

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

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC), the Drug Safety and Risk Management Advisory Committee (DSaRM), and the Pediatric Advisory Committee (PAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 15-16, 2016

AGENDA

The purpose of this public advisory committee meeting is to discuss the appropriate development plans for establishing the safety and efficacy of prescription opioid analgesics for pediatric patients, including obtaining pharmacokinetic data and the use of extrapolation.

Day 1: Thursday, September 15, 2016

8:00 a.m.	Call to Order and Introduction of Committees	Raeford E. Brown Jr., MD, FAAP Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	Stephanie L. Begansky, PharmD Designated Federal Officer, AADPAC
8:10 a.m.	FDA Introductory Remarks	Sharon Hertz, MD Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	AMERICAN ACADEMY OF PEDIATRICS PRESENTATION Prescription Opioids in Children - Towards a Safer and Pain-free Tomorrow	Rohit Sheno, MD, FAAP Associate Professor of Pediatrics Baylor College of Medicine Attending Physician, Emergency Center Texas Children's Hospital, Houston
8:30 a.m.	FDA PRESENTATIONS Pediatric Drug Development Regulatory Considerations	Lynne Yao, MD Director Division of Pediatric and Maternal Health Office of Drug Evaluation IV (ODE-IV) OND, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Additional Safeguards for Children in
Clinical Investigations (21 CFR 50, Subpart
D)

Robert “Skip” Nelson, MD, PhD
Deputy Director and Senior Pediatric Ethicist
Office of Pediatric Therapeutics (OPT)
Office of Special Medical Programs (OSMP)
Office of the Commissioner, FDA

Pediatric Utilization of Opioid Analgesic
Products

Tracy Minh Pham, PharmD
Drug Utilization Analyst
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and Epidemiology (OPE)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

9:30 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS (CONT.)**

Current Approach to Studying Opioid
Analgesics in Pediatric Patients

Steven Galati, MD
Medical Reviewer
DAAAP, ODE-II, OND, CDER, FDA

Clinical Pharmacology Considerations for
Pediatric Studies of Opioid Drug Products

Srikanth C. Nallani, PhD
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology 2
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS), CDER, FDA

11:15 a.m. Clarifying Questions

11:45 p.m. **LUNCH**

12:45 p.m. **GUEST SPEAKER PRESENTATION**

Pharmacotherapy for Pediatric Acute Pain,
Chronic Pain, and Palliative Care

Charles Berde, MD, PhD
Sara Page Mayo Chair and Chief, Division of Pain
Medicine, Department of Anesthesiology,
Perioperative and Pain Medicine
Boston Children’s Hospital
Professor of Anaesthesia (Pediatrics)
Harvard Medical School

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AGENDA (cont.)

1:15 p.m. **PEDIATRIC ORTHOPAEDIC SOCIETY OF
NORTH AMERICA PRESENTATION**

The Use of Opioid Narcotics for the
Pediatric Orthopaedic Patient

Harold J. P. van Bosse, MD
Associate Professor of Orthopaedic Surgery
Temple University, Philadelphia
Attending Pediatric Orthopaedic Surgeon
Shriners Hospital for Children, Philadelphia

1:45 p.m. Clarifying Questions

2:15 p.m. **BREAK**

2:30 p.m. **GUEST SPEAKER PRESENTATIONS**

Ethical Framework for Considering
Pediatric Opioid Policy

Chris Feudtner, MD, PhD, MPH
Director, Department of Medical Ethics
The Children's Hospital of Philadelphia
Professor of Pediatrics, Medical Ethics and Health
Policy
The Perelman School of Medicine at the University of
Pennsylvania

The Challenges of Conducting Opioid
Clinical Trials in Pediatrics

Steven J. Weisman, MD
Jane B. Pettit Chair in Pain Management
Children's Hospital of Wisconsin
Professor of Anesthesiology and Pediatrics
Medical College of Wisconsin

Opioid Misuse and Opioid Use Disorders in
Adolescents

Sharon Levy, MD, MPH
Associate Professor of Pediatrics
Harvard Medical School
Director, Adolescent Substance Abuse Program
Boston Children's Hospital

4:00 p.m. Clarifying Questions

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

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AGENDA (cont.)

Day 2: Friday, September 16, 2016

8:00 a.m.	Call to Order and Introduction of the Committees	Raeford E. Brown Jr., MD, FAAP Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	Stephanie L. Begansky, PharmD Designated Federal Officer, DSARM
8:10 a.m.	FDA Introductory Remarks	Sharon Hertz, MD Director DAAAP, ODE-II, OND, CDER, FDA
8: 15 a.m.	Clarifying Questions	
8:30 a.m.	OPEN PUBLIC HEARING	
10:30 a.m.	Break	
10:45 a.m.	Charge to the Committee	Sharon Hertz, MD
11:00 a.m.	Questions to the Committee/Discussion	
11:45 a.m.	LUNCH	
12:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
3:00 p.m.	BREAK	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	ADJOURNMENT	