

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 12, 2018

DRAFT MEETING ROSTER

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Jay R. Fajiculay, PharmD

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

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Voting)

Robin H. Bogner, PhD

Professor
University of Connecticut
School of Pharmacy
Department of Pharmaceutical Sciences
Storrs, Connecticut

Michael A. Carome, MD, FASHP

(Consumer Representative)
Director of Health Research Group
Public Citizen
Washington, District of Columbia

Seemal R. Desai, MD, FAAD

President and Medical Director
Innovative Dermatology
Plano, Texas

Padma Gulur, MD

Vice Chair, Operations and Performance
Duke University School of Medicine
Department of Anesthesiology
Duke University Medical Center
Durham, North Carolina

Stephen W. Hoag, PhD

Professor
Department of Pharmaceutical Science
University of Maryland, Baltimore
Baltimore, Maryland

William A. Humphrey, BSPHarm, MBA, MS

Director, Pharmacy Operations
St. Jude Children's Research Hospital
Memphis, Tennessee

Elizabeth Jungman, JD

Director, Public Health Programs
The Pew Charitable Trusts
Washington, District of Columbia

Kuldip R. Patel, Pharm.D.

Associate Chief Pharmacy Officer
Duke University Hospital
Durham, North Carolina

Allen J. Vaida, BSc, PharmD, FASHP

Executive Vice President
Institute for Safe Medication Practices
Horsham, Pennsylvania

Jurgen Venitz, MD, PhD

(Chairperson)
Professor and Vice Chairman
Virginia Commonwealth University
School of Pharmacy, Department of Pharmaceutics
Richmond, Virginia

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DRAFT MEETING ROSTER (cont.)

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

Donna Wall, PharmD

*(National Association of Boards of Pharmacy
Representative)*

Clinical Pharmacist
Indiana University Hospital
Indianapolis, Indiana

PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Non-Voting)

William Mixon, RPh, MS, FIACP

(Industry Representative)

Former Owner
The Compounding Pharmacy
Hickory, North Carolina

Christopher J. Smalley, MS, MBA

(Industry Representative)

Compounding Pharmacy Consultant
Valsource
Downingtown, Pennsylvania

TEMPORARY MEMBERS (Voting)

Thomas Chelimsky, MD

*(Participation in alpha lipoic acid, coenzyme Q10,
and creatine monohydrate discussion)*

Tenured Professor of Neurology
Medical College of Wisconsin
Milwaukee, Wisconsin

Marc Gregory Ghany, MD, MHSc, FAASLD

*(Participation in alpha lipoic acid, coenzyme Q10,
and creatine monohydrate discussion)*

Investigator
Liver Diseases Branch
National Institute of Diabetes and Digestive and
Kidney Diseases
National Institutes of Health
Bethesda, Maryland

Hrissanthi (Chris) Ikonomidou, MD, PhD

*(Participation in alpha lipoic acid, coenzyme Q10,
creatine monohydrate, and pyridoxal 5 phosphate
monohydrate discussion)*

Professor of Child Neurology (Tenured)
Department of Neurology
University of Wisconsin, School of Medicine and
Public Health
Madison, Wisconsin

Sandeep Khurana, MBBS

*(Participation in alpha lipoic acid, coenzyme Q10,
and creatine monohydrate discussion)*

Medical Director
Liver Transplantation
Geisinger Health System
Danville, Pennsylvania

Jeanne H. Sun, PharmD

(U.S. Pharmacopeia Representative)

Manager, Compounding
U.S. Pharmacopeial Convention
Rockville, Maryland

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DRAFT MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Julie Dohm, JD, PhD

Senior Science Advisor for Compounding
CDER, FDA

Frances Gail Bormel, RPh, JD

Director
Division of Prescription Drugs
Office of Unapproved Drugs and Labeling
Compliance (OUDLC)
OC, CDER, FDA

Rosilend Lawson, VMD, JD

Lead Regulatory Counsel (Acting)
Pharmacy Compounding Advisory Committee
Team, Division of Prescription Drugs
OUDLC, OC, CDER, FDA

Susan Johnson, PharmD, PhD

Associate Director
ODE IV, OND, CDER, FDA

Ruey Ju, JD, PharmD

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Office of Compliance (OC), CDER, FDA

Sara Rothman, MPH

Senior Policy Advisor
OUDLC, OC, CDER, FDA

Charles Ganley, MD

Director
Office of Drug Evaluation IV (ODE IV)
Office of New Drugs (OND), CDER, FDA

Michael Brave, MD

(morning session only)
Medical Officer
Division of Oncology Products I
Office of Hematology and Oncology Products
OND, CDER, FDA