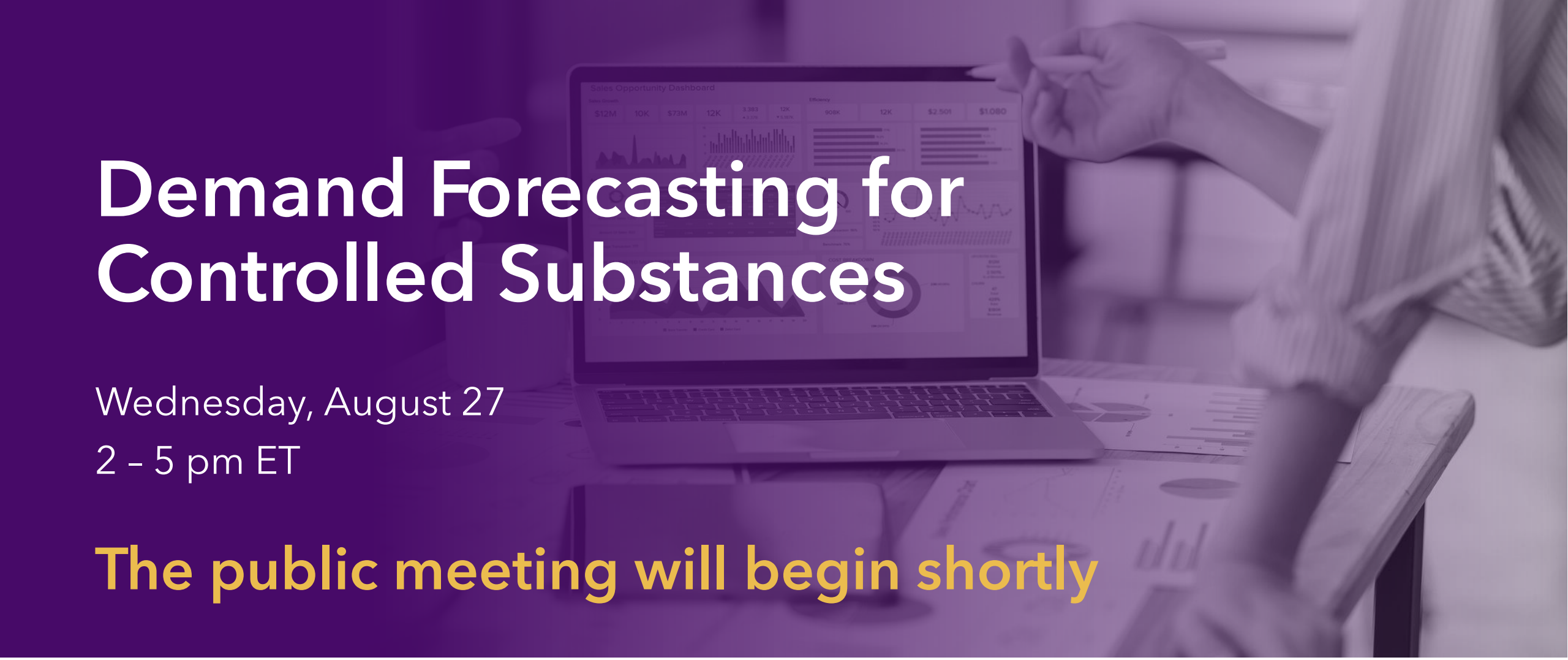

Demand Forecasting for Controlled Substances

Wednesday, August 27

2 – 5 pm ET

The public meeting will begin shortly

This activity is one part of a multi-part Foundation project related to substance use disorder. The multi-part project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of $2,470,442 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

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Welcome

Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA

Housekeeping

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Due to the meeting size, your microphone and video will remain off during the meeting

Please share your questions using the Zoom Q&A function

This public meeting is being recorded.

The slides, transcript, and video will be available at www.ReaganUdall.org

Agenda

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2 pm	Welcome
2:05 pm	FDA Opening Remarks
2:10 pm	CDER Fireside Chat
2:20 pm	Overview
2:35 pm	Public Comment
4 pm	Experts Panel
5 pm	Adjourn

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FDA Opening Remarks

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

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CDER Fireside Chat

Featuring

Marta Sokolowska, PhD

Deputy Center Director for Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Overview

Amar Bhat, PhD
Chief Operating Officer
Reagan-Udall Foundation for the FDA

Demand Forecasting for Controlled Substances: An Overview

Amar Bhat, PhD
Reagan-Udall Foundation for the FDA
August 27, 2025

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Project Origins

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The Collateral Damage of A.D.H.D. Drug Shortages

As a new school year begins, parents and doctors find medication shortages are leading to declines in learning and self-esteem.

Nationwide ADHD medication shortage is 'an ongoing problem' in metro Detroit

Amid the Adderall Shortage, People With A.D.H.D. Face Withdrawal and Despair

Without medication, patients are wondering what comes next.

ADHD medications still in shortage, frustrating patients and doctors

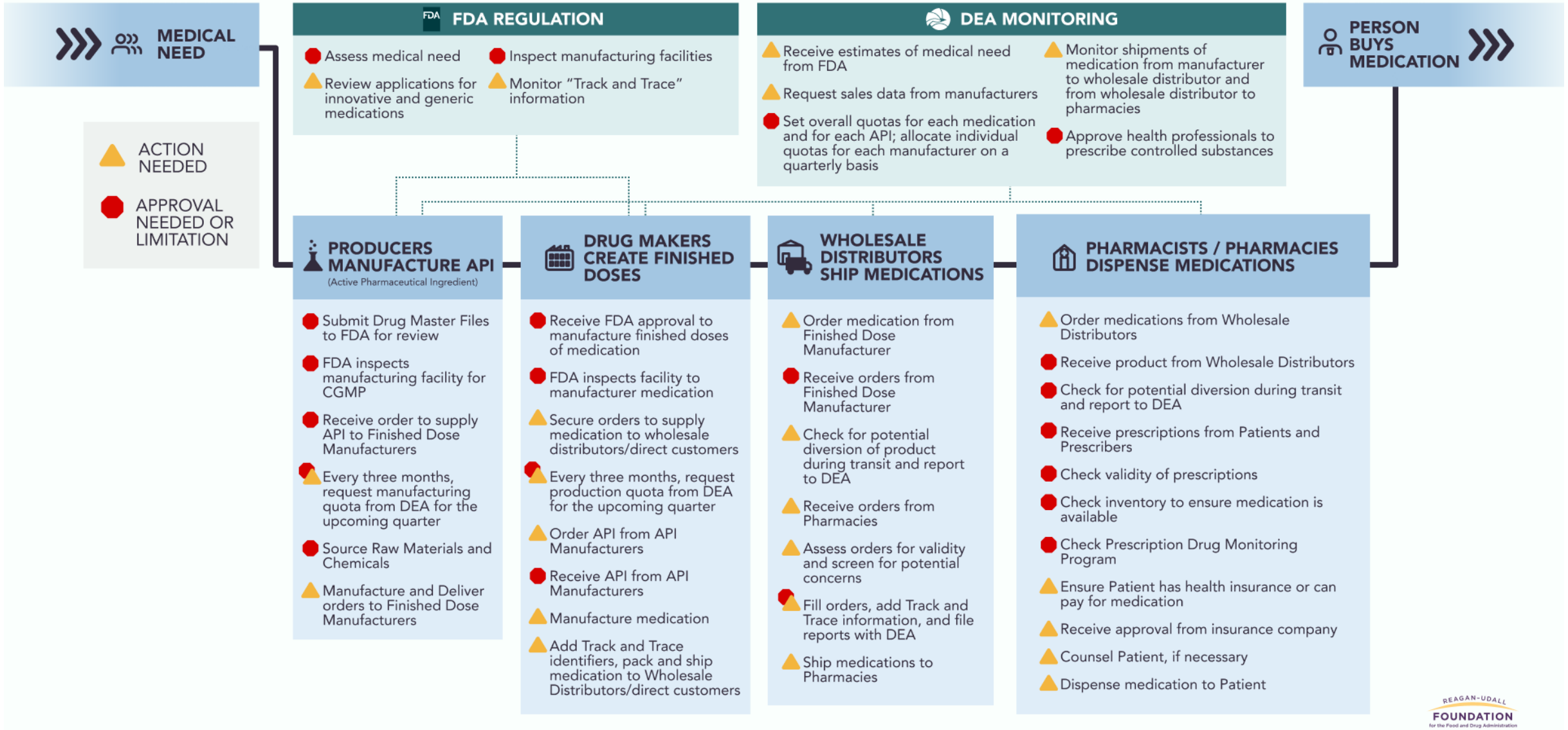
No End in Sight for National ADHD Drug Shortage

How the Adderall shortage is affecting college students

HEALTH

More adults sought help for ADHD during pandemic, contributing to drug shortages

FACTORS THAT AFFECT PRESCRIPTION STIMULANT AVAILABILITY



https://reaganudall.org/factors-affect-prescription-stimulant-availability

Controlled Substances Act and the Quota System

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DEA MONITORING

- Receive estimates of medical need from FDA
- Request sales data from manufacturers
- Set overall quotas for each medication and for each API; allocate individual quotas for each manufacturer on a quarterly basis
- Monitor shipments of medication from manufacturer to wholesale distributor and from wholesale distributor to pharmacies
- Approve health professionals to prescribe controlled substances

What is Demand Forecasting?

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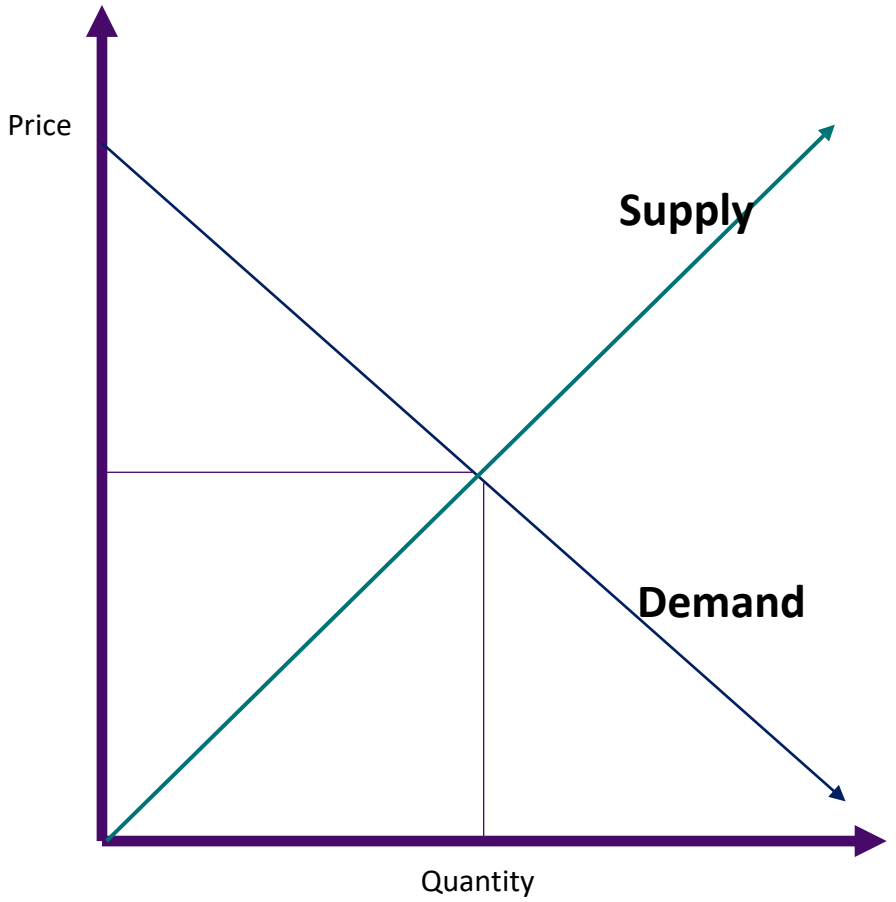
Definition: The process of predicting quantity of product required to be manufactured to meet the needs of consumers at a future point in time.

Demand forecasting helps to ensure that supply meets demand, avoiding overproduction (waste) and underproduction (shortage)



Why Demand Forecasting?

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- Demand forecasting can help companies plan and allocate resources efficiently.
- Accurately predicting future demand also can help businesses better prepare for potential disruptions, such as sudden changes in market conditions.
- Manufacturers take in data from multiple sources. They also put their forecasts to multiple uses, resulting in different types of forecasts developed for different purposes.

Differing Motivations for Forecasting

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Pharmaceutical demand forecasting plays an important role for any entity along the drug supply chain.

Manufacturers, wholesalers and pharmacies need to predict customer orders, maximize profit and efficiency, minimize risks and waste

- Timelines and level of specificity vary from 6 months to 5+ years depending on the need and the user

DEA and FDA need to ensure legitimate medical need is met, while minimizing risk of diversion

- Timelines and allocations are generally for the year coming up

Statistical Modeling Techniques Have Become More Sophisticated Over Last 100 Years

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1920s-1970	1980s-2000s	2010s	2020s
• Exponential Smoothing • Moving Averages • Time-Series Analysis	• Exogenous Variables • Hybrid Models • Early Neural Networks	• Machine Learning, • New Probabilistic Approaches	• Probabilistic Forecasting, • More Advanced Neural Models

On-Market Products vs. New Product Launches

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On-Market Products

- Utilizes short-term forecasts (12-18 months)
- Short time horizons, e.g., monthly, are more useful when anticipating only minor changes in demand and no major exogenous factors

New Products

- Uses long-term forecasting (5-10 years)
- Requires a long lead time to see impacts
- More common when anticipating a new product, new indication, or increase in manufacturing capacity

Data Sources: Whom do you trust?

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Internal sales data are most important

- May indicate seasonal fluctuations, e.g., allergy/cold medicines

Commercial datasets purchased from trusted sources

- Supplement to internal sales data
- Helps to understand how the competition is doing in specific market segments
- No one external dataset can perfectly meet all data needs; all are considered flawed in some way

Experience and judgment are needed to apply and validate information from datasets properly

Exogenous Factors and Demand Sensing

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- Exogenous factors are real-time factors that impact pharmaceutical demand, but are NOT reflected in historical data, e.g., sales data.
  - Cannot predict impact of exogenous factors by looking backwards in time.

- Demand sensing focuses on identifying and incorporating various exogenous factors into the forecast
  - For pharmaceutical industry, incorporating exogenous factors into simpler, more agile statistical models, e.g., exponential smoothing, moving averages, etc., have been more impactful than creating more sophisticated models using machine learning or neural networks.

Typical Exogenous Factors

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Public Health Events

- Pandemics

Policy Changes

- New laws or regulations impacting uptake

Manufacturing Constraints

- Supply disruptions, failed inspections, product wastage

Demographics

- increase in patient populations, new indications

Media Effects

- News coverage, social media trends

Market Conditions

- New competitors, generic entry

Estimating Medical Need

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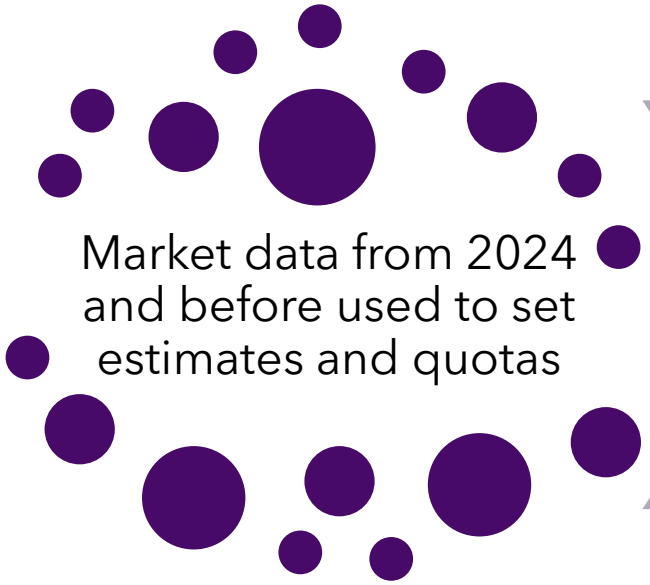

Manufacturers need 9-12 months to source, manufacture and transport product

Products reach the pharmacies and patients can access their medications

2025 2026 2027

Once a Shortage Occurs, It Can Be Hard to Catch Up

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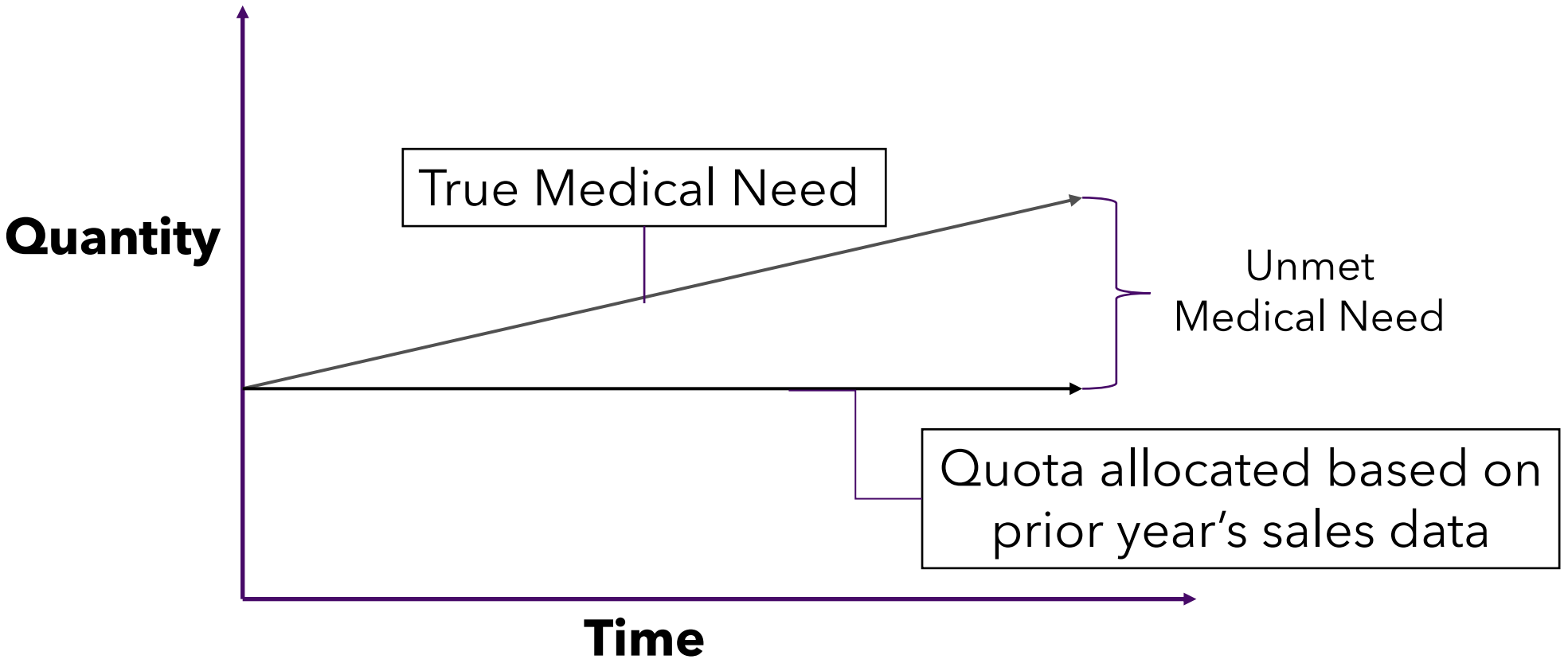

Thank you!

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Public Comment

Each person will have a maximum of three minutes

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

Public Comment

Topic 1

Sally Balsamo

Public Comment

Topic 1

Bill Grubb

Public Comment

Topic 1

Pat Irving

Public Comment

Topic 1

Marc Wagner

Public Comment

Topic 1

Terri Lyle Wilson

Public Comment

Topic 2

Lucas Gerler

Public Comment

Topic 2

Paul Giacinto

Public Comment

Topic 2

Richard Lawhern

Public Comment

Topic 2

Stacey McKenna

Public Comment

Topic 2

Rachel Robinson

Public Comment

Topic 2

David Smith

Public Comment

Topic 3

Giuseppe Randazzo

Public Comment

Topic 3

Rose Bigham

Public Comment

Topic 3

Jessica Collier

Public Comment

Topic 3

Toni Collins

Public Comment

Topic 3

Tandi Crowder-Blonigen

Public Comment

Topic 3

Jeanette French

Public Comment

Topic 3

Monty Goddard

Public Comment

Topic 3

Brandy Hoerauf

Public Comment

Topic 3

Cammie LaValle

Public Comment

Topic 3

Danita Marrs

Public Comment

Topic 3

Claudia Merandi

Public Comment

Topic 3

Kate Nicholson

Public Comment

Topic 3

Geoffrey Rosenberg

Public Comment

Topic 3

Bev Schechtman

Panel Discussion

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- **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

Thank You for Joining Us!

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