



Demand Forecasting for Controlled Substances

Hybrid Public Meeting

Rooftop Meeting Space | 1333 New Hampshire Ave NW | Washington, DC 20036

August 27, 2025

2 - 5pm (eastern)

Agenda

2 pm Welcome

- **Susan C. Winckler, RPh, Esq**, CEO, Reagan-Udall Foundation for the FDA

2:05 pm FDA Opening Remarks

- **Lowell Zeta, JD**, Deputy Commissioner for Strategic Initiatives and Special Counsel, U.S. Food and Drug Administration

2:10 pm CDER Fireside Chat

- **Marta Sokolowska, PhD**, Deputy Center Director for Substance Use and Behavioral Health, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- **Susan C. Winckler, RPh, Esq**

2:20 pm Overview

- **Amar Bhat, PhD**, COO, Reagan-Udall Foundation for the FDA

2:35 pm Public Comment

Each commenter will have 3 minutes to speak

Topics:

1. Methods and processes used in forecasting demand and considerations for the unique circumstances of estimating demand for controlled substances
2. The effects of misuse/diversion on controlled substances and how they should be considered in demand forecasting
3. Potential impacts of underestimation or overestimation of demand on patients who are prescribed Schedule II substances

4 pm Demand Forecasting Panel

Panelists:

- **Laura Bray, MBA**, Chief Change Maker and Founder, Angels for Change
- **John A. Gilbert, JD**, Director, Hyman, Phelps & McNamara
- **Nicolette Louissaint, PhD**, Chief Policy Officer, Healthcare Distribution Alliance
- **Emily Tucker, PhD**, Dean's Assistant Professor, Department of Industrial Engineering, Clemson University
- **Jillanne Schulte Wall, JD**, Senior Director of Health and Regulatory Policy, American Society of Health-System Pharmacists

5 pm Adjourn

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