US Government Covid Task Force - Moving to Action

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Agenda

- Overview of COVID and its impact to suppy chains
- The current state of supply chains
- Possible changes on the horizon for our industry (clinical trials, data governance, and analytics),
- Working through today's supply chain limitations versus establishing tomorrow's resilient supply chain

Supply Chain Resource Cooperative

Center for thought leadership

20-25 practicum projects per semester

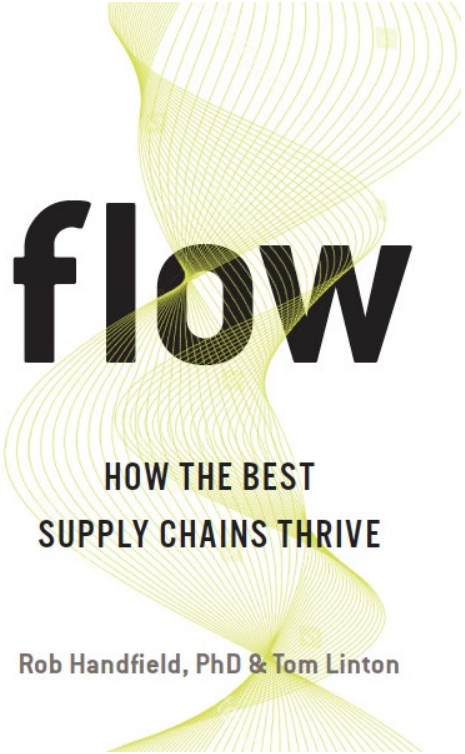
New members: **Altria, Siemens, VF, UPS, Gilead Science, ThermoFisher, Western Digital, Micron**

More than 50,000 visits to supply chain blog monthly

https://scm.ncsu.edu/scm-articles/article/category/directors-blog

NC STATE UNIVERSITY

How can we get supply chains to FLOW once again?



Why do supply chains matter to leaders?

All Resources are Delivered by or Depend on Supply Chains

- Resources are vital to provide value to customers
- No Resources = No Value Creation = No Revenue
- Current Supply Chain Issues Highlight Complexity
  - Complexity driven by
    - Horizontal Integration
    - Global Diversification
  - This complexity has leveraged comparative advantage, created massive corporate wealth, reduced prices for consumers, and created global interdependencies (goods and markets)
- Complexity has also led to lack of vision – leaders can no longer see what/who they are depending on to create value for customers

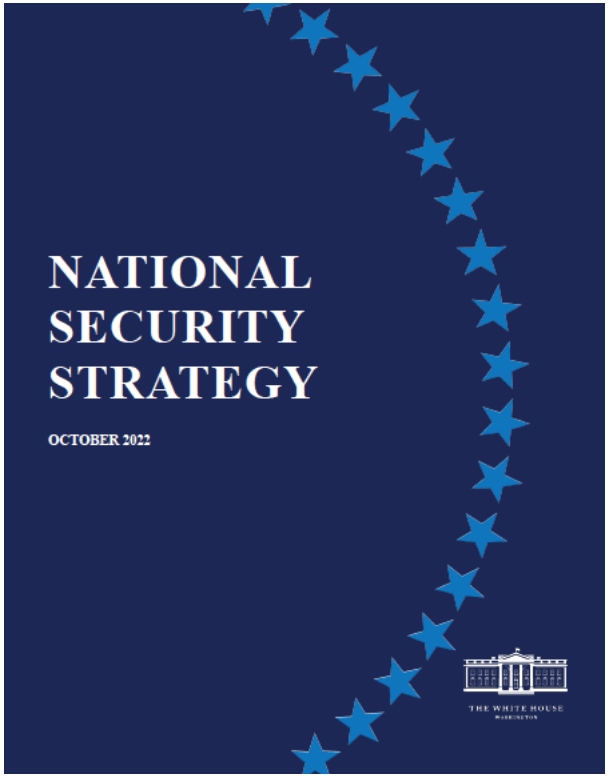
Supply Chains have become a matter of national security

- The NSS refers to the need to "build robust and durable **supply chains** so that countries cannot use economic warfare to coerce others."

- "Research exploring how to create agile manufacturing has primarily focused on how an organization's leadership, culture, structures, and processes can be transformed to create an agile response to dynamic environments."

- "…a modern industrial strategy that makes strategic public investments in America's workforce, and in **strategic sectors and supply chains**, especially critical and emerging technologies, such as microelectronics, advanced computing, **biotechnologies,** clean energy technologies, and advanced telecommunications.

www.whitehouse.gov/wp-content/uploads/2022/10/Biden-Harris-Administrations-National-Security-Strategy-10.2022.pdf



Drug Supply Chain Security Act (2013)

Updated Guidance

- *The DSCSA requires product tracing, product identifier, authorized trading partner, and verification requirements* in section 582 of the FD&C Act apply to *trading partners*

- Product tracing, product identifier, authorized trading partner, and verification requirements in section 582 of the FD&C Act apply to *product* as defined in section 581(13) of the FD&C Act. Product means “a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).”

- The DSCSA also requires that trading partners of manufacturers, wholesale distributors dispensers, and re-packagers must meet the applicable requirements for being “authorized trading partners.”

The deeper you go in the supply chain, the lower the visibility AND the greater the likelihood of a disruptive event

Many failure points and disruptions affect the entire supply chain network

Tier 1

100-1,000 direct suppliers
High % spend but low % revenue at risk

Visibility 75%
Risk 5-20%

Tier 2

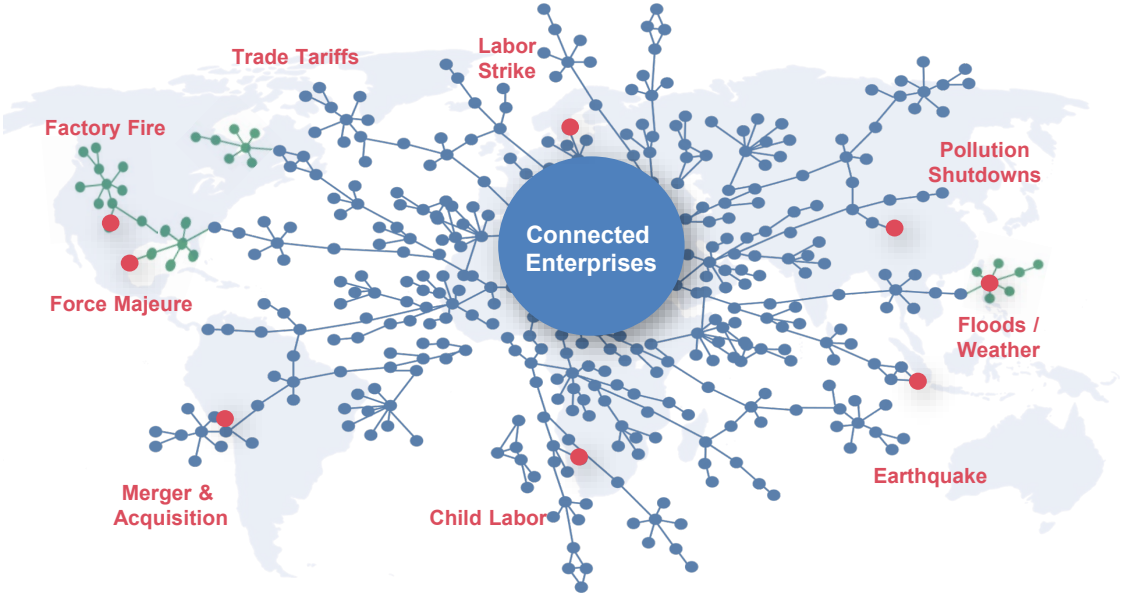
Many more sub suppliers per T1

Visibility 20%
Risk: 20-50%

Tier 3+

Often low visibility in your enterprise

Visibility 5%
Risk: 50-90%



Global Supply Chain Risk increased 67% in 2020 → Enterprises can't afford to stay reactive

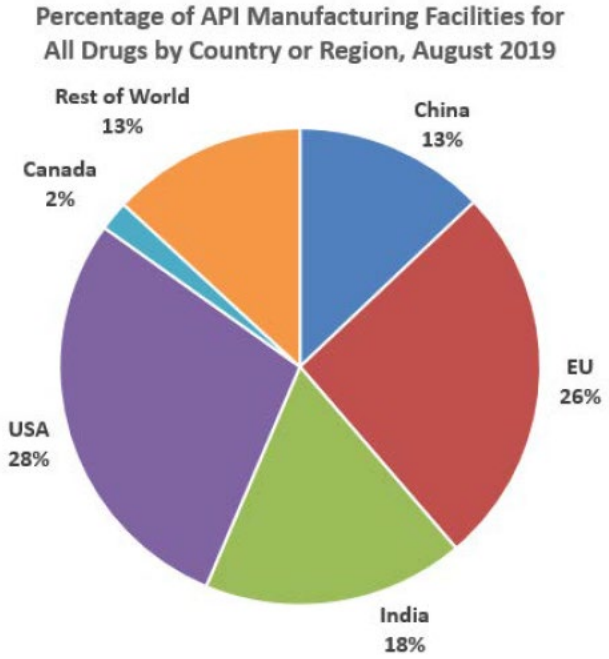
Near-Misses - Chinese API

In August 2018 FDA issued an alert that a Chinese API manufacturer, Sichuan Friendly Pharmaceutical Co. Limited, was recalling certain lots of porcine thyroid API due to inconsistent quality of the API.[4] This thyroid API comes from porcine (pig) thyroid glands and is used to make a medicine to treat hypothyroidism (underactive thyroid). FDA laboratory testing confirmed that the Sichuan Friendly API had inconsistent levels of active ingredients and should not be used to manufacture or compound drugs for patient use. Risks associated with over- or undertreatment of hypothyroidism could result in permanent or life-threatening adverse health consequences.

In December 2015, FDA alerted drug compounders that certain lots of baclofen API manufactured by Chinese manufacturer Taizhou Xinyou Pharmaceutical & Chemical Co., Limited might be at risk for contamination with particulates and should not be used to compound sterile injectable drugs. Taizhou manufactures APIs for repackagers and distributors, some of which sell these products to compounding facilities in the United States.

https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019

The Major Sources of API



Limitations of CDER

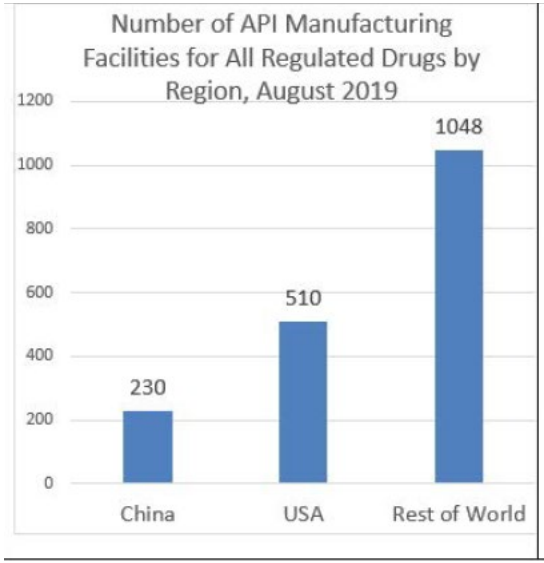
CDER maintains a Site Catalog ("Catalog") of all manufacturing facilities making drugs for the U.S. market, either through an approved application or that have registered and listed to supply drugs for the U.S market….

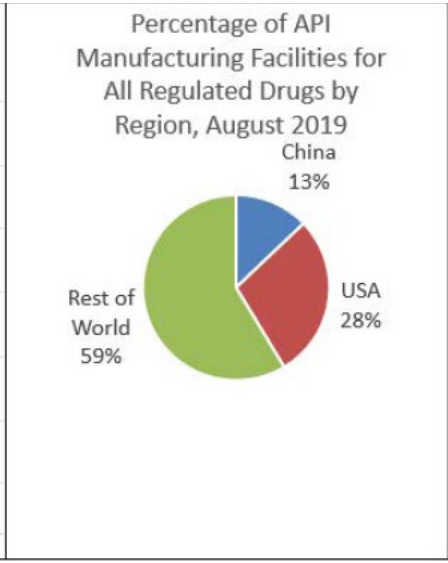
BUT:

- Facilities listed in the Catalog may or may not be producing APIs. Including a facility in an application or the registration and listing process does not require a facility to produce API. Producing an API at the facility, or not producing it, is a business decision made by the company.
- Manufacturers are not required to report to FDA whether they are actually producing an API at a facility, and if they are, the volume they are producing.
- APIs made in listed facilities may be used in drugs for both the U.S. and other markets, and some APIs distributed in the United States are subsequently formulated into FDF that are then exported.
- Some FDF applications list more than one API supplier in the application. FDA has no visibility into which API supplier an FDF manufacturer uses at any given time.
- CDER has limited information about API suppliers for products that do not need an approved application from FDA to be marketed, such as compounded and OTC monograph drugs. API suppliers for such products may not register their facility with FDA if they are sending material to a drug product manufacturer outside the United States to make the FDF, which is then sold in the United States.
- Information in the Catalog is continually being updated.

Implication: CDER has no visibility!

Although CDER can describe the locations of API manufacturing facilities, they cannot determine with any precision the volume of API that China is actually producing, or the volume of APIs manufactured in China that is entering the U.S. market, either directly or indirectly by incorporation into finished dosages manufactured in China or other parts of the world





How resilient is the US manufacturing base?

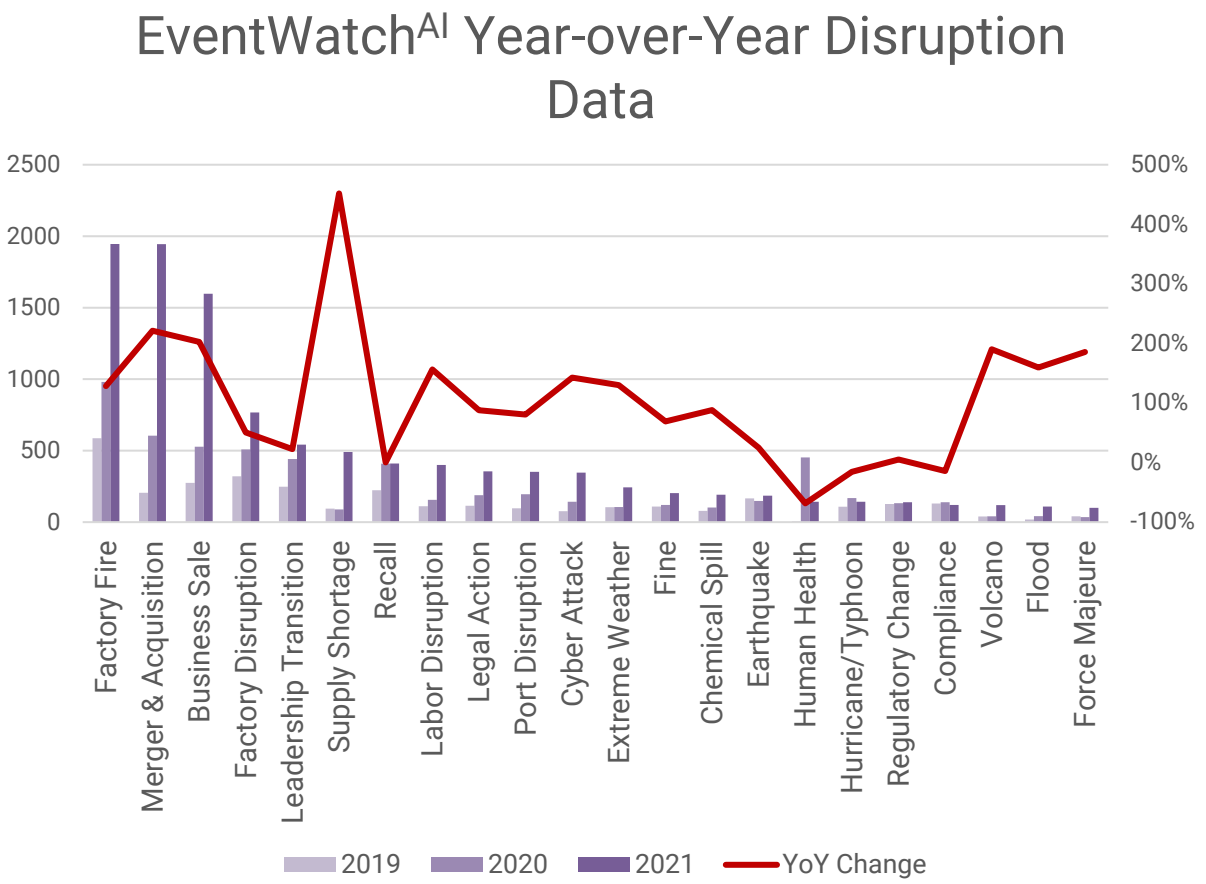
To answer this question, FDA would need to know:

- How much unused capacity exists in the U.S. manufacturing base for APIs;
- How much additional API this capacity could supply within a given time period;
- How far this capacity would go in filling the gap between U.S. patients' needs and the amount available if China or India, or another country, were to reduce or stop the supply to the U.S. market; and
- How long would it take to increase production enough to meet patients' needs, and whether the financial investment would be sustainable for the pharmaceutical industry.

THE PERFECT STORM

Multiple waves intersecting through the supply chain ecosystem

- COVID-19: Still disrupting global supply chains
- **Russia/Ukraine Conflict**
- Extreme and widespread demand shifts
- Dozens of large factory fires
  - Suppliers across semiconductor
- Commodity Shortages
  - Semiconductor shortages
  - Plastics shortages
  - Rubber shortages
  - Wood shortages
- Logistics / Transportation Risk
- Price increases and inflation
- Labor movement and shortages (across the skills spectrum)
- High incidence of factory fires, chemical leaks due to shortcuts in safety measures during pandemic lockdowns



H.R.5376 - Build Back Better Act – Inflation Reduction Act

SEC. 31022. FUNDING FOR PUBLIC HEALTH AND PREPAREDNESS RESEARCH, DEVELOPMENT, AND COUNTERMEASURE CAPACITY.

$1,300,000,000

(1) to support surge capacity, including through construction, expansion, or modernization of facilities, to respond to a public health emergency, and for development, procurement, and domestic manufacture of drugs, active pharmaceutical ingredients, vaccines and other biological products, diagnostic technologies and products, medical devices (including personal protective equipment), vials, syringes, needles, and other components or supplies for the Strategic National Stockpile

(2) to support expanded vaccine production capacity and capabilities, including by developing or acquiring new technology and expanding manufacturing capacity through construction, expansion, or modernization of facilities;

(3) to support activities to mitigate supply chain risks and enhance supply chain elasticity and resilience for critical drugs, active pharmaceutical ingredients, and supplies (including essential medicines, medical countermeasures, and supplies in shortage or at risk of shortage), drug and vaccine raw materials, and other supplies, as the Secretary determines appropriate, including construction, expansion, or modernization of facilities, adoption of advanced manufacturing processes, and other activities to support domestic manufacturing of such supplies;

H.R.5376 - Build Back Better Act – Inflation Reduction Act

SEC. 31401. MANUFACTURING SUPPLY CHAIN RESILIENCE.

$5,000,000,000, to remain available until September 30, 2026, to the Office of the Secretary of Commerce, to support the resilience of manufacturing supply chains affecting interstate commerce and related administrative costs, by—

(1) mapping and monitoring manufacturing supply chains;

(2) facilitating and supporting the establishment of voluntary standards, guidelines, and best practices relevant to the resilience of manufacturing supply chains;

(3) identifying, accelerating, promoting, demonstrating, and deploying technological advances for manufacturing supply chains; and

(4) providing grants, loans, and loan guarantees to maintain and improve manufacturing supply chain resiliency.

What are we missing?

Buyer Preference – Often a Hidden Choice

- Investment in capacity must be followed by purchase
  - Ex. N-95 capacity v. production buy
- Transparency for Consumers – will they choose domestic sources with increased prices?
- Visibility for Government Acquisition, Medicare, and Dispensers – can they choose domestic sources?
- Informed decision making – where to invest in capacity – and how much to invest?
- Buy American or buy from allied countries?

Key Functionality

Considering Current Events and New/Upcoming Regulations

- Interoperability
  - Internal and Trading Partner Systems
  - FDA and Civil Agencies
- Verified Multi-Tier Mapping
  - Part-Site Level Mapping
- Connectivity to Entire Value Chain
  - Must Identify the Kill Shot
- Proactive and Reactive
  - Strong Due-Diligence Capabilities
  - Continuous Monitoring
- Customizable
  - Adoption Rate – Become Part of Workflow
- Support Tactical/Operational/Strategic Objectives

Thanks