



# How FDA Plans to Use Drug Amount Reporting Data

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Reporting Drug Amount Under Section 510(j)(3) of the FD&C Act  
September 8, 2022

# Overview



- FDA's vision for the use of drug amount reporting data
- How drug amount reporting data will enhance the Agency's understanding of drug supply chains
- How FDA plans to use drug amount reporting data to support efforts on supply chain issues and drug shortages

# FDA's Vision For Using Drug Amount Reporting Data

# FDA Plans to Use Drug Amount Reporting Data to Enhance Understanding of Drug Supply Chain Issues



## Drug Amount Reports (Across Establishments and Products)

NDC	DUNS	Business Operation	Amount
12345-6789-0	123456789	MANUFACTURE	100
12345-6789-1	123456789	MANUFACTURE	500
12345-6789-2	123456789	MANUFACTURE	1000

NDC	DUNS	Business Operation	Amount
12345-6789-0	523456789	MANUFACTURE	600
12345-6789-1	523456789	MANUFACTURE	300
12345-6789-2	523456789	MANUFACTURE	4000



## Other FDA Operational and Regulatory Data

Drug Registration  
and Listing



Regulatory  
Submissions/Forms



External Data  
(e.g., Sales)

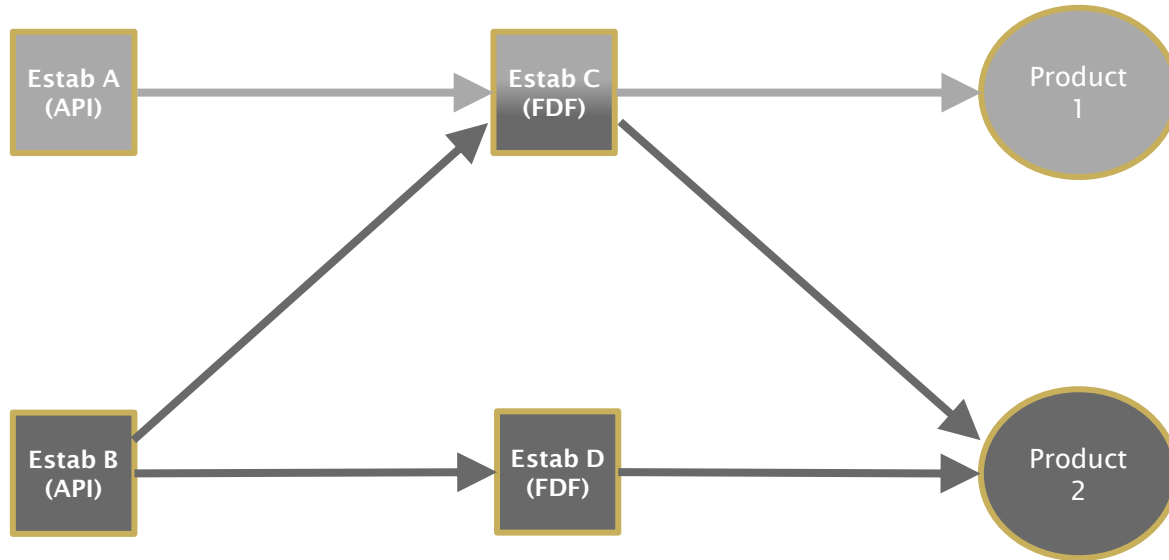


## Enhanced Understanding of Drug Supply Chain Issues and Drug Shortages

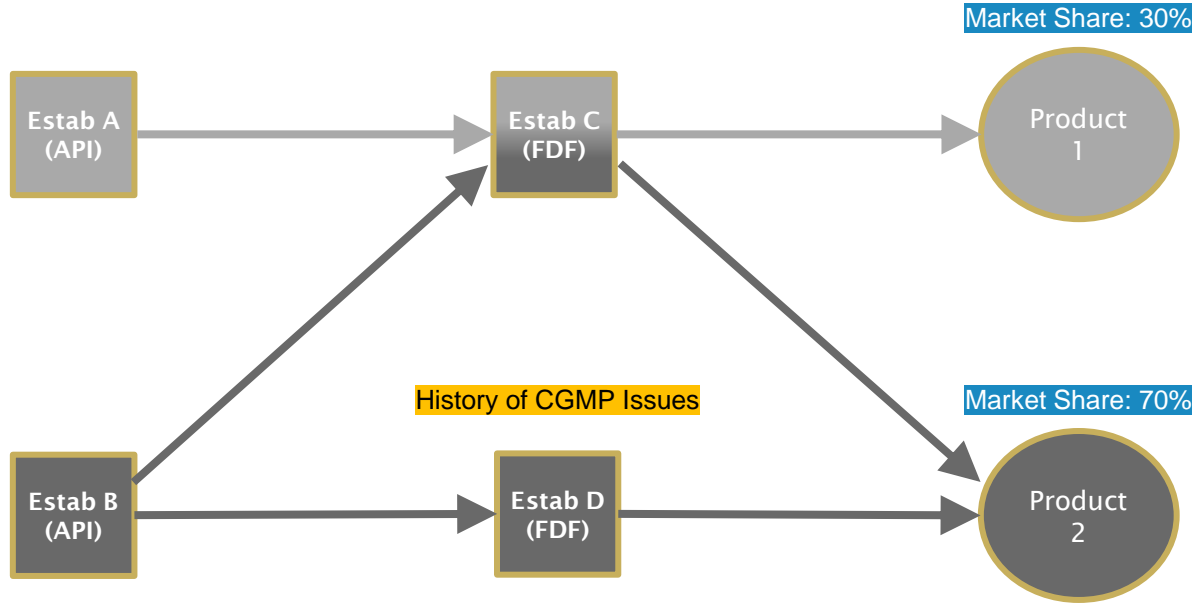


# How These Data Enhance Understanding of Drug Supply Chains

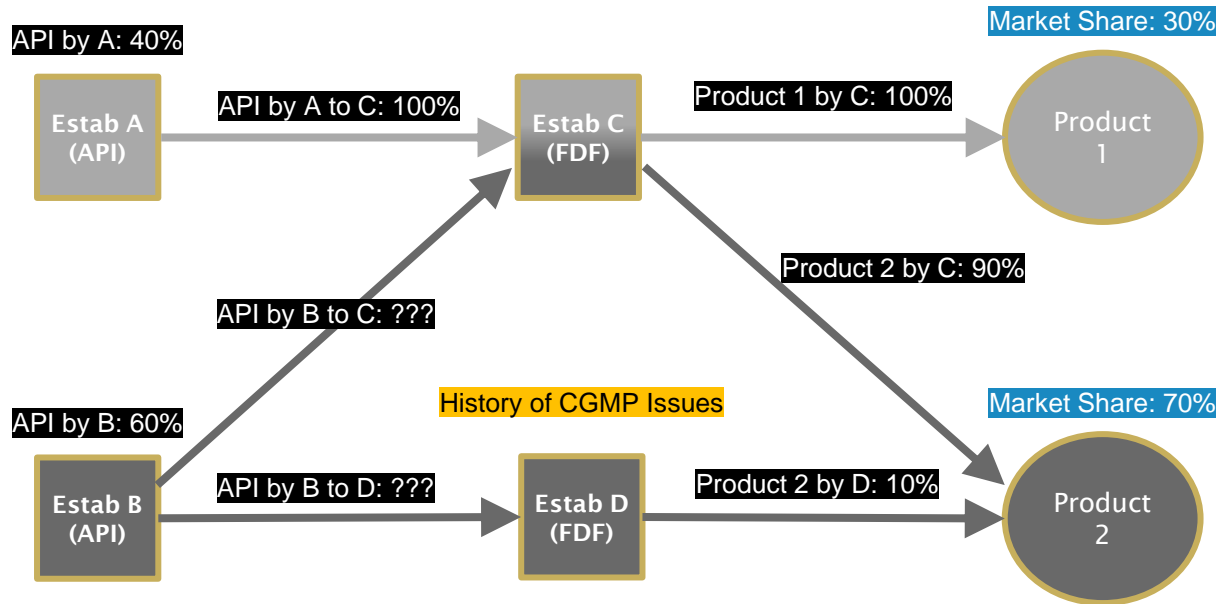
# A Hypothetical Drug Supply Chain



# FDA Insights Prior to Drug Amount Reporting



# Drug Amount Reporting Will Help FDA Understand Dependence on Specific Establishments





# How Drug Amount Reporting Data Support FDA Efforts

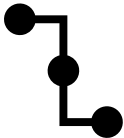
# Three Main FDA Efforts Supported By Drug Amount Reporting



Analyzing the **globalization of the U.S. drug supply chain** (e.g., location of manufacturing)



Enhancing the assessment of each establishment's patient exposure in the **site selection model**



Evaluating immediate and long-term supply chain vulnerabilities to help **respond to and potentially predict supply chain issues** (e.g., drug shortages)

# Drug Amount Reporting Will Help FDA Move Beyond Analyzing Establishment Location



**52% of Finished Dosage Form (FDF) Establishments Outside of the U.S.**

**73% of Active Pharmaceutical Ingredient (API) Establishments Outside of the U.S.**

Figure 4: Percentage of FDF Manufacturing Facilities for All Drugs by Country or Region, March 2021

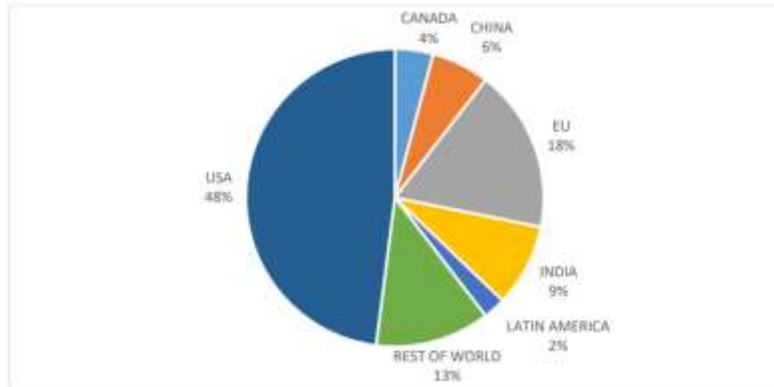
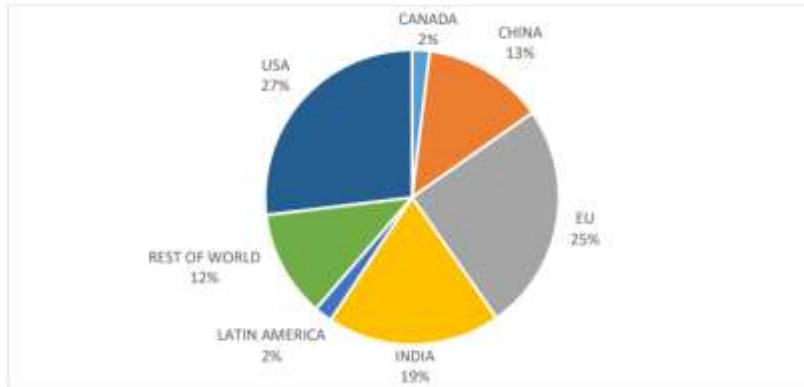


Figure 5: Percentage of API Manufacturing Facilities for All Drugs by Country or Region, March 2021



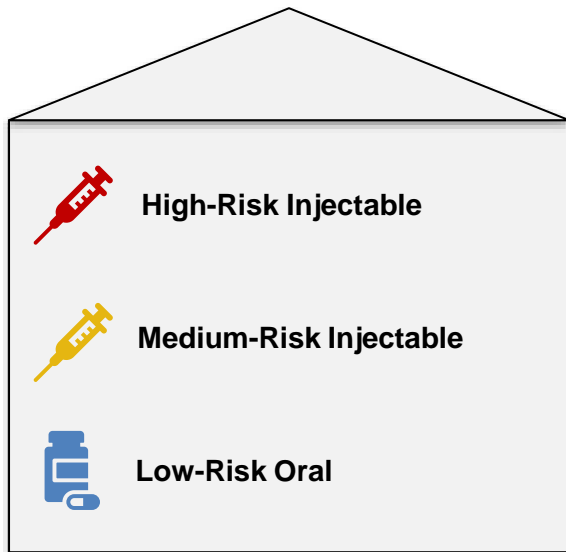
**Drug Amount Data: Which products, and how much of their volume, are manufactured outside of the U.S.?**

Source: 100-Day Reviews Under Executive Order 14017, June 2021, Pages 215-216  
<https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>

# Drug Amount Reporting Will Help Enhance FDA's Risk-Based Inspection Prioritization

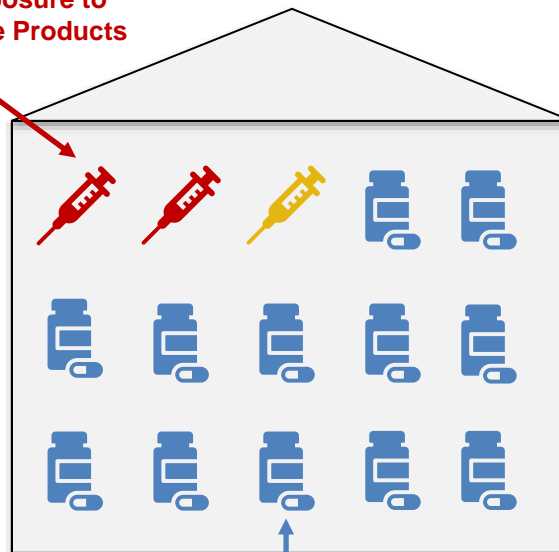


Products at Hypothetical  
Establishment



Hypothetical Drug  
Amount Report

Lower Patient Exposure to  
High-Risk Injectable Products



Higher Patient Exposure to  
Low-Risk Oral Products

# Drug Amount Reporting Will Help FDA Respond to Potential Drug Shortages in Emergencies



## Drug Shortages After the Eastern Japan Earthquake: Experiences in a Tertiary Referral Center

Jinichi Mori, MD, Kenichi Hasui, Tetsuya Tanimoto, MD, more...

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First Published May 29, 2012 | Research Article | Check for updates

<https://doi.org/10.1177/0092861512448569>

*Hurricane Damage in Puerto Rico Leads to Fears of Drug Shortages Nationwide*

MANUFACTURING

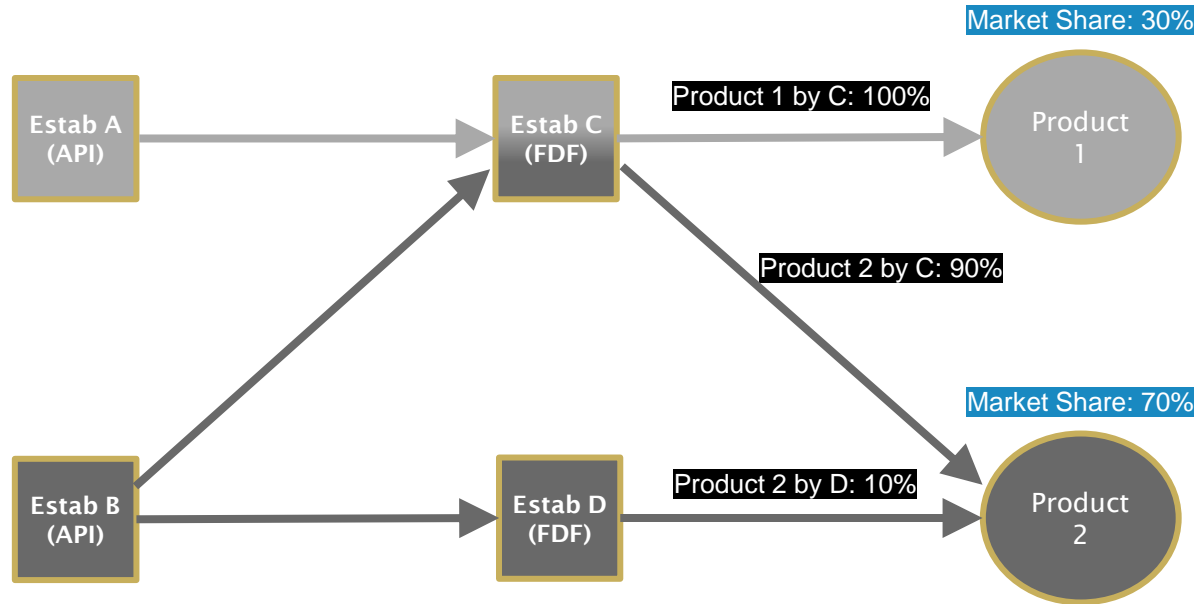
**FDA anticipates disruptions, shortages as China outbreak plays out**

By Eric Palmer • Feb 17, 2020 10:27am



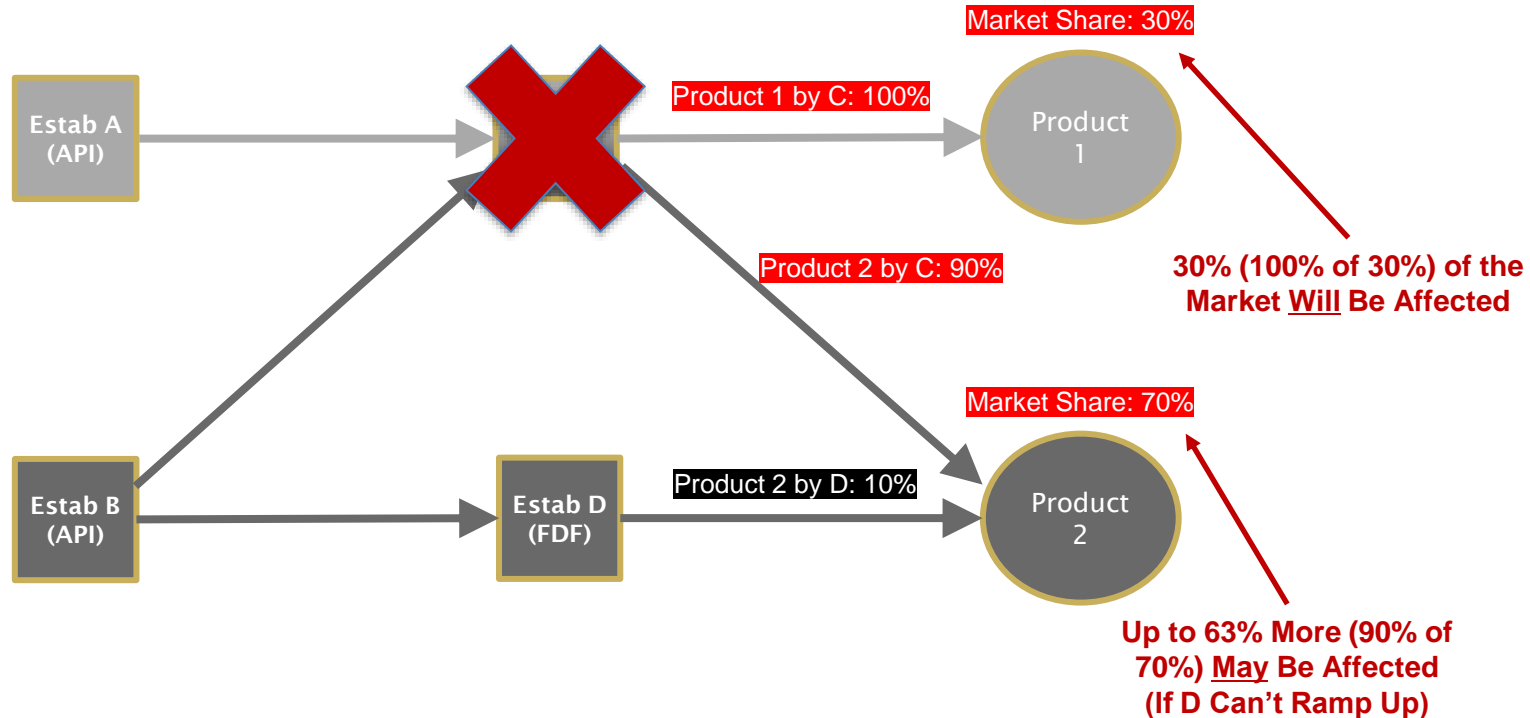


# What if Establishment C Ceases Production?





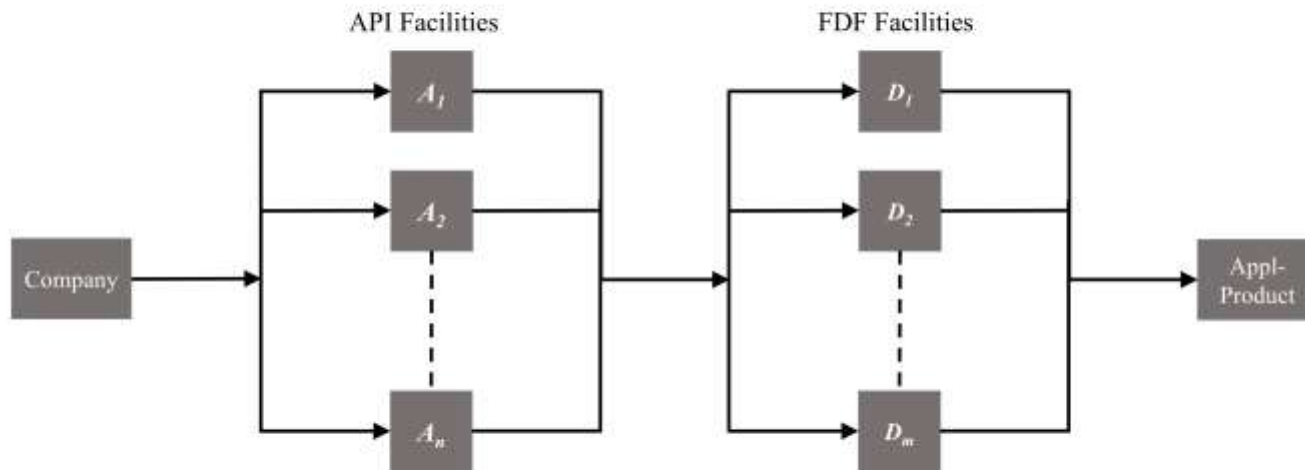
# What if Establishment C Ceases Production?



# Drug Amount Reporting Could Help FDA Measure Supply Chain Vulnerabilities

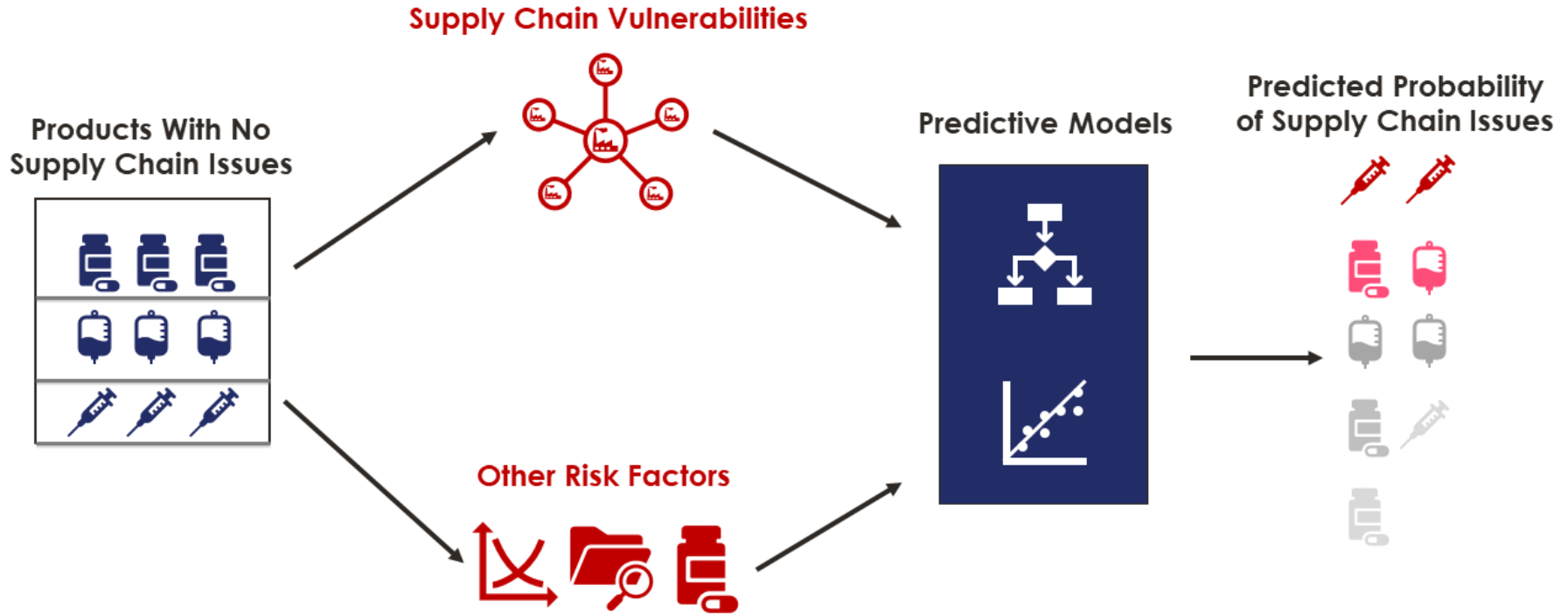


FDA is exploring systems engineering approaches for incorporating drug amount reporting data into quantitative measures of supply chain vulnerability



Source: Tillman et al. A System Reliability Approach for Assessing the Vulnerability of United States Pharmaceutical Supply Chains. 2020 ESREL Conference Proceedings.  
<https://www.rpsonline.com.sg/proceedings/esrel2020/html/4832.xml>

# Which Could Potentially Help FDA Predict Future Supply Chain Issues



# Supply Chain Issues Can Have Substantial Public Health Impacts



**Norepinephrine Shortage Per FDA Website<sup>1</sup>:**  
Feb 2011 – Feb 2012

**2017 JAMA Study<sup>2</sup>:** During the Shortage...

Patients switched to alternatives like phenylephrine

Deaths increased by **3.7 percentage points**

**Nationally Projected Losses<sup>3</sup>: \$13.7 Billion**

<sup>1</sup>Sources: FDA Website

<sup>2</sup>Vail et al. *Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock*. JAMA. 2017.

<sup>3</sup>We project to all US septic shock admissions using Rhee et al. 2017 and Table 82 of Health, United States 2016. We assume a value of mortality risk reduction of \$10 million.



# Summary



# Summary

- FDA plans to combine drug amount reporting data with other information to enhance its understanding of drug supply chain issues and drug shortages
- Drug amount reporting data will help FDA evaluate the dependence of drug supply chains on each establishment
- Several FDA efforts will benefit from drug amount reporting data, including risk-based inspection prioritization and response to supply chain issues (including drug shortages)



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