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 Shenoi, 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
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
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**
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