



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

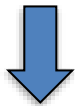
FDA Plans to Use Drug Amount Reporting Data to Enhance Understanding of Drug Supply Chain Issues



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



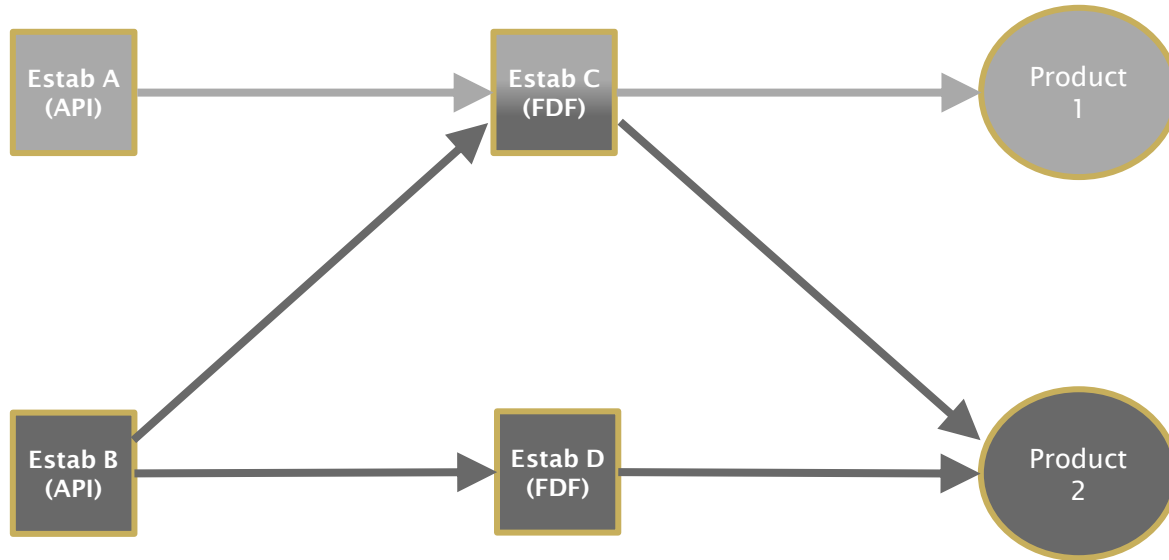
External Data
(e.g., Sales)



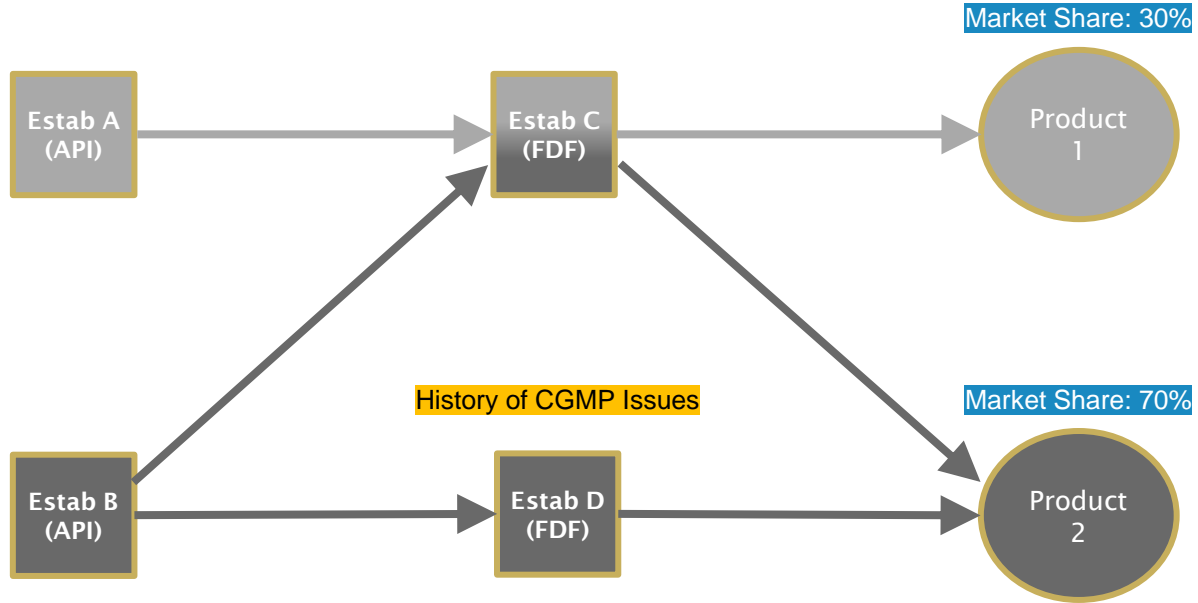
Enhanced Understanding of Drug Supply Chain Issues and Drug Shortages

How These Data Enhance Understanding of Drug Supply Chains

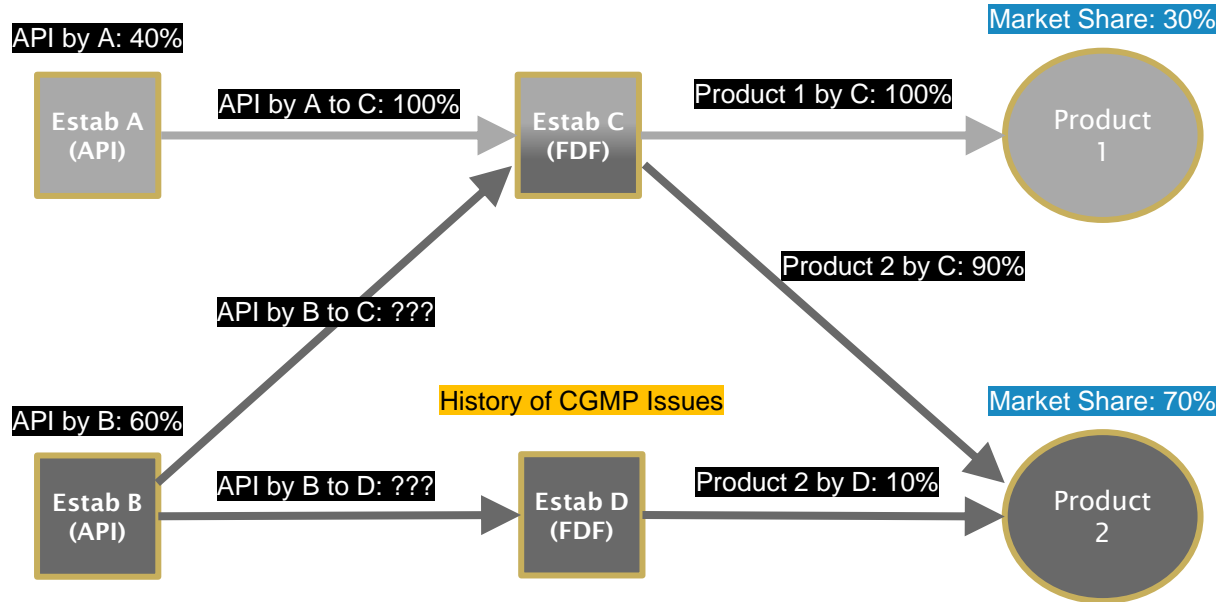
A Hypothetical Drug Supply Chain



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

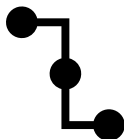
Three Main FDA Efforts Supported By Drug Amount Reporting



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

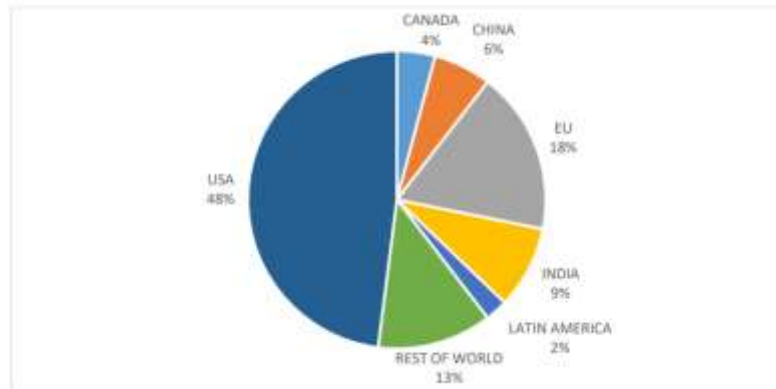
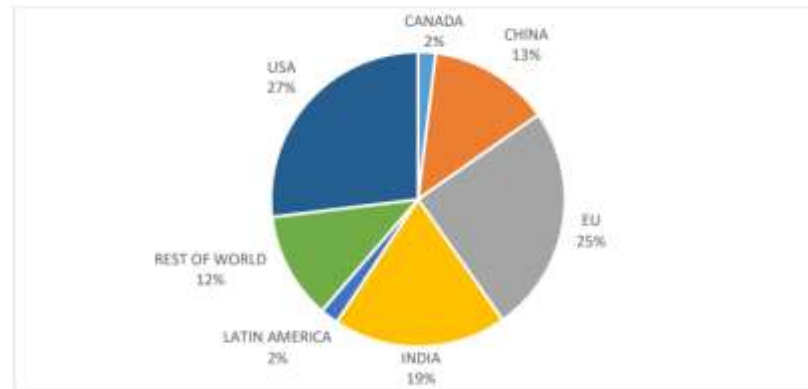


Figure 5: Percentage of API Manufacturing Facilities for All Drugs by Country or Region, March 2021



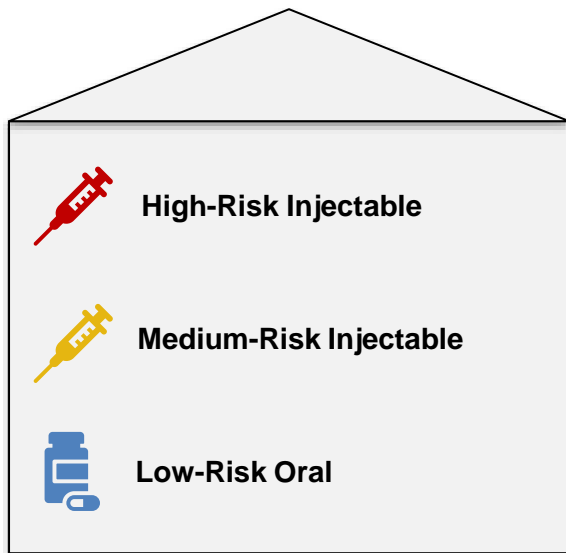
Drug Amount Data: Which products, and how much of their volume, are manufactured outside of the U.S.?

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

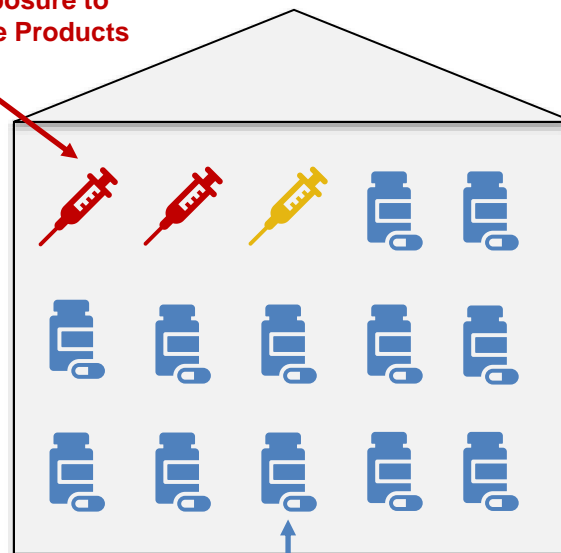


Products at Hypothetical
Establishment



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

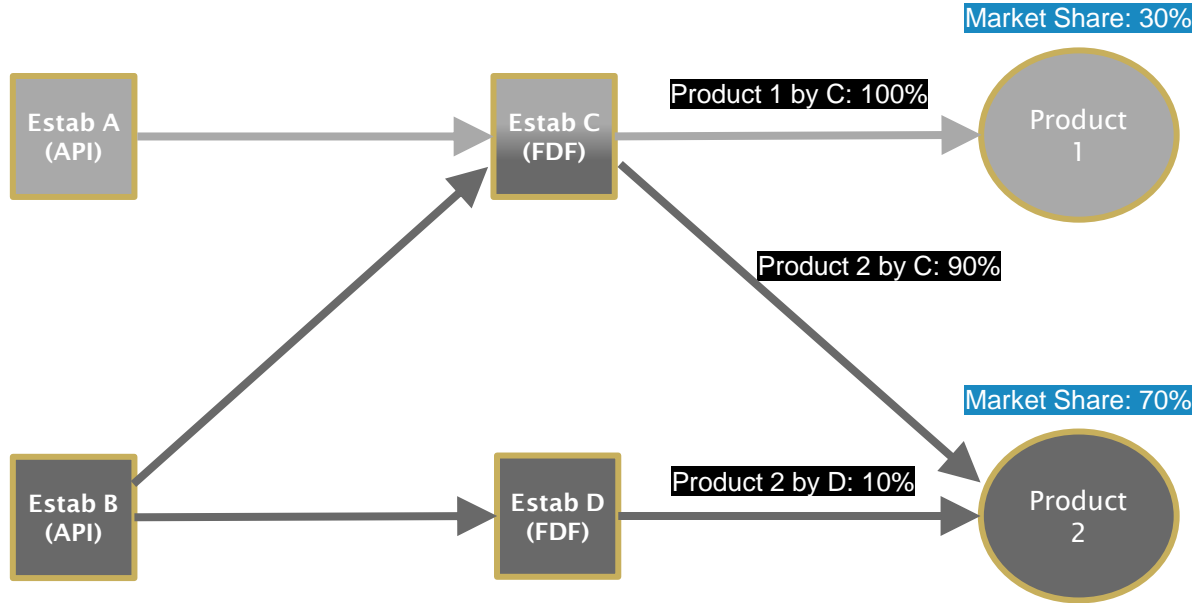
Hurricane Damage in Puerto Rico Leads to Fears of Drug Shortages Nationwide

MANUFACTURING

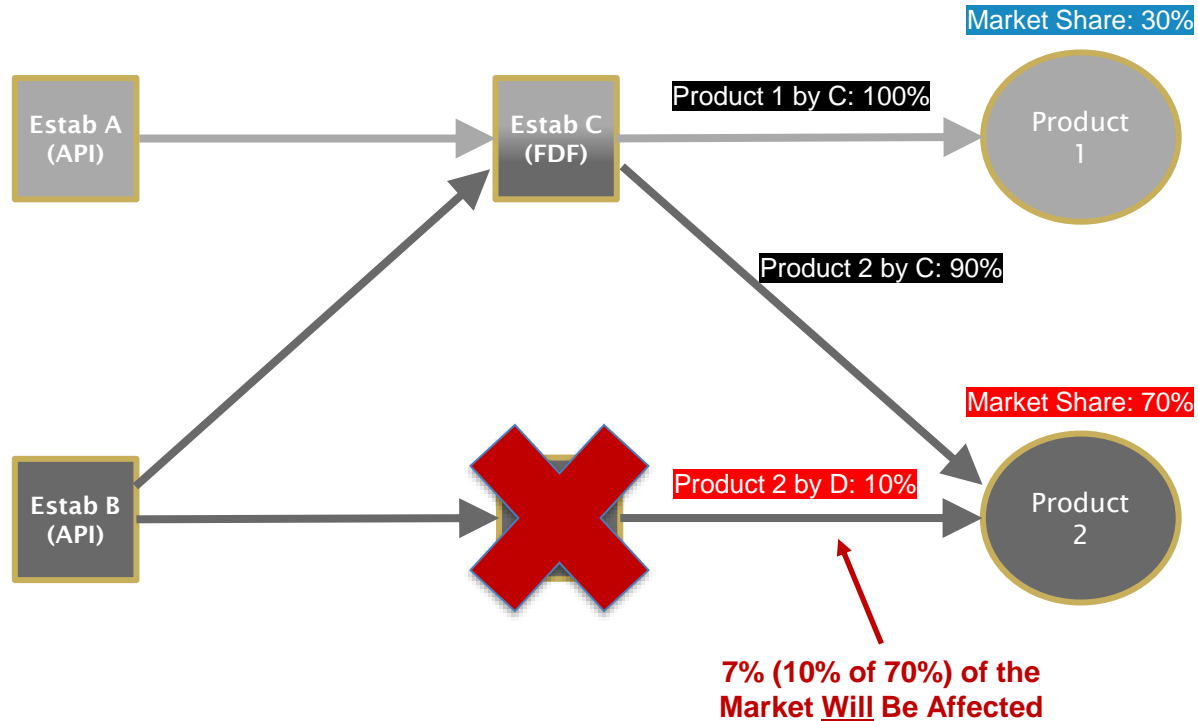
FDA anticipates disruptions, shortages as China outbreak plays out

By Eric Palmer • Feb 17, 2020 10:27am

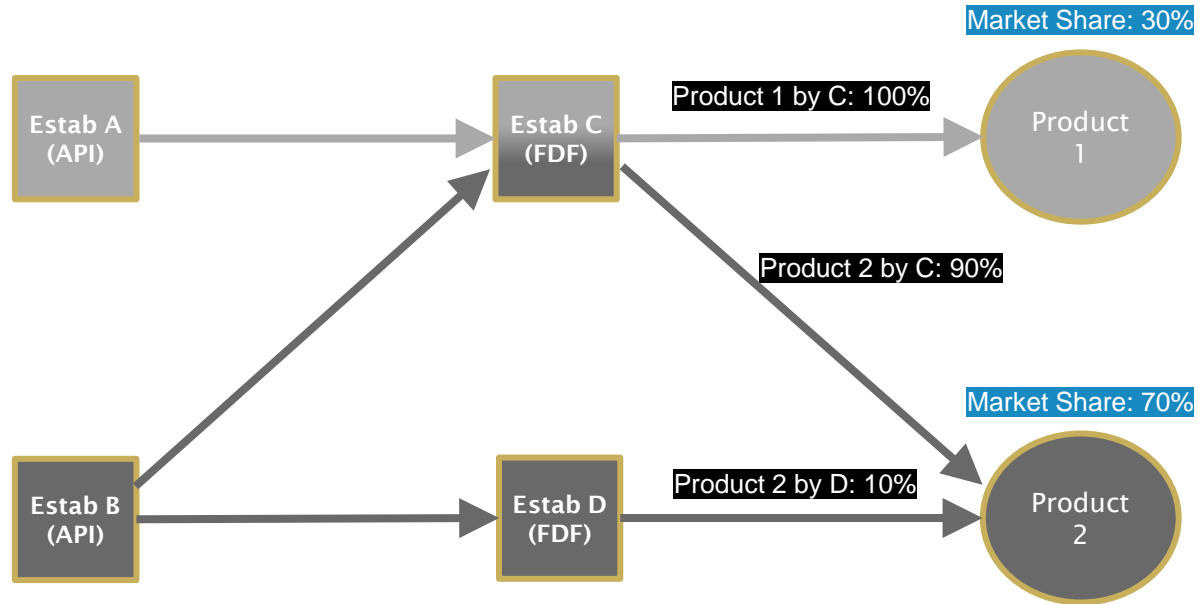
Is There a Potential Drug Shortage if Establishment D Ceases Production?



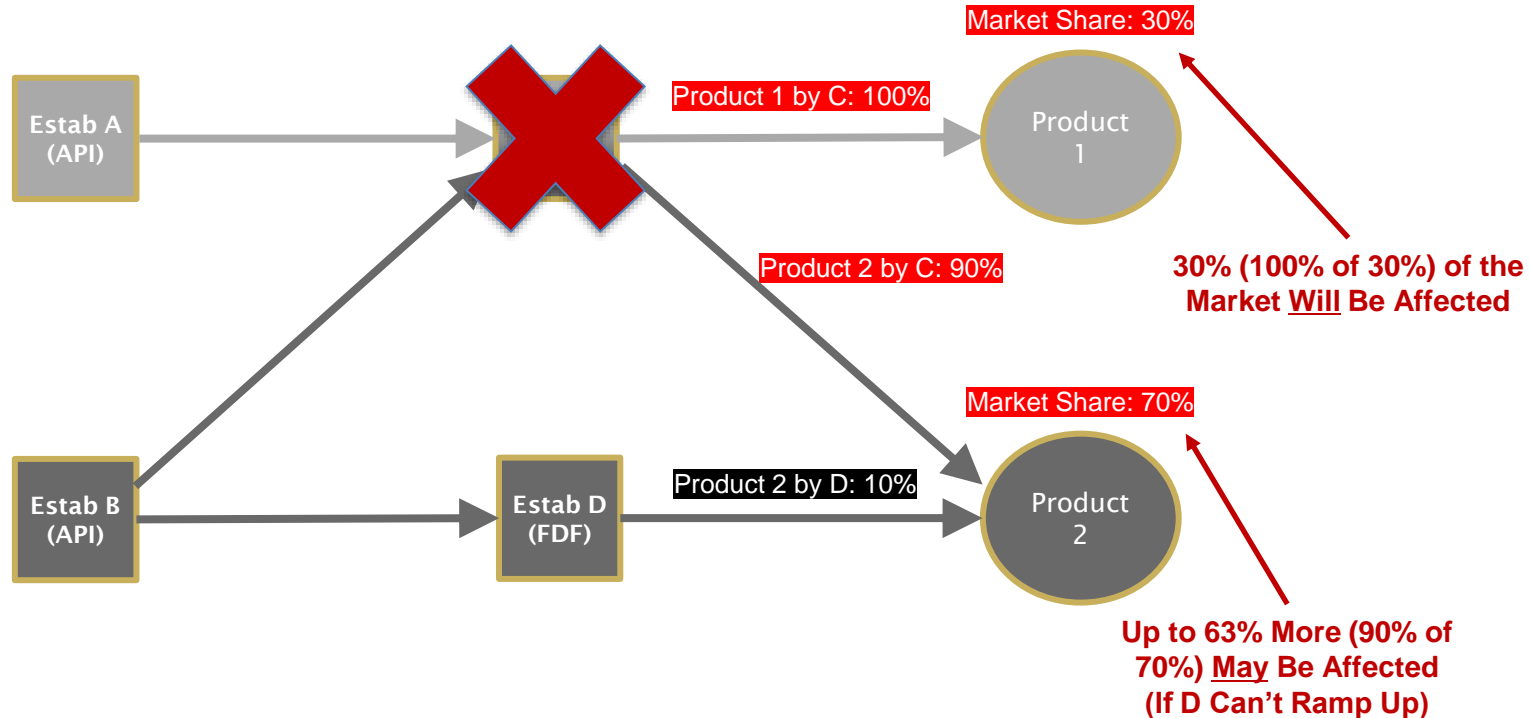
Is There a Potential Drug Shortage if Establishment D Ceases Production?



What if Establishment C Ceases Production?



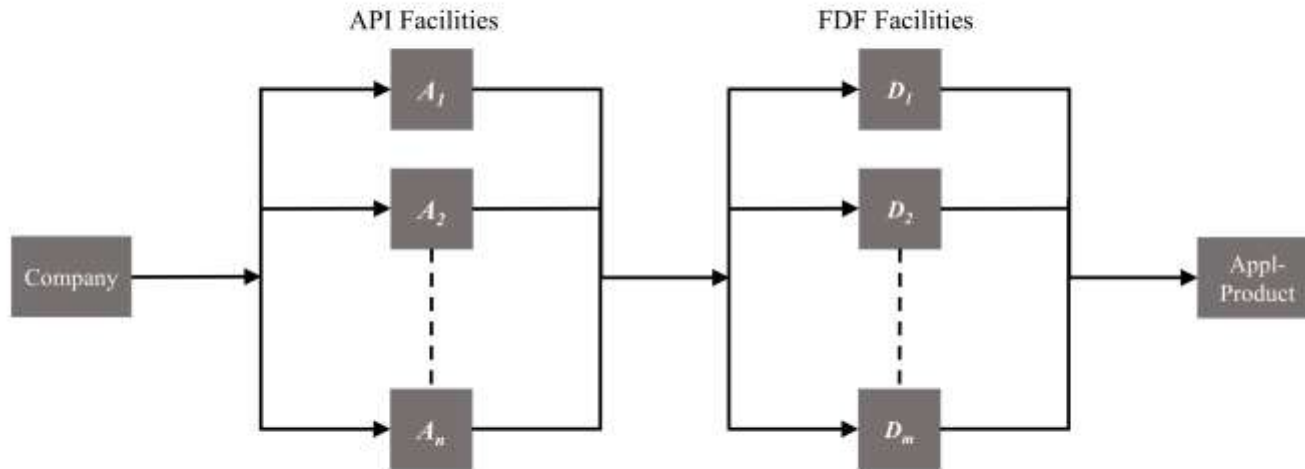
What if Establishment C Ceases Production?



Drug Amount Reporting Could Help FDA Measure Supply Chain Vulnerabilities

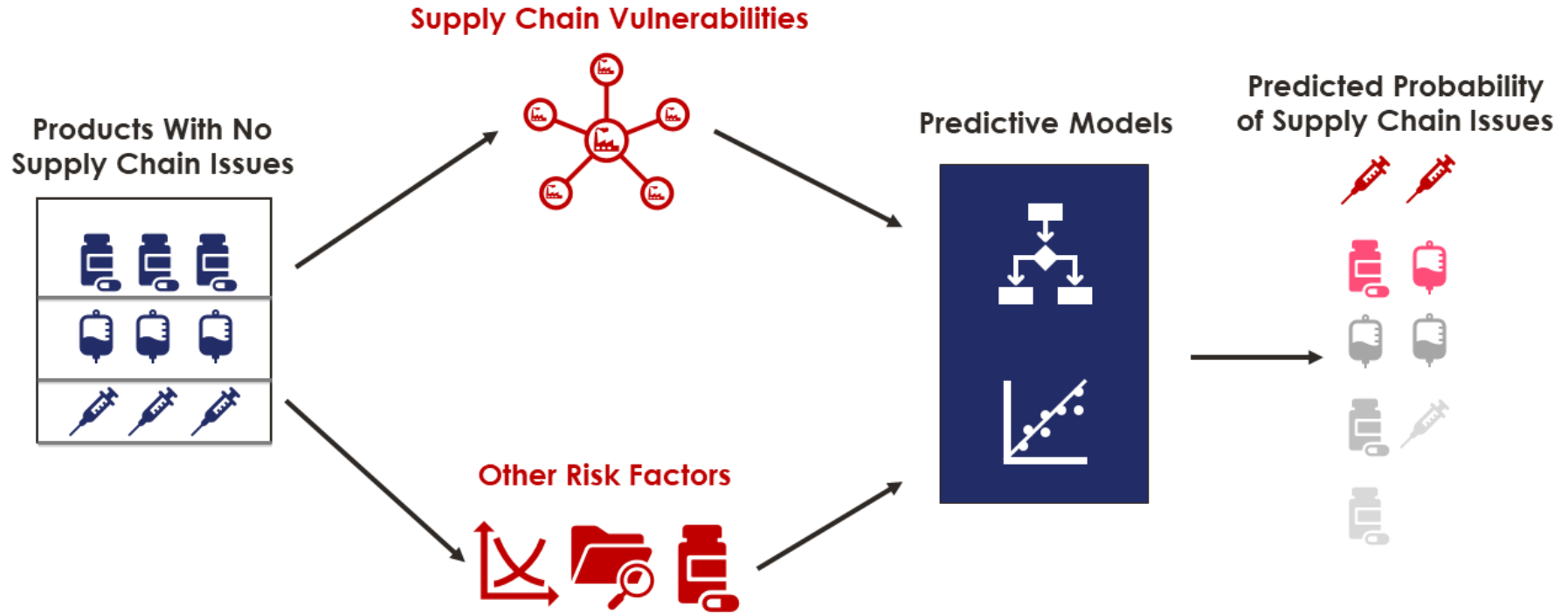


FDA is exploring systems engineering approaches for incorporating drug amount reporting data into quantitative measures of supply chain vulnerability



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 Website¹:
Feb 2011 – Feb 2012

2017 JAMA Study²: During the Shortage...

Patients switched to alternatives like phenylephrine

Deaths increased by **3.7 percentage points**

Nationally Projected Losses³: \$13.7 Billion

¹Sources: FDA Website

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

³We 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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