



Researched Abuse, Diversion and Addiction-Related Surveillance System



## First Quarter 2016 Newsletter

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### Did You Know?

Did you know that the FDA announced enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death?



### RADARS® SYSTEM 10<sup>th</sup> ANNUAL SCIENTIFIC MEETING

MAY 5–6, 2016



The RADARS® System Annual Scientific Meeting encourages prescription drug abuse experts, representatives from the pharmaceutical industry, medical professionals, and federal regulatory agencies to discuss current trends in prescription drug abuse research and to develop strategies to ensure the safe and proper use of prescription medications.

Westin Georgetown  
2350 M Street, NW  
Washington, DC

#### **Thursday, May 5, 2016**

##### **International Pre-Symposium:**

##### **Prescription Drug Misuse – A Global Crisis?**

1:30pm - 5:00pm

##### **Networking Welcome Reception**

5:00pm - 7:00pm

#### **Friday, May 6, 2016**

##### **10<sup>th</sup> Annual Scientific Meeting:**

##### **Diverging Perspectives of Prescription Opioid Abuse**

8:30am - 3:30pm

Please RSVP by Friday, April 29, 2016. Please note that space is limited and we ask that you register early to guarantee your attendance.

Register now! <https://www.radarsevent.com/>



## **RADARS® SYSTEM 10<sup>th</sup> ANNUAL SCIENTIFIC MEETING**

**MAY 5–6, 2016**



### **RADARS® System Tenth Annual Scientific Meeting International Pre-Symposium: Prescription Drug Misuse – A Global Crisis? Thursday, May 5<sup>th</sup> 2016, Westin Georgetown, Washington, D.C.**

Our first two international pre-symposiums, Monitoring Prescription Drug Abuse Across the Globe (2014) and Emerging Global Trends in Prescription Drug Misuse (2015), were great successes. Building on this momentum, we are pleased to offer an international pre-symposium as part of this year's meeting.

This year's international pre-symposium, Prescription Drug Misuse – A Global Crisis?, will highlight RADARS® System international data updates along with our featured presentations. Concluding the day will be a panel discussion followed by a networking welcome reception.

#### **Featured Presentations**

##### **Misuse of Medications in the UK and Related Advisory Council on Misuse of Drugs (ACMD) Activities Professor Raymond G. Hill, B.Pharm., Ph.D, DSc (Hon), FMedSci**



From 1990 until his retirement in 2008 Dr. Hill worked in drug discovery research for Merck / MSD as Head of the European licensing group. He chaired the MRL Analgesia Task Force, and he had Neuroscience research oversight responsibility at Banyu Research Labs (Tsukuba; 1997-2002). Since retirement from the pharmaceutical industry Dr. Hill serves as non-executive director on the boards of Orexo, Avilex, and Asceneuron.

Dr. Hill received his academic training at the University of London. He was a lecturer in Pharmacology at the University of Bristol School of Medicine (1974-1983) and supervisor in Pharmacology at Downing College, University of Cambridge (1983-1988). He joined the pharmaceutical industry in 1983 as Head of Biology at the Park Davis Research Unit, Cambridge. In 1988 he joined Smith, Kline and French (UK) as Group Director, Pharmacology. He serves on the editorial boards of a number of

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## Hill cont.

journals, has been a Council Member of the British Pain Society, is President Emeritus – British Pharmacological Society and was coopted Member of Council, Academy of Medical Sciences. He was also a member of the ABPI R&D committee, of the EFPIA Research Directors Group, and of the Nuffield Council on Bioethics. Dr. Hill is a member of the Advisory Council on the Misuse of Drugs.

## Trends of Prescription Drug Misuse in the UK and Singapore

**David Wood, MD, FRCP, FEAPCCT, FACMT, FBPhS**



Dr. David Wood is a Consultant Physician and Clinical Toxicologist at Guy's and St Thomas' NHS Foundation Trust and King's Health Partners, London UK and an honorary senior lecturer at King's College London, London, UK. In addition he is an accredited clinical pharmacologist and a fellow of the British Pharmacological Society. He has a clinical, academic and research interest in the epidemiology of use and acute harms associated with the use of classical recreational drugs and novel psychoactive substances ("bath salts" or "legal highs"). Included in this is work studying the non-medical use of prescription and over the counter medication in the UK. This has focused on undertaking population surveys on the non-medical use of opioids and non-opioid medications using both Internet-based consumer panels and direct face-to-face interviews in nightclubs/other night-time economy venues. More recently this work has been extended to include surveys using Internet-based consumer panels in Singapore. He is also a co-opted member of the UK Advisory Council on the Misuse of Drugs (ACMD) Diversion and Illicit Supply of Medicines Working Group.



## **RADARS® SYSTEM 10<sup>th</sup> ANNUAL SCIENTIFIC MEETING**

**MAY 5–6, 2016**



### **RADARS® System Tenth Annual Scientific Meeting Diverging Perspectives of Prescription Opioid Abuse Friday, May 6<sup>th</sup> 2016, Westin Georgetown, Washington, D.C.**

Year after year the RADARS® System annual meeting continues to bring industry and regulatory experts as well as researchers together to discuss the latest in prescription drug abuse. This year is no exception and will include:

- RADARS® System data updates from 2015
- Presentations on the many perspectives of prescription opioid abuse

### **Featured Presentations**

#### **The Political Factors Affecting the Abuse Deterrent Formulations**

**Dan Cohen, MALS**



Mr. Cohen is the Executive Vice President, Government and Public Relations with KemPharm, Inc., a biopharmaceutical company which develops and commercializes Abuse Deterrence Formulations (ADF) for opioid analgesics. He also serves as the Forum Chair of the US Abuse Deterrent Coalition, a “talk group” of over 30 ADF manufacturers, patient advocates and related organizations seeking to expand access to ADF technologies.

In addition, he formerly served as consulting Head of North American Government Relations, for biopharmaceutical ADF development company Grünenthal USA, and as Senior Vice President for Government Relations, External Affairs and Health Policy with EnteroMedics, an early-stage medical device company developing obesity treatments.

Moreover, as Managing Director/Global Government Relations for The Depository Trust & Clearing

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### **Cohen cont.**

Corporation, he was responsible for leading government relation functions, including formulating the overall strategy, representing the DTCC before the U.S. Congress, European Parliament, Asian governments and their respective regulatory bodies.

Cohen earned a bachelor's degree in Sociology in 1978 from Willamette University and received a master's degree in International Affairs from Georgetown University in 1985.

### **Prescription Opioid and Heroin Abuse in the United States**

**Christopher M. Jones, PharmD, MPH**



Christopher M. Jones, PharmD, MPH, currently serves as Director of the Division of Science Policy in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services (HHS). The Division serves as the ASPE lead on public health and biomedical science issues and initiatives, including programmatic and policy areas that involve complex or rapidly evolving science and technology. The Division is responsible for policy coordination; long-range planning; legislative development; economic, program, and regulatory analysis; and evaluation focused on the HHS science agencies. Dr. Jones previously served as senior advisor in the Office of Public Health Strategy and Analysis in the Office of the Commissioner at the FDA, led CDC's drug abuse and overdose activities, and served as Senior Public Health Advisor to the White House Office of National Drug Control Policy (ONDCP).



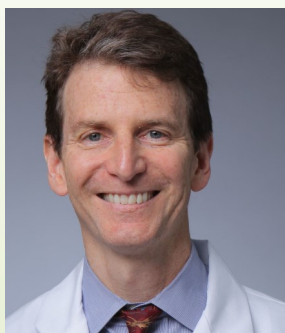
## RADARS® SYSTEM 10<sup>th</sup> ANNUAL SCIENTIFIC MEETING

MAY 5–6, 2016



### Setting the Stage: Are Abuse Deterrent Formulations Ready for Prime Time?

Lewis S. Nelson, MD



Dr. Nelson is Professor and Vice-Chair in the Department of Emergency Medicine at New York University School of Medicine, and an attending physician at both NYU Langone Medical Center and Bellevue Hospital Center. He is the Director of the Fellowship in Medical Toxicology at NYUSOM and the New York City Poison Control Center. He is a Past-President of the American College of Medical Toxicology, former Chair of the FDA Drug Safety and Risk Management Advisory committee, and an editor of the textbook Goldfrank's Toxicologic Emergencies, now in its 10th edition. He organized the NYC Task Force on Opioid Misuse, and participated with

the American College of Emergency Physicians Opioid Guideline Writing Panel, a CDC-funded panel of toxicologists and medical examiners to develop guidelines for the classification of opioid-related death, and the CDC Chronic Opioid Therapy Guideline Expert Panel. He continues to research, publish, and speak on the subject of opioid abuse, overdose, and addiction, as well as emerging drugs of abuse, and medication safety.

### NSDUH Trends in Nonmedical Use of Prescription Opioids

Scott P. Novak, PhD



Scott Novak, PhD, holds research interests in the causes, correlates, and consequences of prescription drug abuse, including the behavioral and psychiatric sequelae. He currently directs the program of research on prescription drug abuse within RTI's behavioral health epidemiology program. He is also active in studies investigating the epidemiology of new synthetic/designer drugs of abuse in the United States and internationally as well as the use and abuse of marijuana.

Dr. Novak leads an evaluation of the Prescription Drug Overdoses for State initiative, a



## RADARS® SYSTEM 10<sup>th</sup> ANNUAL SCIENTIFIC MEETING

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### Novak cont.

CDC-funded cooperative agreement that provides over 60 million in funding to the states as part of their prescription drug misuse and overdose prevention efforts. He also works on a federal initiative to create community-level estimates for illicit drug abuse from 22 local antidrug coalitions. In addition, he is the principal investigator for a surveillance system in eight European Union countries to monitor prescription drug abuse.

Before coming to RTI in 2004, he was on the faculty of Brown University in the Department of Community Health, and was a Robert Wood Johnson Faculty Fellow in the Department of Health Care Policy/Maternal and Child Health at Harvard University.

### Understanding Drug Overdose Mortality Using the National Vital Statistics System

**Margaret Warner, PhD**



Dr. Margaret Warner is an injury epidemiologist at the Centers for Disease Control and Prevention, National Center for Health Statistics, Division of Vital Statistics.

Dr. Warner's research focuses on fatal injury and poisoning surveillance. As part of her work on surveillance, Dr. Warner is coordinating and promoting public health surveillance efforts in the offices of medical examiners and coroners. In addition to her research efforts, Dr. Warner provides consultation on the analysis and interpretation of injury related data to a wide range of constituents from both the public and private sectors.

Dr. Warner received her doctorate from the Johns Hopkins School of Public Health and studied injury epidemiology on a Fulbright Fellowship at the University of Otago in New Zealand. She is married with two school age children.

## Recent Journal Article of Interest

A review article recently published in the *New England Journal of Medicine* (January 2016) highlights the relationship between nonmedical prescription opioid use and heroin use. This major public health issue is characterized by both its high overall prevalence and increases in associated morbidity and mortality:

10.3 million persons reported using prescription opioids in 2014 nonmedically (i.e., using medications not prescribed for them or taken only for the experience/feeling that they caused).

Further, emergency department visits involving misuse or abuse of prescription opioids, admissions to substance-abuse treatment programs linked to prescription opioids, and the rates of death from prescription opioid overdose have all increased markedly in recent years.

The authors conclude that available data indicate that the nonmedical use of prescription opioids is a strong risk factor for heroin use. However, heroin use among people who use prescription opioids for nonmedical reasons is rare, and the transition to heroin use appears to occur at a low rate despite the fact that the majority of current heroin users report having used prescription opioids nonmedically before initiating heroin use. Further research is warranted to evaluate whether restrictions on prescribing or formulation changes increased the frequency or intensity of heroin use among those who had already begun using heroin.

Efforts aimed at impacting opioid prescribing may not be to blame for this relationship between nonmedical prescription opioid use and heroin use; instead, increases in heroin use may be explained by a progression of addiction severity for some (e.g. predictors of transition to heroin include prescription opioid use disorder and presence of multiple other drug use/disorders) as well as by heroin's recent reduced prices, increase availability and higher purity. In conclusion, the authors write, "Although some authors [of other studies] suggest that there is an association between policy-driven reductions in the availability of prescription opioids and increases in the rates of heroin use, the timing of these shifts, many of which began before policies were robustly implemented, makes a causal link unlikely."

Compton WM, Jones CM, Baldwin GT. "Relationship between Nonmedical Prescription-Opioid Use and Heroin Use." *New England Journal of Medicine* 2016; 374:154-163 DOI: 10.1056/NEJMra1508490.

### Did You Know?

Did you know that the FDA released draft guidance intended to support industry in their development of generic versions of approved opioids with abuse-deterrent formulations?



## RADARS® System Abstracts

### RADARS System Conference Attendance: January 2016–March 2016

#### 32<sup>nd</sup> American Academy of Pain Medicine (AAPM) Annual Meeting

##### Palm Springs, CA

February 18, 2016—February 21, 2016

**The changing landscape of prescription opioid abuse in the United States**

Dart RC



#### CBI's Abuse-Deterrent Formulations Summit

##### Alexandria, VA

March 9, 2016 – March 10, 2016

**Investigate challenges and opportunities in post marketing surveillance of ADFs**

Dart RC



#### American College of Medical Toxicology (ACMT) Annual Scientific Meeting

##### Huntington Beach, CA

March 18, 2016—March 20, 2016

[Prescription opioid death rates are greater for females than males](#)

Iwanicki JL, LeLait MC, Severtson SG, Bucher-Bartelson B, Dart RC



## Upcoming RADARS® System Conference Attendance: April 2016 – June 2016

### **Pediatric Academic Societies Meeting**

Baltimore, MD

April 30, 2016 – May 3, 2016

- **Unintentional exposures to prescription opioid analgesics among children under age six: trends over time:** Wang GS, McDaniel H, Bucher Bartelson B, Green JL, Dart RC

### **American Pain Society 36<sup>th</sup> Annual Scientific Meeting**

Austin, TX

May 11, 2016 – May 14, 2016

- **Routes of administration of tapentadol products as reported to poison centers:** Severtson SG, Bucher Bartelson B, Green JL, Dart RC

### **Society of General Internal Medicine 2016 Annual Meeting**

Hollywood, FL

May 11, 2016 – May 14, 2016

- **Trends in benzodiazepine and opioid analgesic abuse and mortality in the United States:** Calcaterra SL, Severtson SG, Bucher-Bartelson B, Bau G, Margolin Z, Green JL, Dart RC

### **36<sup>th</sup> International Congress of the European Association of Poisons Centres and Clinical Toxicologists**

Madrid, Spain

May 24, 2016 – May 27, 2016

- **Characterization of marijuana use in college students as reported to an online survey:** Wang GS, Besharat AC, LeLait MC, Haynes C, Dart RC, Roosevelt G
- **Tracking the trends over time of global adult human exposures to benzodiazepines and opioids reported to poison centres in the Global Toxicsurveillance Network:** Johnson DJG, Cooper G, Davanzo F, Ebbecke M, Eddelston M, Garnier R, Margolin ZR, Megarbane B, Schaper A, Sesana F, Thomas SHL, Thompson JP, Vale AJ, Green JL
- **Tracking the trends over time of unintentional pediatric exposures to benzodiazepines and opioids reported to poison centres in the Global Toxicsurveillance Network:** Johnson DJG, Cooper G, Davanzo F, Ebbecke M, Eddelston M, Garnier R, Margolin ZR, Megarbane B, Schaper A, Sesana F, Thomas SHL, Thompson JP, Vale AJ, Green JL
- **Online survey on prescription medicine misuse: what is the evidence for prescription opioid misuse in Singapore?** Chan WL, Besharat AC, McDaniel HA, Green JL, Dargan PI
- **Abuse of immediate release opioid analgesics as compared to extended release formulations in the United States:** Iwanicki JL, McDaniel HA, Severtson SG, Green JL, Dart RC
- **Abuse deterrent formulations of the opioids and their relation to heroin:** Dart RC
- **Trends in opioid analgesics abuse and mortality in Europe:** Green JL

## Upcoming RADARS® System Conference Attendance: April 2016 – June 2016

### 12<sup>th</sup> European Opiate Addiction Treatment Association Conference

Leiden, The Netherlands

May 27, 2016 – May 29, 2016

- **A characterization of first-time enrollees and repeated enrollees entering medication-assisted substance abuse treatment programs:** Margolin Z, Bau G, McBride K, Guareschi M, Hill D, D'Agnone O, Auriacombe M, Daulouède JP, Villèger P, Touzeau D, Benyamina A, Scherbaum N, Deruvo G, Clausen T, Fonseca MF, Goodman E, Bacciardi S, Green JL, Dart RC, Maremmani I
- **Reported route and source of primary drugs of abuse by patients entering medication-assisted substance abuse treatment programs in Europe:** McBride K, Guareschi M, Bau G, Margolin Z, Hill D, D'Agnone O, Auriacombe M, Daulouède JP, Villèger P, Touzeau D, Benyamina A, Scherbaum N, Deruvo G, Clausen T, Fonseca MF, Bacciardi S, Goodman E, Green JL, Dart RC, Maremmani I
- **RADARS System collaboration: European opioid treatment program goals and data:** Green JL

### International Conference on Opioids 2016

Boston, MA

June 5, 2016 – June 7, 2016

- **Types of post-marketing studies to support abuse deterrent claims:** Dart RC

**RADARS® System Quarterly Technical Report  
First Quarter 2016 Edition**

*Coming Soon!*

### RADARS® System in Social Media – Get Connected!



Follow us at [@RADARS\\_System](https://twitter.com/RADARS_System). You can find news relating to prescription drug surveillance and abuse in the US and abroad. RADARS® System tweets include publication announcements, conference attendance, program updates and more.



Publication and conference attendance news can be found on our LinkedIn site ([www.linkedin.com/company/radars-system](http://www.linkedin.com/company/radars-system)).



Visit [www.RADARS.org](http://www.RADARS.org) for active links to presentations, conference and manuscript abstracts.

## Contact Information

### Account, Subscription, Program or Data Inquiries:

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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.

## 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. The RMPDC has been in operation for more than 50 years, making it one of the oldest poison control centers in the nation. Denver Health 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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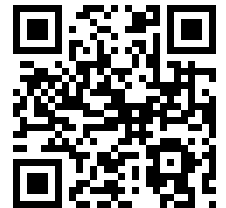


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