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| 11:00 am – 11:30 am EDT | A New Frontier: Prescription Drug Abuse Beyond Opioids                   | Richard C. Dart, MD, PhD                                                  | Executive Director, RADARS® System, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority | President, Canadian Consumer Product and Pharmaceutical Safety Inc.  
RADARS System continues to provide rapid and accurate data for prescription drug abuse 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 and Europe. |
| 11:30 am – 12:30 pm EDT | Mortality Data: Preventing the Next Wave                                  | Margaret Warner, PhD                                                      | Senior Epidemiologist, National Center for Health Statistics, Centers for Disease Control and Prevention | This talk will discuss how NCHS views the challenges ahead regarding mortality data and how utilizing newer resources such as DMI may help us frame our understanding of drug associated mortality. |
| 11:30 am – 12:00 pm EDT | Vital Statistics Mortality Data                                           | Margaret Warner, PhD                                                      | Senior Epidemiologist, National Center for Health Statistics, Centers for Disease Control and Prevention | This talk will discuss how NCHS views the challenges ahead regarding mortality data and how utilizing newer resources such as DMI may help us frame our understanding of drug associated mortality. |
| 12:00 pm – 12:30 pm EDT | One Drug? Two Drugs? Polydrug Mortality Is More Common Than We Think       | Joshua C. Black, PhD                                                      | Associate Research Scientist, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority | The occurrence of polydrug mortality is rising, particularly for substances found frequently on death certificates. Nearly all deaths have more than one drug listed on death certificates. This talk will show how drug mentions are interconnected with each other. Network maps reveal insights on how drugs contribute to mortality. |
| 12:30 pm – 1:00 pm EDT   | Break                                                                    |                                                                         |                                                                           |                                                                                                                                                                                                           |
| 1:00 pm – 1:30 pm EDT   | Key Priorities for FDA’s Controlled Substance Program                     | Marta Sokolowska, PhD (invited)                                           | Associate Director for Controlled Substances                                | Office of the Center Director, Center for Drug Evaluation & Research, Food & Drug Administration  
This talk will present the key priorities for the newly established FDA’s Controlled Substance Program. |

**AGENDA**

**TUESDAY, MAY 12, 2020**

A New Frontier

Prescription Drug Abuse Beyond Opioids
1:30 pm – 3:15 pm EDT

1:30 pm – 2:00 pm EDT
**Pharmacoepidemiologic Research on Drugs of Abuse**  
Judy A. Staffa, PhD, RPh  
Associate Director for Public Health Initiatives  
Office of Surveillance & Epidemiology, Center for Drug Evaluation & Research, Food & Drug Administration

FDA epidemiologists recently co-authored a new chapter in the textbook *Pharmacoepidemiology* (eds Strom, Kimmel, Hennessy), which was published in December 2019. I will be presenting some of the highlights from this chapter that describe our regulatory scientific approach in studying drugs of abuse, for consideration and discussion.

2:00 pm – 2:30 pm EDT
**How Low Can You Go: Solving the Challenge of Low Endorsements in the General Population**  
Joshua C. Black, PhD  
Associate Research Scientist, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority

The challenge is that the newer a drug and the lower the abuse, the more difficult it is to do surveillance. What tools can you use to find the proverbial needle in a haystack?

2:30 pm – 3:15 pm EDT
**Real World Evidence, Real World Solutions**  
John Schwarz, PhD  
Director of Biostatistics, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority  
Nabarun Dasgupta, MPH, PhD  
Core Faculty, University of North Carolina in Chapel Hill  
Consultant – RADARS® System, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority

How can safety evaluations of new products be integrated? The journey begins with traditional high level view surveillance during early phases. This is followed by inferential (causal) approaches looking at specific behaviors (and route of administration). A new empirical approach to identifying comparators is presented. Finally we describe a new approach to identify relative differences in community-level outcomes by addressing confounding. This framework synthesizes observational data going beyond unadjusted presentations of surveillance data.

3:15pm – 4:00 pm EDT
**Panel Discussion and Summary**  
Richard C. Dart, MD, PhD (Moderator)  
Executive Director – RADARS® System, Rocky Mountain Poison & Drug Safety, Denver Health and Hospital Authority  
President, Canadian Consumer Product and Pharmaceutical Safety Inc.

4:00 pm EDT
**Adjournment**