Overreliance on Chinese and Indian Manufacturers of Drugs: A Recipe for Public Health Disaster

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The Phenomenon

Roughly 90% of all medications dispensed in American pharmacies are generic.

- Over the last 10 years, generic drugs helped the U.S. health care system save nearly two trillion dollars
- U.S. national health spending projected to reach $6.2 trillion by 2028 from $3.6 trillion in 2018 (CMS.gov)
- Generic medications are an absolute necessity
- China and India are currently the manufacturers of generic medications
- India is a leading manufacturer of Finished Drug Products (FDP) bound to United States
- China is the world's largest supplier of Active Pharmaceutical Ingredients (API) – the raw material for manufacturing FDPs in India. The problem with overseas generic manufacturing is summarized into the following categories:
  1. Rising diplomatic tension with China as the world largest supplier of API
  2. Lack of oversight on foreign generic manufacturers
  3. Lack of strategic supply management during emergencies

"If China shut the door on exports of medicines and their key ingredients and raw materials, U.S. hospitals and military hospitals and clinics would cease to function within months, if not days."
- Rosemary Gibson, Senior Adviser at Hasting Center

The Recipe for Disaster

Figure 2: Finished Drug Product Sites Bound for US Market (August 2019)

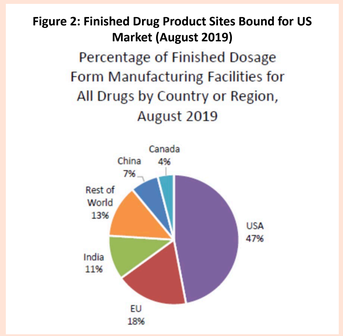
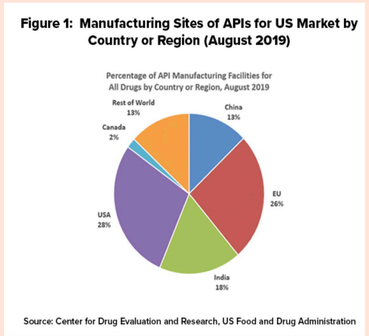


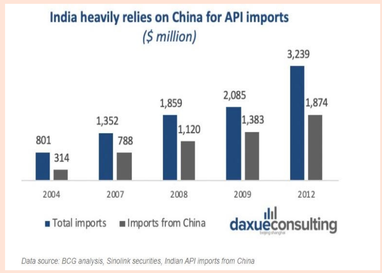
Figure 1: Manufacturing Sites of APIs for US Market by Country or Region (August 2019)



Source: Center for Drug Evaluation and Research, US Food and Drug Administration

1. US Reliance on China and India

13% of the US's APIs come from China. 18% of the US's APIs come from India, but also 11% of the US total FDP comes from India, who relies heavily on China for their API's to make it.



2. Lack of Trust with Overseas Products

Quality control issues for Chinese API:

- 2008: Sudden anaphylactoid reactions observed in patients in the US who received heparin; 100 died
- 2017: The FDA inspected a Chinese API manufacturer called Zhejiang Huahai Pharmaceuticals Co. and found that "they omitted from official test results that drug batches failed to meet US quality standards and instead recorded passing grades" (White 2019). API for angiotensin II receptor blocker products had unacceptably high level of *N*-Nitrosodimethylamine (NDMA), a potential carcinogen

3. Lack of Emergency/Crisis Plans

As of March 11, 2020, the US had 99 drug shortages. Many are a direct result of U.S. dependence on China for many critical drugs. If the US continues to face diplomatic tensions with China during a pandemic like COVID-19, the US will lose a significant amount of medicine imported from China and India.

What's Next? Emergency Preparedness

U.S. should implement a federal initiative to develop our own generic drugs for high demand medications.

- Then U.S. manufacturers should expand to producing our own supply of API
- California is attempting to create its own line of generic drugs
- U.S. can begin to acquire a reservoir of manufacturing capacity
- This will:
  1. Alleviate U.S. reliance on Indian FDPs
  2. Ease the reliance on China's exports of API

Bring our overseas manufacturers back to the US or operate in other countries that will consent to increased FDA oversight.

- Decreases the chance of impurities in FDPs
- Ensures manufacturing maintains FDA standards for quality control and quality assurance
- Could be done using tax incentives to support U.S. manufacturing

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