



THURSDAY, MAY 13, 2021

## Postmarketing Surveillance: What's the Next Move?

11:00 am – 11:45 am EDT

### Postmarketing Surveillance: What's the Next Move?

**Richard C. Dart, MD, PhD**

*Executive Director, RADARS<sup>®</sup> System, Rocky Mountain Poison & Drug Safety,  
Denver Health and Hospital Authority  
President, Canadian Consumer Product and Pharmaceutical Safety Inc.*

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RADARS System continues to provide rapid and accurate data for prescription drug misuse of all types. The past year has seen continuing shifts in abuse and deaths from various prescription drugs. This talk will set the stage for subsequent discussions about the remarkably diverse set of psychoactive drugs that are being abused and causing death in the United States, Europe, and Canada.

11:45 am – 12:15 pm EDT

### Meeting the Challenges of COVID-19 in Postmarketing Surveillance

**Janetta L. Iwanicki, MD**

*Chief Scientific Officer, Research and Consulting, Rocky Mountain Poison & Drug Safety,  
Denver Health and Hospital Authority*

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The novel coronavirus pandemic has provided unique challenges and changed the world we live in, with significant impacts both on substance use and on how we can measure those patterns of use. This talk will explore impacts of COVID-19 on substance use and data collection, treatment of substance use disorders, policy changes, and lessons learned for future public health challenges.

12:15 pm – 12:45 pm EDT

### Defining Populations of Interest for Postmarketing Studies

**Nabarun Dasgupta, MPH, PhD**

*Senior Scientist and Innovation Fellow, Gillings School of Global Public Health,  
University of North Carolina in Chapel Hill  
Consultant – RADARS<sup>®</sup> System, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority*

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We examine three sub-populations of interest relevant to opioid safety studies, including people with chronic pain and those with problematic nonmedical use. Measurement issues and causal inference will be discussed.

12:45 pm – 1:00 pm EDT

**Break**



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## **Postmarketing Surveillance: What's the Next Move?**

**1:00 pm – 2:15 pm EDT**

### **The Rest of the Story: Other Drugs Misused in the United States**

**Janetta L. Iwanicki, MD (Moderator)**

*Chief Scientific Officer, Research and Consulting, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority*

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### **Prescribing and Over-The-Counter Drugs; A Vast Range of Misusing Opportunities**

**Professor Fabrizio Schifano**

*Chair in Clinical Pharmacology and Therapeutics and Consultant Psychiatrist (Addictions); Psychopharmacology, Drug Misuse and Novel Psychoactive Substances Research Unit, School of Life and Medical Sciences, University of Hertfordshire, UK*

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A large number of approved drugs, both prescription and non-prescription, are abused, and the abuse of non-traditional drugs is increasing. This talk will present the abuse of prescription drugs in the context of novel psychoactive substances.

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### **Understanding Stimulant Use in the General Population: Prevalence and Patterns of Non-Medical Use**

**Joshua C. Black, PhD**

*Senior Research Scientist, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority*

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This talk will provide a broad understanding of the prevalence of stimulant non-medical use, the reasons and methods of non-medical use, and trends over time. Data demonstrate that adults who non-medically use stimulants are a heterogeneous group with different patterns and motivations of use.

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### **It's not Easy Being Buprenorphine: Identifying Unique Substance Use Patterns Associated with Buprenorphine**

**Matthew Ellis, MPE, PhD(c)**

*Research Faculty Instructor, Department of Psychiatry, Washington University in St. Louis, School of Medicine*

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Shifting policies and perceptions have driven the expansion of buprenorphine as a gold standard in the treatment of opioid use disorder. As buprenorphine dispensing increases, it is necessary to monitor adverse outcomes or changes in substance use patterns associated with buprenorphine medications. This talk will discuss recent patterns in buprenorphine-associated substance use among individuals entering treatment for opioid use disorder across the United States.



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## Postmarketing Surveillance: What's the Next Move?

### Changes in Diversion of Buprenorphine and Gabapentin

**Mance E. Buttram, PhD**

*Associate Professor, Nova Southeastern University*

*Associate Director, Center for Applied Research on Substance Use and Health Disparities*

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Recent attention has been given to the misuse of buprenorphine and gabapentin among people who use opioids. However, systematic data related to diversion are lacking. This presentation will examine changes in the diversion of buprenorphine and gabapentin over time, as well as qualitative data describing motivations for diversion and misuse.

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**2:15 pm – 2:45 pm EDT**

### FDA's Holistic Approach to Addressing Polysubstance Use and the Drug Overdose Crisis

**Marta Sokolowska, PhD**

*Associate Director for Controlled Substances, Office of the Center Director,*

*Center for Drug Evaluation & Research, Food & Drug Administration*

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FDA takes a holistic approach to addressing the risks of polysubstance use and the drug overdose crisis. One of our highest priorities is advancing development of novel treatments for different substance use disorders. We will discuss our efforts in this space, including funding research, gathering stakeholder input, and exploring novel measures and meaningful endpoints.

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**2:45 pm – 3:30 pm EDT**

### Panel Discussion and Summary

**Richard C. Dart, MD, PhD (Moderator)**

*Executive Director, RADARS<sup>®</sup> System, Rocky Mountain Poison & Drug Safety,*

*Denver Health and Hospital Authority*

*President, Canadian Consumer Product and Pharmaceutical Safety Inc.*

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**3:30 pm EDT**

### Adjournment