also at the same time, OAS is experiencing significant personnel and resource constraints, making it impossible for OAS to continue to respond to external requests to the same extent that it was able to do in the past.

### Planned Steps to Address Situation:

OAS staff have met with legal counsel in the Office of the General Council of SAMHSA and the OAS CIPSEA coordinator to discuss the determination of designated CIPSEA agents, on-site monitoring of agents, instructions to agents on use of data, developing security and dissemination protocols, and so forth. OAS staff also are working diligently with SAMHSA technical support personnel and SAMHSA legal counsel to develop a method for permitting greater access to the DAWN data via a revised DAWN-Live! and the development of DAWN public use files for the SAMHSA website.



## Recent RADARS System Publications and Presentations

- Smith MY, Rosenblum A, Parrino M, Haddox JD, Fong C, Colucci S. Validity of self-reported abuse of prescription opioid analgesics. *Substance Use and Misuse*. 2010; *In Press*.
- Dasgupta N, Bailey JE, Cicero T, Inciardi JA, Parrino M, Rosenblum A, Dart RC. Post-marketing surveillance of methadone and buprenorphine in the United States. *Pain Medicine*. 2010; *In Press*.
- Cicero TJ, Ellis MS, Paradis A, Ortblal Z. Determinants of Fentanyl and Other Potent  $\mu$  Opioid Agonist Misuse in Opioid-Dependent Individuals. *Pharmacoepidemiology and Drug Safety*. 2010; 19: 1-7.
- Cicero T, Inciardi JA, Surratt H, Horbay G, Bordman J, Forster I. Characteristics of Prescription Opioid Abuse in the United States and Canada. *Canadian Journal of Addiction Medicine*. 2010; *In Press*.
- Buchholtz C, Thomasset C, Bailey JE, Dart RC. Administration routes involved in non-medical use of long-acting opioids in the RADARS(R) System College Survey and Poison Center Programs. North American Congress of Clinical Toxicology Conference. Denver, CO. October, 2010.
- Inciardi JA, Surratt HL, Cicero TJ, Rosenblum A, Ahwah C, Bailey JE, Dart RC, Burke JJ. Prescription Drugs Purchased Through the Internet: Who are the End Users? *In Press*, 2010.
- Reifler LM, Droz D, Bartelson BB, Bailey JE, Dart RC. RADARS® System Poison Center opioid abuse and misuse rates over time in states with and without active prescription monitoring programs. American Public Health Association. Denver, CO. November, 2010.
- Reifler LM, Droz D, Bartelson BB, Bailey JE, Schnoll, SH, Dart RC, RADARS System Poison Center Group. Reduction over time in RADARS(R) System Poison Center opioid abuse/misuse rates associated with prescription monitoring programs. North American Congress of Clinical Toxicology Conference. Denver, CO. October, 2010.
- Schnoll SH, Sembower MA, Shiffman S, Varughese S, Ertischek MD, St. Jean E, Rosen S. Non-Medical Use of Extended Release Prescription Stimulants: An Examination of Amphetamine and Methylphenidate. The College on Problems of Drug Dependence. Scottsdale, AZ. June, 2010.
- Varughese S, Rosen S, Ertischek MD, Sembower MA, St. Jean E, Schnoll S. Non-Medical Use Surveillance and Signal Identification of Lisdexamfetamine Dimesylate, a Pro-Drug Stimulant for the Treatment of ADHD. American Psychiatric Association. New Orleans, LA. May, 2010.
- Varughese S, Rosen S, Lindholm A, Ertischek MD, Sembower MA, St. Jean E, Schnoll S. Non-medical use surveillance and signal identification of lisdexamfetamine dimesylate, a pro-drug stimulant for the treatment of ADHD. Canadian Psychiatric Association. Toronto, Canada. September, 2010.

## Upcoming Meetings of Interest

- American Psychological Association, August 12-15, 2010. San Diego, California
- International Society for Pharmacoepidemiology, August, 19-22, 2010. Brighton, United Kingdom
- National Association of Community Health Centers, September 10-14, 2010. Dallas, Texas
- American Society of Crime Laboratory Directors, September 12-16, 2010. Baltimore, Maryland
- Association of Occupational Health Professionals in Healthcare, September 15-18, 2010. Boston, Massachusetts
- American Academy of Pain Management, September 21-24, 2010. Las Vegas, Nevada
- American College of Emergency Physicians, September 28-October 1, 2010. Las Vegas, Nevada
- North American Congress of Clinical Toxicology 2010, October 7-12, 2010. Denver, Colorado

## Did You Know?

A summary of the RADARS System Fourth Annual Scientific Meeting – Evaluation of REMS for Opioids is now available at RADARS.org - Please type the following into web browser.

[http://www.radars.org/  
LinkClick.aspx?fileticket=  
P9lt73X54fE%3d&tabid=1481](http://www.radars.org/LinkClick.aspx?fileticket=P9lt73X54fE%3d&tabid=1481)

## Contact Information

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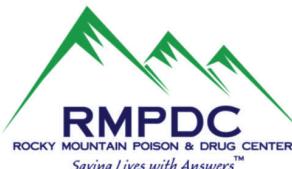
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## RADARS System Mission Statement

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.

## Rocky Mountain Poison and Drug Center and Denver Health and Hospital Authority

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 1 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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