# FDA-University of Maryland CERSI Public Workshop:
# Development of Antihypertensive Products for Use in Pediatric Patients

## Dates: July 15th – 16th, 2026

## Hybrid/FDA White Oak Campus, Great Room

## Silver Spring Maryland

## Background and Synopsis:

Treatment of chronic hypertension in pediatric patients, particularly children from birth to under 6 years of age, remains an area of unmet medical need, with limited FDA-approved therapies for use in this age group. Products are also being developed for the treatment of uncontrolled and/or resistant hypertension in adults. This public workshop will bring together key stakeholders, including clinicians, academicians, regulators, industry, and patients/caregivers, to discuss the similarities and differences in disease pathophysiology and drug response across age groups, determine the extent to which efficacy can be extrapolated, identify development priorities for both initial therapy and uncontrolled hypertension, and explore feasible strategies to generate evidence for the safe and effective use of antihypertensive treatment(s) in pediatric patients with hypertension.

DAY 1

## *Welcome & Introduction*

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| **9:00 AM – 9:10 AM** | **Welcome and Introduction** | |
| | **Lily Mulugeta, PharmD** | **Associate Director for Policy and Research, DPMH, ORPURM, CDER, FDA** |
| **9:10 AM – 9:20 AM** | **Keynote Talk** | |
| | **Hylton Joffe, MD** | **Director, OCHEN, CDER, FDA?** |
| **9:20 AM – 9:35 AM** | **Regulatory Framework for Drug Development in Children and Extrapolation of Safety and Efficacy Data from a Reference Population** | |
| | **Lily Mulugeta, PharmD** | **Associate Director for Policy and Research, DPMH, ORPURM, CDER, FDA** |
| **9:35 AM – 9:55 AM** | **Landscape of Drug Development for Management of Hypertension** | |
| | **Kirtida Mistry, MD, FASN** | **Medical Officer, DCN, CDER, FDA** |

## *Session 1: Chronic Hypertension*

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| **9:55 AM – 10:25 AM** | **Overview of Pediatric Hypertension and Similarities/Differences in Hypertension in Adults and Pediatric Patients** | |
| | **Joshua Samuels, MD, MPH** | **Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth Houston** |
| **10:25 AM – 10:45 AM** | **Similarities and Differences in Response to Anti-hypertensive Agents in Adult and Pediatric Patients** | |
| | **Joseph T. Flynn, MD, MS** | **Professor, Pediatrics, University of Washington School of Medicine; Chief, Division of Nephrology, Seattle Children's** |
| **10:45 AM – 10:55 AM** | **BREAK** | |
| **10:55 AM - 11:15 AM** | **Off-label Prescribing Practices** | |
| | **Douglas Blowey. MD** | **Medical Director, Chief Clinical Integration Officer, Children's Mercy Integrated Care Solutions** |
| **11:15 AM – 11:30 AM** | **Considerations for Age-Appropriate Pediatric Formulations—Industry Perspective** | |
| **11:30 AM – 11:45 AM** | **Off-label Prescribing: Medication Errors and Formulation Related Limitations** | |
| | **Rachel Meyers, PharmD, BCPS, BCPPS, FPPA** | **Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University; Pediatric Clinical Pharmacist, Cooperman Barnabas Medical Center** |
| **11:45 AM – 12:00 PM** | **Q&A/Clarifying Questions** | |
| **12:00 PM – 1:00 PM** | **Panel Discussion** | |
| ***Moderator:*** | **Mona Khurana, MD** | **Pediatric Team Leader, DPMH, ORDPURM, OND, CDER, FDA** |

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| | ***Panelists:*** | **Kirtida Mistry, MD, FASN** | **FDA-Liaison, CDER, FDA** |
| | | **Joshua Samuels, MD, MPH** | **Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth Houston** |
| | | **Joseph T. Flynn, MD, MS** | **Professor, Pediatrics, University of Washington School of Medicine; Chief, Division of Nephrology, Seattle Children's** |
| | | **Douglas Blowey. MD** | **Medical Director, Chief Clinical Integration Officer, Children's Mercy Integrated Care Solutions** |
| | | **Rachel Meyers, PharmD, BCPS, BCPPS, FPPA** | **Clinical Professor, Ernest Mario School of Pharmacy, Rutgers University; Pediatric Clinical Pharmacist, Cooperman Barnabas Medical Center, Livingston NJ** |
| | | **Industry** | |
| | | **Industry** | |
| | | **FDA** | |
| **1:00 PM – 2:00 PM** | | **LUNCH** | |

## *Session 2: Extrapolation and Trial Design Considerations—Chronic Hypertension*

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| **2:00 PM – 2:15 PM** | | **Dose-Response and Extrapolation of Efficacy from Older Pediatric Patients** | |
| | | **Sudharshan Hariharan, PhD** | **Master Pharmacokineticist, OCP, FDA** |
| **2:15 PM – 2:30 PM** | | **Safety Assessment and Pediatric Specific Considerations** | |
| | | **Ricardo Fonseca Martins, MBA** | **Senior Medical Manager, Pharmacovigilance, E. Lilly and Company** |
| **2:30 PM – 3:00 PM** | | **Panel: Lessons Learned from Conducting Clinical Trials in Pediatric Hypertension, including Uncontrolled Hypertension** | |
| | ***Moderator:*** | **Jennifer S. Li, MD** | **Pediatric Cardiologist, Duke Children's Cardiology Creekstone** |
| | ***Panelists:*** | **Monica Bengus, MD** | **Principal Medical Director, Cardiovascular, Roche** |
| | | **Joseph T. Flynn, MD, MS** | **Professor, Pediatrics, University of Washington School of Medicine; Chief, Division of Nephrology, Seattle Children's** |
| | | **Tammy McLoughlin Brady** | |
| | | **Joshua Samuels, MD, MPH** | **Professor; Director, Nephrology Fellowship Program; Director, Hypertension Program, McGovern Medical School, UTHealth Houston** |
| **3:00 PM – 3:10 PM** | | **BREAK** | |
| **3:10 PM – 3:25 PM** | | **Dose Prediction and Modeling and Simulation—Industry Perspective** | |
| **3:25 PM – 3:40 PM** | | **Innovative Trial Designs and Leveraging Existing Data** | |
| | | **Brian Benneyworth?** | |
| **3:40 PM – 4:40 PM** | | **Panel and Stakeholder Discussion** | |
| | ***Moderator:*** | **Kirtida Mistry, MD, FASN** | **Medical Officer, DCN, CDER, FDA** |
| | ***Panelists:*** | **Aliza M. Thompson, MD, MS** | **Director, DCN, CDER, FDA** |
| | | **Sudharshan Hariharan, PhD** | **Master Pharmacokineticist, OCP, FDA** |
| | | **Ricardo Fonseca Martins, MBA** | **Senior Medical Manager, Pharmacovigilance, E. Lilly and Company** |
| | | **Brian Benneyworth?** | |

**Industry**

**4:40 PM – 4:50 PM** **Closing Remarks—Day 1**

DAY 2

## *Session 3: Management of Uncontrolled Hypertension*

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| **9:00 AM – 9:10 AM** | **Welcome and Summary of Day 1** | |
| **9:10 AM – 9:25 AM** | **Treatment of Uncontrolled Hypertension: Similarities/Differences Adult and Pediatric Patients Across Age Spectrum** | |
| | **Carissa M. Baker-Smith, MD, MPH, MS** | **Cardiologist, Director, Nemours Preventative Cardiology Program, Nemours Children's Hospital** |
| **9:25 AM – 9:40 AM** | **Evaluation of Response—Treatment of Uncontrolled Hypertension in Adults Versus Pediatric Patients Across Age Spectrum** | |
| | *TBD* | |
| **9:40 AM – 10:00 AM** | **BREAK** | |
| **10:00 AM – 11:20 AM** | **Panel Discussion** | |
| ***Moderator:*** | ***TBD*** | |
| ***Panelists:*** | **Tammy McLoughlin Brady** | |
| | **Carissa M. Baker-Smith, MD, MPH, MS** | **Cardiologist, Director, Nemours Preventative Cardiology Program, Nemours Children's Hospital** |
| | **FDA** | |
| | **Industry** | |
| | **Industry** | |
| **11:20 AM – 11:30 AM** | **Closing Remarks** | |
| | **Aliza Thompson, MD, MS** | **Director, DCN, CDER, FDA** |