

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM)
and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)***
FDA White Oak Campus, Bldg. 31, Conference Center, Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 11-12, 2019

DRAFT AGENDA

FDA is seeking public input on the clinical utility of and safety concerns associated with the higher range of opioid analgesic dosing (both in terms of higher strength products and higher daily doses) in the outpatient setting. FDA is interested in better understanding current clinical use and situations that may warrant use of higher doses of opioid analgesics. We are also interested in discussing the magnitude and frequency of harms associated with higher doses of opioid analgesics relative to lower doses, as well as optimal strategies for managing these risks while ensuring access to appropriate pain management for patients.

Day 1: Tuesday, June 11, 2019

8:00 a.m.	Call to Order and Introduction of Committee	Sonia Hernandez-Diaz, MD, MPH, DrPH Chairperson, DSaRM
8:05 a.m.	Conflict of Interest Statement	Moon Hee V. Choi, PharmD Designated Federal Officer, AADPAC
8:15 a.m.	FDA Introductory Remarks	Judy Staffa, PhD, RPh Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA
8:30 a.m.	FDA PRESENTATIONS	
	A Framework for Assessing the Impacts of Strategies to Manage Risks of Higher Dose and Higher Dosage Strengths Opioid Analgesic Products	Sara Eggers, PhD Operations Research Analyst Decision Support and Analysis Team Office of Program and Strategic Analysis Office of Strategic Programs, CDER, FDA
	Regulatory Background for Opioid Analgesics	Ning Hu, MD, MS Medical Officer Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA

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DRAFT AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Dispensing Patterns and Clinical Use of
Higher Dose Opioid Analgesics in the U.S.

Corinne Woods, RPh, MPH
Drug Utilization Team 4 Lead
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and
Epidemiology (OPE), OSE, CDER, FDA

Review of Epidemiologic Studies of the
Associations Between Higher Dose Opioid
Analgesics and the Risks of Abuse,
Addiction, and Overdose

Rose Radin, PhD, MPH
Acting Team Lead, Drug Abuse Team 2
DEPI-II, OPE, OSE, CDER, FDA

9:30 a.m. Clarifying Questions

9:45 a.m. **BREAK**

10:00 a.m. **GUEST SPEAKER PRESENTATIONS: *Clinical Need and Risks Associated with Higher Daily Dose and Higher Dosage Strength Opioid Analgesics***

Clinician Perspectives

Dosing How Context Creates Dilemmas

John Markman, MD
University of Rochester
Professor of Neurosurgery and Neurology
Director, Neuromedicine Pain Management
Director, Translational Pain Research
University of Rochester School of Medicine and
Dentistry

Clinician and Clinical Research
Perspectives on Opioid Analgesic Tolerance
and Hyperalgesia

Michael Rowbotham, MD
Chief Research Officer, Sutter Health
Adjunct Professor of Anesthesia, Emeritus
Professor of Neurology, UCSF
Attending Neurologist, UCSF Pain Management
Center

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DRAFT AGENDA (cont.)

Opioid Utilization Patterns by Home-Based
Hospice Patients: A Longitudinal Review

**Mary Lynn McPherson, PharmD, MA, MDE,
BCPE**
Professor, Executive Director of Advanced Post-
Graduate
Executive Director, Online Master of Science and
Graduate Certificates in Palliative Care
Vice Chair of Teaching Development and
Enhancement
Department of Pharmacy Practice and Science
University of Maryland School of Pharmacy
Hospice and Palliative Care Consultant Pharmacist

**GUEST SPEAKER PRESENTATIONS: *Clinical Need and Risks Associated with Higher Daily Dose
and Higher Dosage Strength Opioid Analgesics (cont.)***

Patient Perspectives

Chronic Pain

Marianne Farrell

Living “Lived Experience”

Andrew Kiezulas

11:40 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. **GUEST SPEAKER PRESENTATIONS: *Considering the Role of Opioid Dose and Dosage Strength
in Abuse, Addiction, and Overdose***

Neurobiology of Addiction and the Role of
Dose

Sandra D. Comer, PhD
Professor of Neurobiology
Department of Psychiatry
Columbia University Irving Medical Center
New York State Psychiatric Institute

Patient-Reported Pathways to Opioid Use
Disorder

Bobbi Jo Yarborough, PsyD
Investigator
Kaiser Permanente Center for Health Research

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DRAFT AGENDA (cont.)

Opioid Misuse and Diversion Among
Chronic Substance Users: The Role of
Dosage Strength, Potency, and Other
Factors

Hilary L. Surratt, PhD
Associate Professor
University of Kentucky, College of Medicine

Understanding Opioid Trajectories:
Decision-Making and High Dosage Opioids

Theodore J. Cicero, PhD
John P. Feighner Professor of Psychiatry
Department of Psychiatry
Washington University in St. Louis, School of
Medicine

Opioid-Involved Fatal Overdoses and the
Role of Higher Dosage Strength Opioid
Products: What We Do and Don't Know

Bruce A. Goldberger, PhD
Division of Forensic Medicine
Department of Pathology, Immunology and Lab
Medicine
University of Florida College of Medicine

2:40 p.m. Clarifying Questions

3:00 p.m. **BREAK**

3:15 p.m. **GUEST SPEAKER PRESENTATIONS: *Efforts to Reduce High-Dose Opioid Prescribing—What Have We Learned?***

Veterans Health Administration Experience

Friedhelm Sandbrink, MD
Acting National Program Director
Pain Management in the Department of Veterans
Affairs

Controlled Evaluation of Group Health
Opioid Risk Reduction Initiatives: 2006-
2014

Michael Von Korff, ScD
Senior Investigator
Kaiser Permanente Washington Health Research
Institute

Patient-Centered Opioid De-Prescribing

Beth Darnall, PhD
Associate Professor
Stanford University School of Medicine
Anesthesiology, Perioperative and Pain Medicine
Psychiatry and Behavioral Sciences (by courtesy)
Principal Investigator, Stanford PCORI Project
on Opioid and Pain Reduction (EMPOWER study)

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DRAFT AGENDA (cont.)

4:15 p.m. Clarifying Questions

5:00 p.m. **ADJOURNMENT**

Day 2: June 12, 2019

8:30 a.m. Call to Order and Introduction of Committee **Sonia Hernandez-Diaz, MD, MPH, DrPH**
Chairperson, DSaRM

8:35 a.m. Conflict of Interest Statement **Moon Hee V. Choi, PharmD**
Designated Federal Officer, AADPAC

8:40 a.m. FDA Introductory Remarks **Sharon Hertz, MD**
Director
DAAAP, ODE-II, OND, CDER, FDA

FDA PRESENTATION

8:50 a.m. Examples of FDA Regulatory Actions to Manage Risks Associated with Opioid Analgesics and a Framework for Evaluating Potential Impacts on Patient and Public Health **Pamela Horn, MD**
Clinical Team Leader
DAAAP, ODE-II, OND, CDER, FDA

9:15 a.m. Clarifying Questions

9:45 a.m. **BREAK**

10:00 a.m. **OPEN PUBLIC HEARING**

12:00 p.m. **LUNCH**

1:00 p.m. Charge to the Committee **Sharon Hertz, MD**

1:10 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion (cont.)

5:00 p.m. **ADJOURNMENT**