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### Regulatory News

[FDA Approves Opioid Pain Reliever with Required Risk Reduction Plan](#)

### Did You Know?

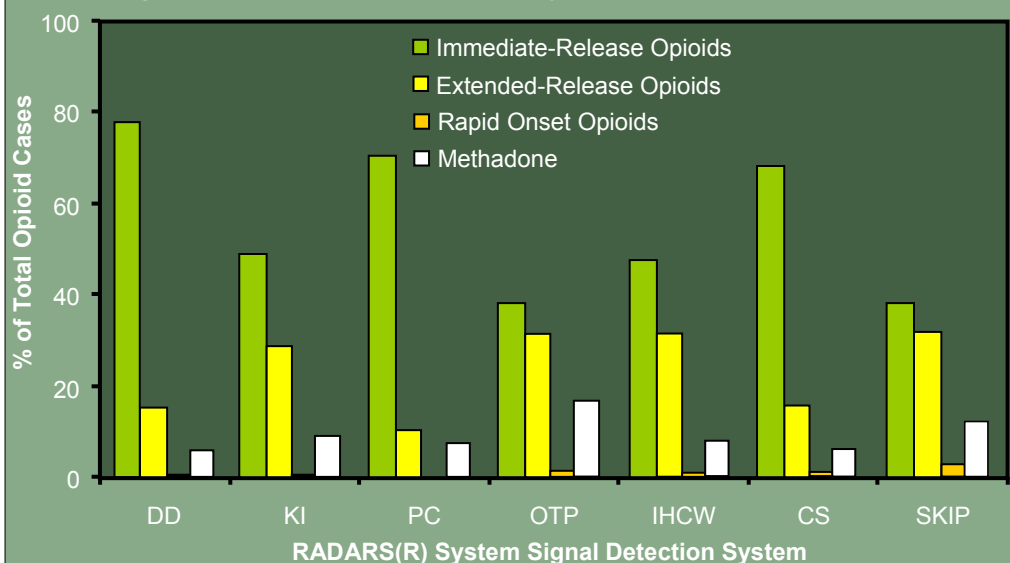
On June 29, 2009 the RADARS System submitted comments to the FDA docket on opioid REMS

## RADARS<sup>®</sup> System Data Indicate Immediate Release Opioids Responsible For Higher Proportion of Misuse, Abuse and Diversion Than Extended Release Opioids.

The Food and Drug Administration (FDA) has focused on extended release (ER) opioid products in the proposed Risk Evaluation and Mitigation Strategy (REMS) for certain opioids. The RADARS System uses multiple detection signals to monitor prescription drug misuse, abuse and diversion (MAD) throughout the United States. According to the RADARS System, the immediate release (IR) opioids are actually responsible for a higher proportion of MAD cases in each signal detection system (see graph below). As such, the FDA's focus on extended release opioids in the proposed REMS for certain opioids may not address the greater problem of prescription opioid MAD and deemphasizes the importance of monitoring IR opioids which could further increase their MAD.

A number of key stakeholder organizations including the American Academy of Pain Medicine have recommended that REMS monitor all opioids. Adding that "The danger in limiting the REMS to slow-release opioids is that if the process of prescribing slow-release opioids were to become more cumbersome than other types of medication, physicians will migrate to short-acting opioids, options will be limited, and healthcare quality will suffer<sup>1</sup>".

Figure 1: Proportion of RADARS(R) System Opioid Data, 2008



Abbreviations: Drug Diversion (DD), Key Informants (KI), Poison Centers (PC), Opioid Treatment Programs (OTP), Impaired Health Care Workers (IHCW), College Survey (CS), Survey of Key Informants' Patients (SKIP).

<sup>1</sup>[http://www.painmed.org/advocacy/advocacy\\_news.html](http://www.painmed.org/advocacy/advocacy_news.html) | FDA REMS on Opioids

## The RADARS System Interviews Dr. Sidney Schnoll: How the Current Proposed REMS for Certain Opioids Will Impact the Pharmaceutical Industry:



*Dr. Sidney Schnoll is an internationally recognized expert in addiction and pain management who has recently applied his extensive experience in academic medicine to the issues of risk management.*

*Dr. Schnoll has served on numerous committees and boards including the Food and Drug Administration's Drug Abuse Advisory Committee NIH study sections, National Board of Medical Examiners test development committees, and was a board member of the College on Problems of Drug Dependence (CPDD). He has received numerous awards including listings in The Best Doctors in America and is a Fellow of CPDD and the American Society of Addiction Medicine.*

*Dr. Schnoll currently serves as a senior scientific advisor to Pinney Associates.*

**RS:** With the FDA's focus primarily on extended release (ER) opioid products, what are some of the unintended consequences of REMS if it is not shifted to include all opioid products?

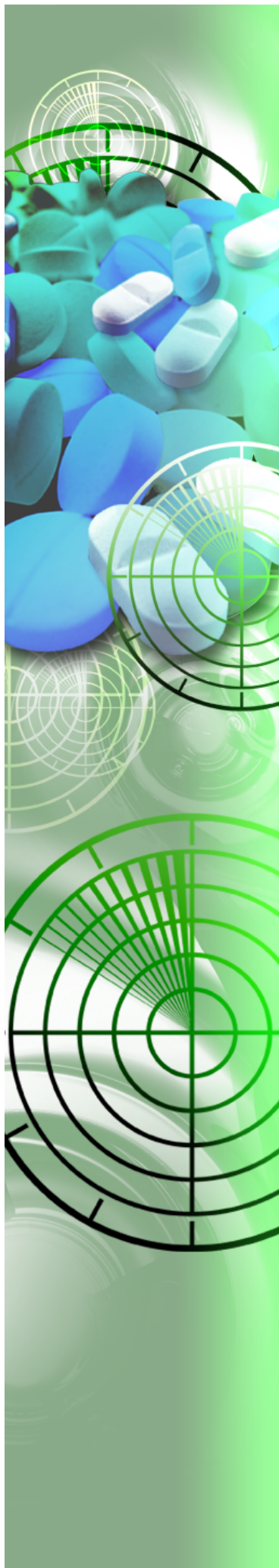
**Dr. Schnoll:** There are numerous issues that can impede the implementation of a REMS for ER opioids: First, the potential shift to IR opioids would mean that larger numbers of pill, tablets etc. will be available for diversion to the illicit market. Not to mention patients whose treatment is not as effective can resort to seeking other sources of pain medication, e.g. the illicit market, the Internet, etc....or there could be an increase in the abuse of illicit opioids like heroin.

Prescribers will drop out of the system and stop prescribing ER opioids and there will undoubtedly be more people unable to get proper treatment for their pain.

**RS:** As the FDA moves closer to guidance for REMS for ER, and possibly IR opioids, what key points in the guidance, as it relates to IR opioids, would you want to be addressed?

**Dr. Schnoll:** First, I don't think there will be an official guidance for the opioids, ER or IR. There will be a guidance for REMS in general. The FDA will make some broad requests for the companies developing any opioid REMS related to prescriber certification, dispenser certification, increased patient and public education, and documentation of patient education by prescribers. After that, the FDA will let the companies figure out how to accomplish all of this.

**RS:** What impact will tamper resistant formulations of opioids have on REMS? Will these formulations, in some part, make it easier for pain patients to receive their prescriptions?



**Dr. Schnoll:** It is not yet clear how the FDA will address the tamper-resistant formulation, one thing is certain, however, there will be no claims allowed in the package insert other than what has been demonstrated in well designed studies. These formulations will probably have to, initially, have the same REMS as other ER products. IR products will have to have their own REMS.

The expenses associated with developing tamper-resistant formulations may place them in a higher tier, which will increase cost and make them less available. Additionally, it will take years of careful post-marketing studies to demonstrate whether or not these products make any difference in abuse and diversion of opioids. They won't make it any easier for patients to get pain medications initially, but if they can prove effectiveness, they more offer some benefit down the road.

**RS:** How important will the role of post-marketing surveillance be for these opioid products?

**Dr. Schnoll:** Post-marketing surveillance will be critical for the existing products and any new products coming in the future. The FDA is very concerned about abuse and diversion and wants to know what is going on. This will be especially true for any new products that want to make claims about reduction in abuse.

**RS:** Depending on the level of scrutiny of REMS, as it pertains to ER opioids, could/will there be less motivation on the part of pharma to promote these drugs?

**Dr. Schnoll:** This is a difficult question to answer, I'm not sure there will be less promotion, but there could be a disincentive for the development of new products and this would be a major setback for public health. As long as there is a market for the products, companies will promote them.

**RS:** If REMS does make obtaining prescription opioids more difficult, do you see other licit drugs coming to the forefront of drug abuse and misuse? If so, what drugs?

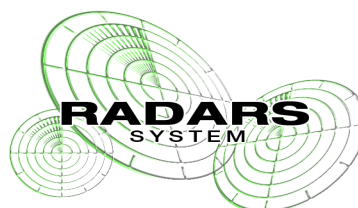
**Dr. Schnoll:** We have seen in the past that the abusers of drugs will use what is most available at the best price. For example, when heroin was not available in Chicago and some other cities in the late 1970s and early 1980s, Talwin (pentazocine) and tripeleminamine combination, known on the street as Ts and Blues, became very popular. When the heroin became available again, this problem disappeared. Additionally, when New York state placed benzodiazepines in schedule II in the state, there was increased use of chloral hydrate, meprobamate and other less effective and more problematic drugs.

There could well be an increase in the abuse and misuse of illicit opioids such as heroin. However, I will not make any predictions since it could give some people ideas about new drugs to try. I don't want to create a self-fulfilling prophecy.

**RS:** How quickly do you think a REMS for ER opioids will be required by the FDA?

**Dr. Schnoll:** The FDA realizes that this will be the largest and most complex REMS ever developed and as such they don't want to make any mistakes that will create new problems that could come back to haunt them. They will take their time to develop this slowly and deliberately, working closely with industry and all the stakeholders.

There is a good chance it will be implemented in stages to test out various aspects of the REMS or with specific products before applying it to the whole class. They will want to make sure that whatever is developed and implemented will not create an uproar from patients and other stakeholders.





## Recent RADARS System Publications and Presentations

- Inciardi JA, Surratt HL, Cicero TJ, Beard RA. Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultrarapid Assessment. *Pain Medicine*. 10(3):537-548, 2009
- Inciardi JA, Surratt HL, Stivers Y, Cicero TJ. FDA Approvals of Generic Drugs: Impact on the Diversion of Opioid Analgesics With a Potential for Abuse. *Journal of Opioid Management* 5:2 81-87, March/April 2009.
- Lindholm A, Varughese S, Rosen S, Sembower M, Ertischek M, St. Jean E, Schnoll S. Innovative Use of Multiple Surveillance Data Sources for the Detection of Misuse, Abuse and Diversion in the Risk Management Plan (RMP) of Stimulant Medications Used in ADHD. Drug Information Association 2009 Annual Meeting. San Diego, CA. June, 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

- CDC Public Health Information Network, August 30-September 03, 2009. Atlanta, Georgia
- American Society of Crime Laboratory Directors, September 13-17 2009. Boston, MA
- North American Congress of Clinical Toxicology, September 21- 26, 2009. San Antonio, TX
- International Society of Addiction Medicine, September 23-26, 2009. Calgary, Canada

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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.

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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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