The American Pharmaceutical Supply Chain: Will COVID-19 Drive Manufacturing Back Home?

Greg Levine, Beth Weinman, Jenna McCarthy, Grant Sims
Ropes & Gray LLP

FDLI

Pre-COVID-19: Growing Public and Political Interest in the Global Drug Manufacturing Supply Chain

Scott Gottlieb, M.D. ✓
@SGottliebFDA
Follow

Globalization of drug manufacturing adds new complexities to the U.S. supply chain. API may be manufactured in one country, shipped to another country for final manufacturing that incorporates ingredients from a third country. The finished product is then imported to the U.S.

8:29 AM - 29 Jan 2019

BIPARTISAN E&C LEADERS REQUEST GAO REVIEW OF FDA'S FOREIGN DRUG INSPECTION PROGRAM

Jun 28, 2019 | Press Release

Committee Leaders Request Additional Information Regarding FDA's Resources, Policies, Management Practices, and Authorities Related to Oversight of Foreign Manufacturing

TESTIMONY

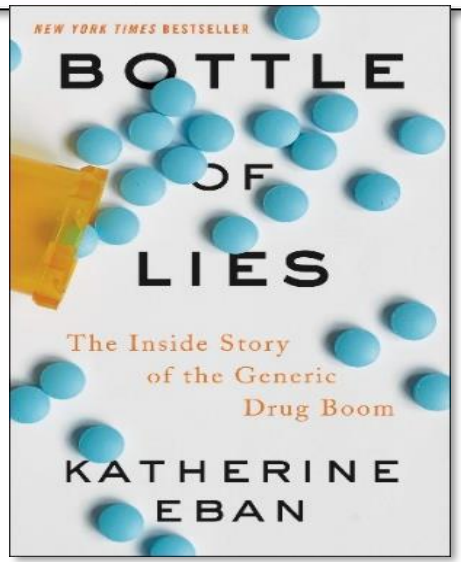
Safeguarding Pharmaceutical Supply Chains in a Global Economy

OCTOBER 30, 2019

Share | Tweet | Linkedin | Email | Print

Testimony of
Janet Woodcock, M.D.
Director - Center for Drug Evaluation and Research

Before the
House Committee on Energy and Commerce, Subcommittee on Health



FDA Keeps Brand-Name Drugs on a Fast Path to Market — Despite Manufacturing Concerns

DAILY BEAST

Bloomberg

America's Love Affair With Cheap Drugs Has a Hidden Cost

Data, documents and interviews show how a focus on cutting prices has come with risks to consumer health.

TESTIMONY

Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program

DECEMBER 10, 2019

Share | Tweet | Linkedin | Email | Print

Testimony of
Janet Woodcock, M.D.
Director - Center for Drug Evaluation and Research

Before the
House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

FDLI

Article Structure

- **Part I: Introduction**
- **Part II: Globalization of the Medical Products Industry and Associated Risks**
- **Part III: Near & Longer-Term Measures to Address Supply Chain Risks**
- **Part IV: Conclusion: What Comes Next?**

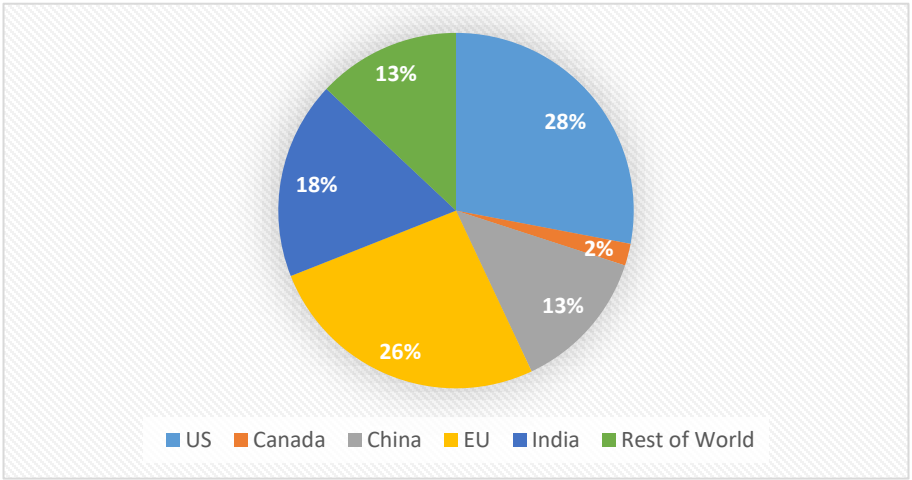
FDLI

Article Structure

Part II: Globalization of the Medical Products Industry and Associated Risks

- Since the 1970s, manufacturing of U.S. medical supplies has been moving overseas
- Since the 1990s, the U.S. has had a trade deficit in pharmaceuticals
- By 2010, about 1/3 of medical devices were imported
- U.S. dependence on foreign supply is particularly acute for API

Figure 1: Percentage of API Manufacturing Facilities for All Drugs, August 2019



Article Structure

Part II: Globalization of the Medical Products Industry and Associated Risks

- The Risks of Overdependence on Foreign Medical Product Manufacturing
  - National Security
  - Product Quality

- National security
  - Vulnerability to foreign supply restrictions

- Product quality
  - Greater frequency of data integrity violations in China and India
    - 55-65% observed to have DI issues vs. 28% of domestic sites
  - Limits of foreign inspection program

FDLI

Article Structure

Part III: Measures to Address Supply Chain Risks

- **Past Efforts**

1999 — **National Strategic Stockpile**

- Congress created the National Pharmaceutical Stockpile—later renamed the National Strategic Stockpile—to ensure that the country would have sufficient supplies of critical drugs and medical products to respond effectively to the most serious public health treats, including pandemics.

2004 — **Project BioShield Act**

- President George W. Bush signed the Project BioShield Act of 2004, a law designed to accelerate research into, and development of, medical countermeasures against biological, chemical, radiological, and nuclear agents.

2006 — **Pandemic and All Hazards Preparedness Act, Creation of BARDA**

- PAHPA created the Biomedical Advanced Research and Development Authority (BARDA), an agency housed within the Department of Health and Human Services. BARDA promotes collaboration and communication between U.S. government agencies, including the FDA, that play a role in public health emergency preparedness.
- The statute also contained broader provisions aimed at coordinating state/federal public health responses.

2012 — **Food and Drug Administration Innovation and Safety Act**

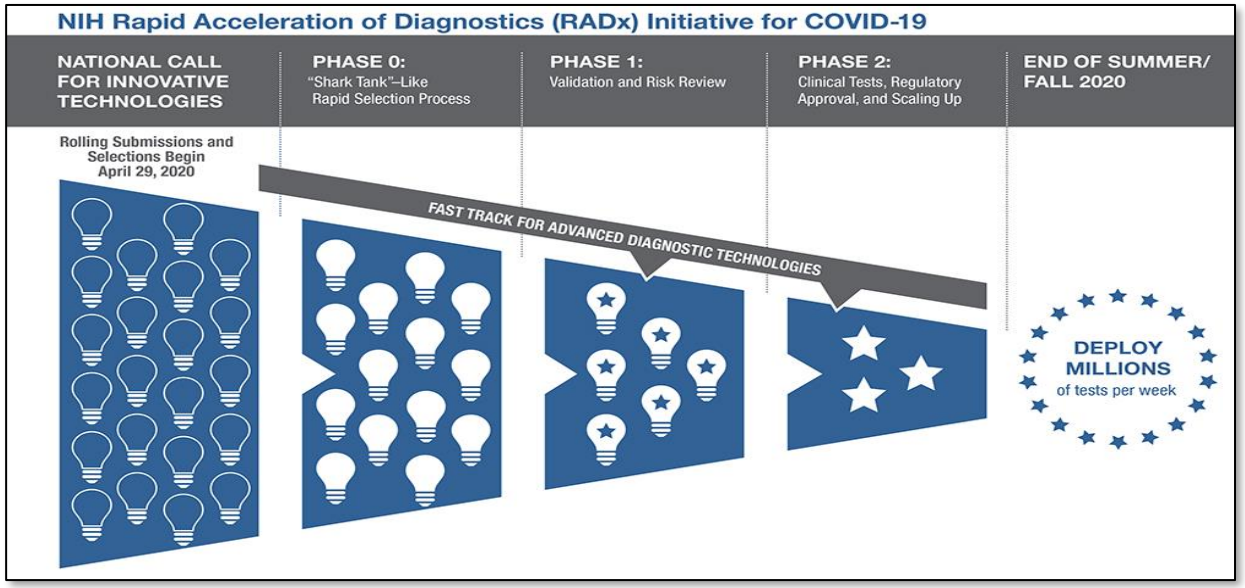
- Among many other things, FDASIA codified and expanded a 2011 executive order that directed drug manufacturers to notify the government of possible shortages. The law granted FDA new authorities to prevent and mitigate drug shortages, including new inspection authorities.

FDLI

Article Structure

Part III: Measures to Address Supply Chain Risks

- **COVID-19: Near-Term Measures**
  - Emergency Use Authorizations
  - The CARES Act
  - Grants and Contracts

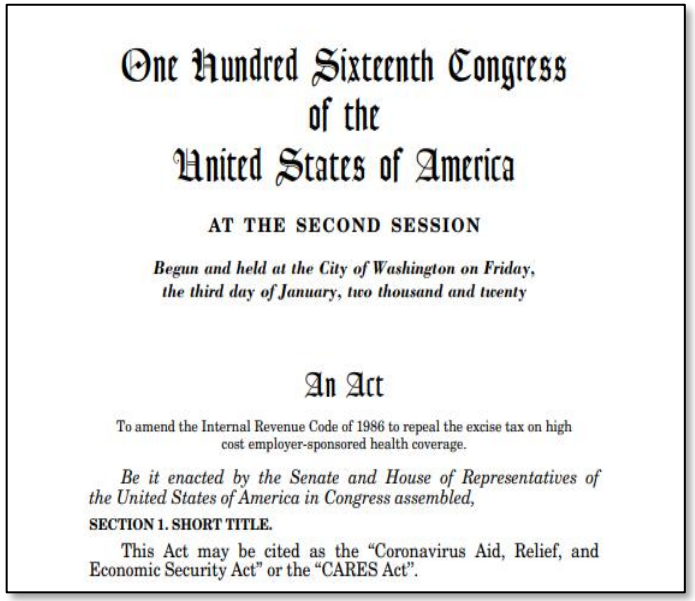


FDLI

Article Structure

Part III: Measures to Address Supply Chain Risks

- **Longer-Term Measures: Looking Past the Pandemic**
  - Buy American Executive Order
  - Tax Incentives
  - Patient Management and Clinical Solutions
  - Reports and Assessments
  - FDA Quality Pilot Programs



One Hundred Sixteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Friday, the third day of January, two thousand and twenty

An Act

To amend the Internal Revenue Code of 1986 to repeal the excise tax on high cost employer-sponsored health coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act".

CORONAVIRUS

Trump signs 'Buy American' executive order for essential drugs

The order aims to guard against shortages of critical medicines and supplies due to breakdowns in the global supply chain.

Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement

A Notice by the Food and Drug Administration on 10/16/2020

FDLI

Article Structure

Part IV: Conclusion: What Comes Next?

- Will public focus on global supply chain risks endure once the COVID-19 public health emergency abates?
- Is “onshoring” economically feasible? Can advanced manufacturing play a role?
- Even if feasible, to what extent is onshoring desirable?
- What other measures can be taken to improve U.S. supply chain preparedness and resiliency for critical medical products?

FDLI