

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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 15, 2018

AGENDA

The committee will discuss the assessment of opioid analgesic sparing outcomes in clinical trials of acute pain. The committee will be asked to comment on the trial design and endpoints of these studies and how to determine the clinical relevance of the results.

8:00 a.m.	Call to Order and Introduction of Committee	Brian Bateman, MD, MSc Acting Chairperson, AADPAC
8:15 a.m.	Conflict of Interest Statement	Moon Hee Choi, PharmD Designated Federal Officer, AAPAC
8: 20 a.m.	FDA Introductory Remarks	Sharon Hertz, MD Division Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	INDUSTRY PRESENTATIONS	Biotechnology Innovation Organization (BIO)
	Methodologies for Determining Opioid Sparing in Acute Pain Models	Richard Scranton, MD, MPH Chief Medical Officer Head Medical Health Sciences Pacira Pharmaceuticals
	Outcome Measures: A Composite Approach for Opioid Sparing Treatments in Chronic Pain	Randall Stevens, MD Chief Medical Officer Centrexion Therapeutics
	Opioid Sparing Considerations in Chronic Pain Trials: Osteoarthritis as a Model Indication	Scott Kelley, MD Chief Medical Officer Flexion Therapeutics, Inc.
9:30 a.m.	Clarifying Questions	

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AGENDA (cont.)

9:45 a.m. **GUEST SPEAKER PRESENTATION**

The Role of Acute Care Prescribing in the
Opioid Epidemic

Chad M. Brummett, MD

Associate Professor
Co-Director, Michigan Opioid Prescribing
Engagement Network (Michigan OPEN)
Director, Pain Research
Department of Anesthesiology
Division of Pain Medicine
Michigan Medicine
University of Michigan

10:15 a.m. Clarifying Questions

10:25 a.m. **BREAK**

10:40 a.m. **GUEST SPEAKER PRESENTATION**

How Risky is Opioid Pain Management
During Adolescence? Persistent Use,
Misuse and Abuse

Terri Voepel-Lewis, PhD, RN

Associate Professor, School of Nursing
Adj. Associate Research Scientist
Department of Anesthesiology
C.S. Mott Children's Hospital
University of Michigan

11:10 a.m. Clarifying Questions

11:20 a.m. **FDA PRESENTATIONS**

Background and Rationale for the
Development of Opioid-Sparing and
Opioid-Replacement Drugs

Mallika Mundkur, MD, MPH

Clinical Reviewer
Division of Pharmacovigilance II (DPV-II)
Office of Pharmacovigilance and
Epidemiology (OPE)
Office of Surveillance and Epidemiology
CDER, FDA

Study Designs and Approved Product
Labeling Relevant to Opioid Sparing

Pamela Horn, MD

Clinical Team Leader
DAAAP, ODE-II, OND, CDER, FDA

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AGENDA (cont.)

12:10 p.m. Clarifying Questions

12:25 p.m. **LUNCH**

1:25 p.m. Open Public Hearing

2:25 p.m. Charge to the Committee **Sharon Hertz, MD**

2:30 p.m. Questions to the Committee/Committee
Discussion

3:30 p.m. **BREAK**

3:45 p.m. Questions to the Committee/Committee
Discussion

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