# Session III

## *Supply Chain System Overview & Key Fragilities*

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# Understanding the System

**Oxygen therapy is a very mature, relatively consistent, and stable business**

- *Under normal conditions, seasonal demand variability is relatively predictable*
  - Demand forecasting models use historical data, regression analysis, and current market data to predict product demand

**Under normal conditions, raw material and component supply chains have highly variable lead times**

- Material/component suppliers rely on demand forecasts from manufacturers and distributors to plan their production and inventory
  - Large percentage of raw materials, components, and finished goods are sourced outside of the US
  - Medical device manufacturers compete with larger industries, with exponentially higher demand
  - Typical lead times for many commodity components is 90-150 days
  - Lead times for high demand materials & components can be as long as 12 months

# Understanding the System

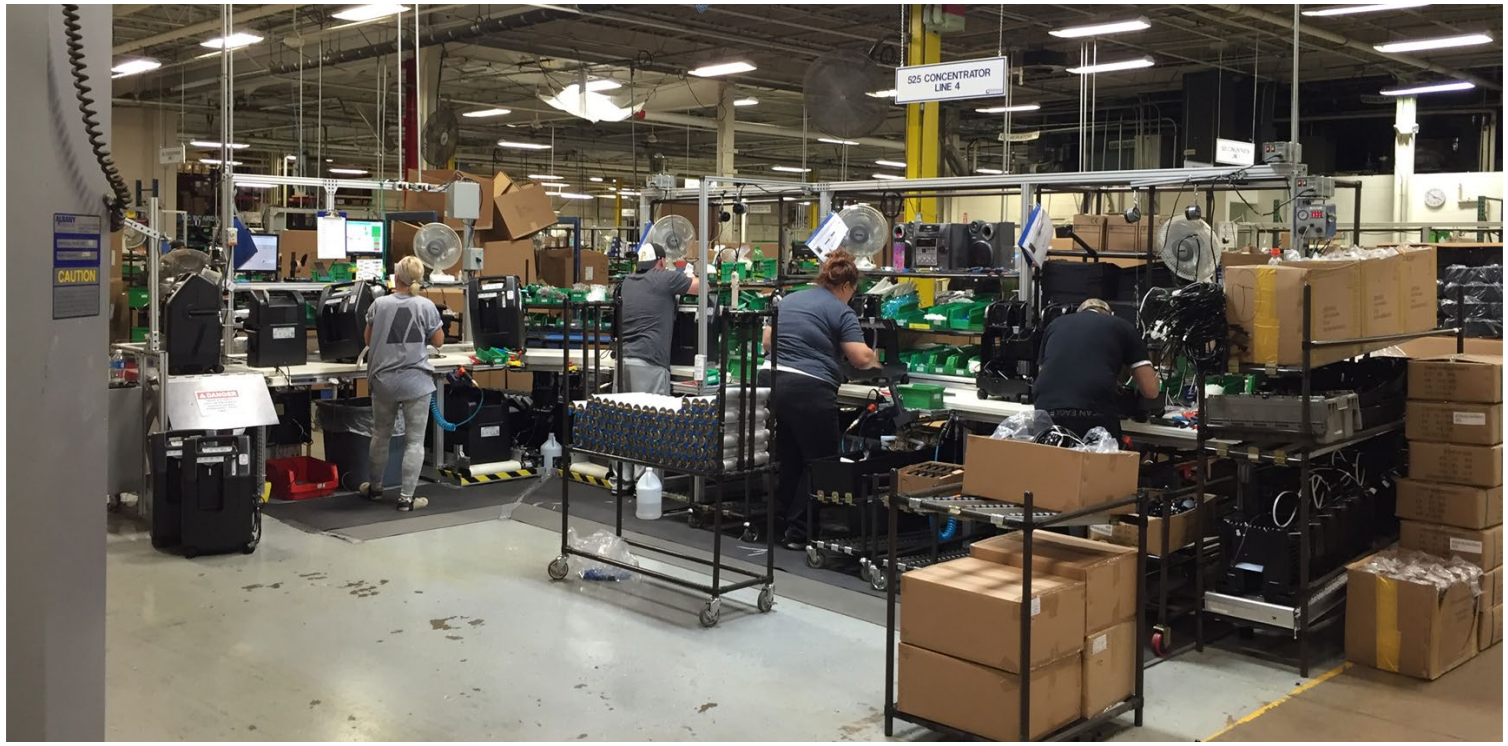
**Manufacturing critical dependencies – *Demand Forecasting***
- In a steady state, predictable, lean and efficient manufacturing operations is the goal

**Responding to un-forecasted demand – *Short Term***
- Exhaust existing FG inventory & safety stock
- Increase current manufacturing capacity

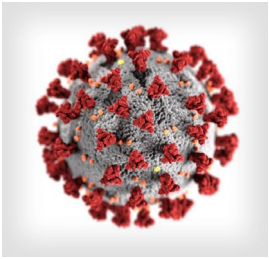
**Responding to un-forecasted demand – *Long Term***
- Add shifts; requires additional staff at all levels
- Add production capacity: additional assembly lines
- Expedited materials
- Expanding material sourcing: new vendors

**Predicting and planning the rapid decrease in demand – *when does the other shoe drop*?**
- Rapid reduction in work force
- Cancel open PO's – often financial penalties
- Overstock of inventory

***"There is one constant in demand forecasting…it will be wrong"***


525 CONCENTRATOR
LINE 4
CAUTION

# Triggers – Shocks to the System



**Unexpected severe respiratory season**
- Epidemic level
- Pandemic level

**Natural disasters**
- Hurricanes
- Blackout

**Government regulations/events**
- COVID restrictions

**Geopolitical issues**
- Heavy dependency of critical materials and finished goods sourced from outside of the US

**Predictability**
- Annual seasonality of respiratory infections and hospitalizations are generally predictable – *the severity of the season is not*

# Potentiators – Structural Vulnerabilities

## On hand inventory

- Manufacturers and oxygen providers maintain modest, limited excess FG inventory (safety stock)

## Shrinking domestic manufacturing capacity

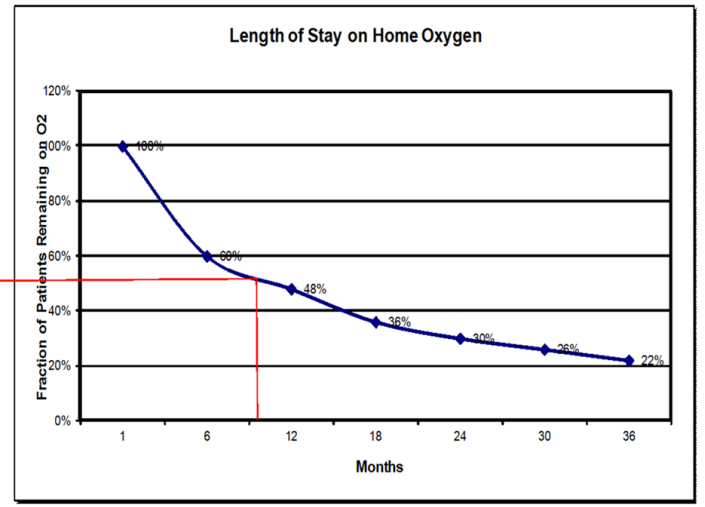
- Over the last 4-years, two of the four largest US oxygen concentrator manufacturers have exited the business due to regulatory issues
- Today, a growing percentage of the stationary concentrators being sold in the US are designed and produced in China
- ***Prior to COVID, and the loss of two manufacturers, approximately >95% of stationary concentrators were produced by US manufacturers***

## Regression to the mean

- Following a rapid surge in demand, there is a slow return to normal
  - Rapid drop in demand for new product
  - ***Medicare home O2 patient median LOS ~11 months***[1]
- Slow return to normal oxygen device demand

| Month | Patients |
|---|---|
| 1 | 100% |
| 6 | 60% |
| 12 | 48% |
| 18 | 36% |
| 24 | 30% |
| 30 | 26% |
| 36 | 22% |

Median




[1]OIG Report-Medicare Home Oxygen Equipment: Cost & Servicing. OEI-09-04-00420 Sept 2006

# Buffers- Sources of Resilience

## Stockpiles

- Most oxygen devices/systems are not designed for long-term storage
  - Compressed oxygen
  - Liquid oxygen systems
  - Oxygen concentrators
  - Oxygen consumables

**Despite decades of R&D, no new oxygen generating method has proven to be as safe, reliable, efficacious, and as cost effective as the 3 traditional systems**

- In the US, *~98% of all home oxygen therapy is provided with a stationary concentrator*[2]
  - Emergency back-up O2 is typically compressed oxygen cylinders
  - These data complicate the provision of home oxygen therapy during natural disasters with prolonged power outages

[2]Data extrapolated from Medicare oxygen device claims data

# Oxygen Conserving Devices

**Oxygen conserving devices**

- Passive or active devices intended to reduce O2 consumption for nasal cannula O2 delivery
- Under-utilized outside of NA
  - Lack of knowledge of device mechanics and efficacy
  - Misunderstanding of benefits in low flow nasal cannula applications
- Oxymizer® conserving cannula demand increased significantly during pandemic
  - Demand for pulse-dose devices actually *decreased*
- Should be considered part of the solution for gaseous systems
  - Minimal savings = 2:1



# Cross-Cutting & Forward-Looking Reflections

**Lessons learned**

- There is a small safety stock of oxygen devices that is rapidly consumed at the onset of a major surge in demand
- There is limited US production capacity for many oxygen devices, some of which has declined significantly since COVID
- Ramping manufacturing for significant volumes of unforecasted medical devices is a multi-variate problem that requires time, and an aligned vision from all stakeholders
- *LMIC markets require devices purposefully designed for the operating environment*


**Knowledge Gaps in Developing Markets**

- LMIC education & training on oxygen therapy devices and systems
- Global demand forecasting
- Oxygen as a service infrastructure