

Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes--Exploring the Path Forward for Assessment: Public Workshop

December 11, 2020

**Docket No. FDA-2020-N-1561
AGENDA**

Meeting Webpage

<https://www.fda.gov/drugs/news-events-human-drugs/evaluating-effect-opioid-analgesics-risk-evaluation-and-mitigation-strategy-education-program>

9:00 am	Welcome/Introductions	Judy Staffa, PhD, RPh Associate Director for Public Health Initiatives Office of Surveillance & Epidemiology (OSE) CDER, FDA
9:15 am	Opening Remarks	Patrizia Cavazzoni, MD Center Director (Acting) Deputy Director for Operations Office of the Center Director (OCD), CDER, FDA
9:20 am	<p>Presentations</p> <p>Background on the OA REMS and overview of the day</p> <p>Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain: An Overview</p> <p>Safer/Competent Opioid Prescribing Education (SCOPE of Pain): Putting the Blueprint into Action</p> <p>Considerations for studying the impact of the OA REMS on practice behaviors and patient outcomes</p>	<p>Claudia Manzo, PharmD Director, Office of Medication Error Prevention and Risk Management, OSE, CDER, FDA</p> <p>LCDR Mark Liberatore, PharmD, RAC Deputy Director for Safety, Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP), Office of Neuroscience (ON), Office of New Drugs (OND), CDER, FDA</p> <p>Julie L. White, MS Director, Continuing Medical Education Boston University School of Medicine</p> <p>Jana McAninch, MD, MPH, MS Senior Medical Epidemiologist Division of Epidemiology, OSE, CDER, FDA</p>
10:20 am	Break	

10:35 am	<p>Presentations</p> <p>A Role of Large Data Sources in Assessing Efforts to Improve Opioid Prescribing</p> <p>Developing and Implementing EHR-based Quality Improvement Opioid Measures</p> <p>Rethinking study designs to quantify REMS effectiveness</p> <p>Opioid Analgesic REMS Assessment plan: Additional indicators of success</p> <p>Can We Improve Physician Performance and Patient Health Outcomes Through CME/CPD?</p>	<p>Alec Walker, MD, DrPH Principal World Health Information Science Consultants</p> <p>Jan Losby, PhD, MSW Branch Chief, Health Systems and Research Branch, Division of Overdose Prevention, Centers for Disease Control (CDC)</p> <p>G. Caleb Alexander, MD Professor of Epidemiology and Medicine Johns Hopkins Bloomberg School of Public Health</p> <p>Doris Auth, PharmD Deputy Division Director (Acting) Division of Risk Management, OSE, CDER, FDA</p> <p>Ronald M. Cervero, PhD Professor and Deputy Director Center for Health Professions Education Uniformed Services University of the Health Sciences</p>
11:50 am	Lunch	
12:30 pm	Topic 1 Panel discussion: Measurable outcomes to evaluate the effectiveness of Opioid Analgesic REMS training	Moderators: Judy Staffa and Jana McAninch
1:30 pm	Topic 2 Panel Discussion: Feasibility of studying the impact of the OA REMS education on prescriber behavior and patient outcomes	Moderators: Judy Staffa and Jana McAninch
3:00 pm	Break	
3:15 pm	Topic 3 Panel Discussion: Alternative approaches to broadly evaluate the impact of CE on prescriber behaviors and patient outcomes	Moderators: Doris Auth, Claudia Manzo
4:15 pm	Pre-registered Public Participation	
4:45 pm	High Level Summary	Judy Staffa and Claudia Manzo
5:00 pm	Meeting adjourns	