CENTER FOR HEALTHCARE ENGINEERING & PATIENT SAFETY
UNIVERSITY OF MICHIGAN

2018 Healthcare Engineering and Patient Safety Symposium

Preventing Drug Shortages: Analysis of Regulatory and Contractual Strategies

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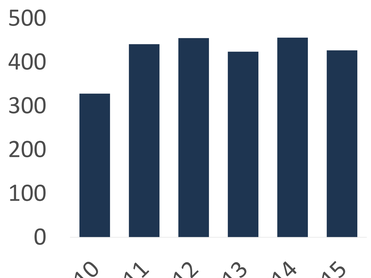
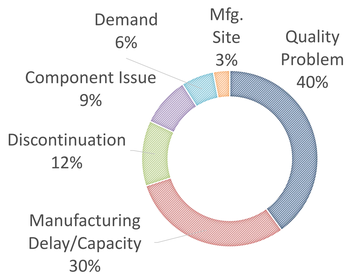
Problem Statement

Public Health Crisis

Within the past 10 years, shortages of prescription drugs have reached crisis levels. Shortages persist for a median of 14 months and are largely caused by disruptions to non-resilient pharmaceutical supply chains.[1,2] Generic sterile injectable drugs with low profit margins, including pediatric cancer drugs, have been commonly affected.



Number of shortages



Causes of shortages

Effects

Shortages impose large costs on the US healthcare system and can have major effects on patient care.[3-5]

- Annual cost of substitute drugs and extra inventory: **~$200 million**
- Annual hospital labor cost to manage shortages**: >$200 million**
- Moderate to very high risk of…
  - **Disease progression**
  - **Wrong substitute** administered
  - **Adverse reaction** to substitute

Research Gap

Conjecture: For some types of drugs, it is not in a company's best interest to produce a reliable supply.

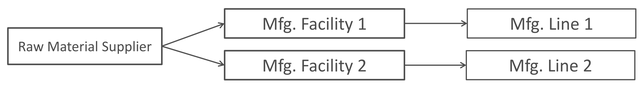
There is a need to better understand how to incentivize companies to reliably produce drugs vulnerable to shortage. The supply chain design literature on disruptions and in regulated industries is limited.

Solution Approach

Model Structure

We developed a new mathematical model to study the design of the supply chain for a single drug. The company aims to maximize its expected profit over two years by selecting how many raw material suppliers, plants, and lines to have. When the decisions are made, there is uncertainty about which, if any, components will be disrupted. After the selections are made, the uncertainty is realized, and the company may or may not be able to meet demand.

Regulatory and contracting policies affect the costs and requirements for the supply chain design. We conducted analyses to determine whether policies that have been proposed would be effective in preventing shortages.



Sample supply chain structure

Policies Evaluated

- Redundancy regulations
- Failure-to-supply penalties

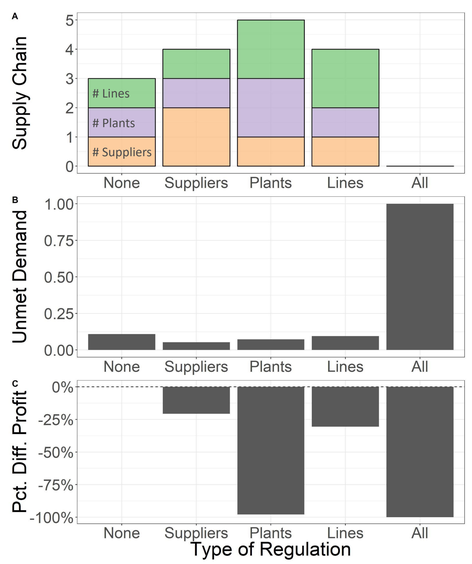
Results

Regulations

Requiring redundancy at **individual levels** reduces the fraction of demand **short** from 0.11 to **0.05**-**0.09**.

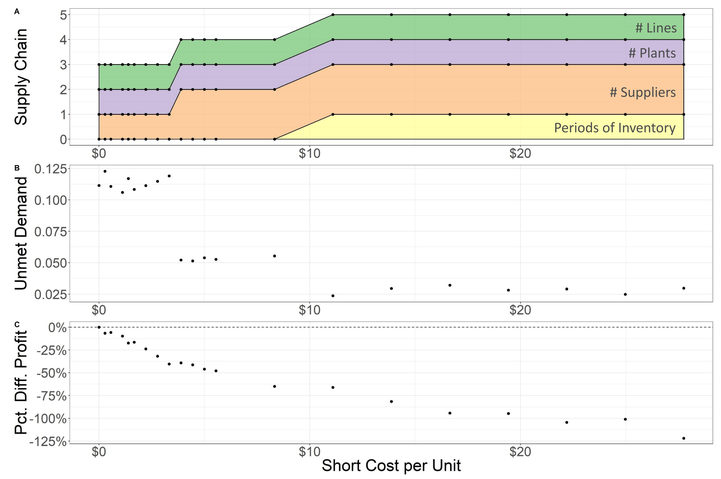
If the supply chain is required to have **multiple suppliers**, the fraction of demand **short** is **0.05**, and the expected annual **profit** is **decreases 21%** vs. baseline.

If redundancy is required at **all levels**, the company **will not produce** the drug.



Results

Failure-to-Supply Penalties



With **no penalty**, the company selects **1 supplier, 1 plant, 1 line**, and **0 months of safety stock**, and the expected fraction short is **0.11**.

With a **penalty of $3.89**, the manufacturer selects to add an **additional supplier**, and the expected fraction **short** drops to **0.05**. The annual **profit decreases 39%** vs. baseline.

With a **penalty of $11.10**, the manufacturer selects to hold **two months of safety stock**. The expected fraction **short** is **0.02**, and the expected annual **profit declines 66%** vs. baseline.

Conclusions

These results suggest that moderate penalties or regulation at individual echelons of the supply chain may be sufficient to induce additional resiliency. Requiring redundancy at each level of the supply chain may cause the company to not produce the drug at all.

Acknowledgements

Funding for this work was provided by MCubed, a University of Michigan seed-funding program, and the National Science Foundation Graduate Research Fellowship Program under Grant No. DGE 1256260. Any opinions, findings, and conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of the National Science Foundation.

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