Center for Drug Evaluation and Research (CDER)

*Pharmacy Compounding Advisory Committee (PCAC) Meeting* December 4, 2024

# **MEETING ROSTER**

## **DESIGNATED FEDERAL OFFICER (Non-Voting)**

## <u>Takyiah Stevenson, PharmD</u>

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

#### Padma Gulur, MD, FASA (via video

*conferencing platform)* Professor of Anesthesiology and Population Health Executive Vice Chair Department of Anesthesiology Director of Pain Management Strategy and Opioid Surveillance Duke University Health System Duke University Medical Center Durham, North Carolina

#### <u>Kathleen M. Gura, PharmD, BCNSP, FASHP,</u> FASPEN

Assistant Professor of Pediatrics Harvard Medical School Manager, Pharmacy Clinical Research Program Boston Children's Hospital Boston, Massachusetts

## Elizabeth Rebello, RPh, MD, FASA, CPPS, CMQ

(Acting Chairperson) Professor Department of Anesthesiology and Perioperative Medicine University of Texas MD Anderson Cancer Center Houston, Texas

#### Timothy D. Fensky, RPh, DPh, FACA

(National Association of Boards of Pharmacy Representative) Chief Pharmacy Officer Advanced Wellness Pharmacy Andover, Massachusetts

#### Anita Gupta, DO, MPP, GMP, PharmD, FASA (via

video conferencing platform) Full Clinical Professor, Medicine University of California Riverside School of Medicine Riverside, California Adjunct Assistant Professor Johns Hopkins School of Medicine Department of Anesthesiology and Critical Care Baltimore, Maryland

#### Linda F. McElhiney, PharmD, RPh, MSP, FAPC, FACA, FASHP, DPLA

Pharmacist Verification 1/Drug Utilization Review Pharmacist Elevance BioPlus Specialty Pharmacy Indianapolis, Indiana

## Brian Serumaga, PhD

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# **MEETING ROSTER (cont.)**

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

#### Allen J. Vaida, BSc, PharmD, FASHP

Former Executive Vice President Institute for Safe Medication Practices Hatfield, Pennsylvania

## PHARMACY COMPOUNDING ADVISORY COMMITTEE MEMBERS (Non-Voting)

## Thomas J. Lupton, PharmD, MBA, BCPS

*(Industry Representative)* Director, Point-of-Care Pharmacy Services On Demand Pharmaceuticals Rockville, Maryland

## **TEMPORARY MEMBERS (Voting)**

#### **Charles Billington, MD**

(AOD-9604-related bulk drug substances (BDSs) Topic Only) Chief, Section of Endocrinology and Metabolism Minneapolis Veterans Affairs Health Care System Minneapolis, Minnesota

## <u>Nina Clark, MD</u>

(Thymosin alpha-1-related BDSs Topic Only) Professor of Medicine Stritch School of Medicine Loyola University Chicago Division Director, Infectious Diseases Loyola University Medical Center Maywood, Illinois

## Amanda H. Corbett, PharmD (via video

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## Donnette D. Staas, PhD

*(Industry Representative)* Vice President, Regulatory Strategy Jazz Pharmaceuticals Philadelphia, Pennsylvania

## Kenneth D. Burman, MD

*(CJC-1295-related BDSs Topic Only)* Endocrine Staff Medstar Washington Hospital Center Professor Department of Medicine at Georgetown University Washington, District of Columbia

#### David W. Cooke, MD (via video conferencing

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## Mark J. Czaja, MD, FAASLD

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## **MEETING ROSTER (cont.)**

#### **TEMPORARY MEMBERS (Voting) (cont.)**

#### <u>Todd Durham, PhD</u>

*(Acting Consumer Representative)* Senior Vice President Clinical and Outcomes Research Foundation Fighting Blindness Columbia, Maryland

#### Marc Ghany, MD, MHSc

(Thymosin alpha-1-related BDSs Topic Only) Senior Investigator, Liver Diseases Branch National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institutes of Health (NIH) Bethesda, Maryland

#### Mark G. Kris, MD

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#### Janet S. Lee, MD (via video conferencing

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Professor of Medicine
Professor of Pathology and Immunology
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#### <u>Alice K. Pau, PharmD</u>

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## Hayley Gans, MD (via video conferencing

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#### Kirk Jensen, MD, LtCol, USAF, MC

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#### Brian P. Lee, MD, MAS (via video conferencing

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## Cecilia Monge, MD, MPH, FACP

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#### George K. Siberry, MD, MPH

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## **MEETING ROSTER (cont.)**

#### **TEMPORARY MEMBERS (Voting) (cont.)**

Susan Z. Yanovski, MD (via video conferencing platform; AOD-9604-related BDSs Topic only) Co-Director, Office of Obesity Research Senior Scientific Advisor for Clinical Obesity Research NIDDK, NIH Bethesda, Maryland

## FDA PARTICIPANTS (Non-Voting)

## <u>Frances Gail Bormel, RPh, JD</u>

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#### Charles Ganley, MD (via video conferencing

*platform)* Director Office of Specialty Medicine (OSM) Office of New Drugs (OND), CDER, FDA

#### Kemi Asante, PharmD, MPH, RAC

Lead Consumer Safety Officer OCQC, OC, CDER, FDA

#### Russell Wesdyk, BS, MBA

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#### **Emily Kneeream, PharmD**

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#### Daiva Shetty, MD

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## Tracy Rupp, PharmD, MPH, BCPS, RD

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#### Elizabeth Hankla, PharmD

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# **MEETING ROSTER (cont.)**

#### FDA PARTICIPANTS (Non-Voting) (cont.)

## <u>Bini Mathew, PhD</u>

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# <u>Mai Tu, PhD</u>

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#### Marianne San Antonio, DO

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