

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

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Stephanie L. Begansky, PharmD

Division of Advisory Committee and Consultant Management
Office of Executive Programs, CDER, FDA

**ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE MEMBERS
(Voting)**

Brian T. Bateman, MD, MSc

Associate Professor of Anesthesia
Division of Pharmacoepidemiology and
Pharmacoeconomics
Department of Medicine
Brigham and Women's Hospital
Department of Anesthesia, Critical Care, and Pain
Medicine
Massachusetts General Hospital
Harvard Medical School
Boston, Massachusetts

David S. Craig, PharmD

Clinical Pharmacy Specialist
Department of Pharmacy
H. Lee Moffitt Cancer Center & Research Institute
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Anita Gupta, DO, PharmD

(via telephone on day 1)
Vice Chair and Associate Professor
Division of Pain Medicine & Regional
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Department of Anesthesiology
Drexel University College of Medicine
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Raeford E. Brown, Jr., MD, FAAP

(Chairperson)
Professor of Anesthesiology and Pediatrics
College of Medicine
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Lexington, Kentucky

Charles W. Emala, Sr., MS, MD

Professor and Vice-Chair for Research
Department of Anesthesiology
Columbia University College of Physicians &
Surgeons
New York, New York

Jennifer G. Higgins, PhD

(Consumer Representative)
Director of Strategic Planning and Business
Development
Center for Human Development
Springfield, Massachusetts

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**ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE MEMBERS
(Voting) (cont.)**

Alan D. Kaye, MD, PhD

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New Orleans, Louisiana

Mary Ellen McCann, MD, MPH

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Senior Associate in Anesthesia
Boston Children's Hospital
Boston, Massachusetts

Abigail B. Shoben, PhD

Assistant Professor, Division of Biostatistics
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ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE MEMBER (Non-Voting)

W. Joseph Herring, MD, PhD

(Industry Representative)
Neurologist
Executive Director and Section Head
Neurology, Clinical Neurosciences
Merck Research Laboratories, Merck & Co.
North Wales, Pennsylvania

DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE MEMBERS (Voting)

Tobias Gerhard, PhD, RPh

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Rutgers University
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Ernest Mario School of Pharmacy
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Linda Tyler, PharmD, FASHP *(via telephone)*

Chief Pharmacy Officer
Administrative Director, Pharmacy Services
University of Utah Health Care
Professor (Clinical) and Associate Dean for
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University of Utah College of Pharmacy
Salt Lake City, Utah

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MEETING ROSTER (cont.)

PEDIATRIC ADVISORY COMMITTEE MEMBERS (Voting)

Mary Cataletto, MD, FAAP

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Professor of Clinical Pediatrics
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Center for Clinical and Community Research
Children's Research Institute
Children's National Medical Center
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Children's Hospital of Wisconsin
Professor, Pediatrics
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Attending, Pediatric Intensive Care Unit
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Michael White, MD, PhD

Pediatric Cardiologist
Ochsner Clinic Foundation
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PEDIATRIC ADVISORY COMMITTEE MEMBERS (Non-Voting)

Bridgette Jones, MD

(Pediatric Health Organization Representative)
Associate Professor of Pediatrics and Medicine
Children's Mercy Hospital
Kansas City, Missouri

Samuel D. Maldonado, MD, MPH, FAAP

(Industry Representative)
Vice-President and Head
Pediatric Drug Development
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Raritan, New Jersey

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Sean P. Alexander, MD *(Day 1 only)*

Director of Inpatient Medicine
Medical Director, Pain Medicine Care Complex
Sheikh Zayed Institute
Children's National Health System
Washington, District of Columbia

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Professor of Pharmacogenomics and
Associate Dean for Research
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School of Medicine and Health Sciences
The George Washington University
Virginia Science and Technology Campus
Ashburn, Virginia

Tamar Lasky, PhD, FISPE

Owner/Consultant
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Melanie Dawn Nelson, PhD

(Patient Representative)
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Medical Director
Mayo Clinic Children's Center
Associate Professor of Anesthesiology and
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Arthur H. Kibbe, PhD

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Associate Professor of Anesthesiology and
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Toxicology
Arkansas Children's Hospital
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TEMPORARY MEMBERS (Voting) (cont.)

Stephen W. Patrick, MD, MPH, MS

Assistant Professor, Pediatrics and Health Policy
Division of Neonatology
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Anne-Michelle Ruha, MD

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FDA PARTICIPANTS (Non-Voting)

Sharon Hertz, MD

Director
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Office of Drug Evaluation II (ODE-II)
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Judy Staffa, PhD, RPh

Acting Associate Director for Public Health
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Office of Surveillance and Epidemiology (OSE)
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Ellen Fields, MD, MPH

Deputy Director
DAAAP, ODE-II, OND, CDER, FDA

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Deputy Director and Senior Pediatric Ethicist
Office of Pediatric Therapeutics
Office of Special Medical Programs
Office of the Commissioner, FDA

Lynne Yao, MD

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Office of Drug Evaluation IV (ODE-IV)
OND, CDER, FDA

LCDR Grace Chai, PharmD

Deputy Director for Drug Utilization
Division of Epidemiology II (DEPI- II)
Office of Pharmacovigilance and Epidemiology
OSE, CDER, FDA