Association for Accessible Medicines

Your Generics & Biosimilars Industry

Quality & Overseas Manufacturing

An Ongoing U.S. Policy Debate

Jeff Francer, Interim CEO

The 5th Indian Pharmaceutical Forum 2020

February 27, 2020

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90%

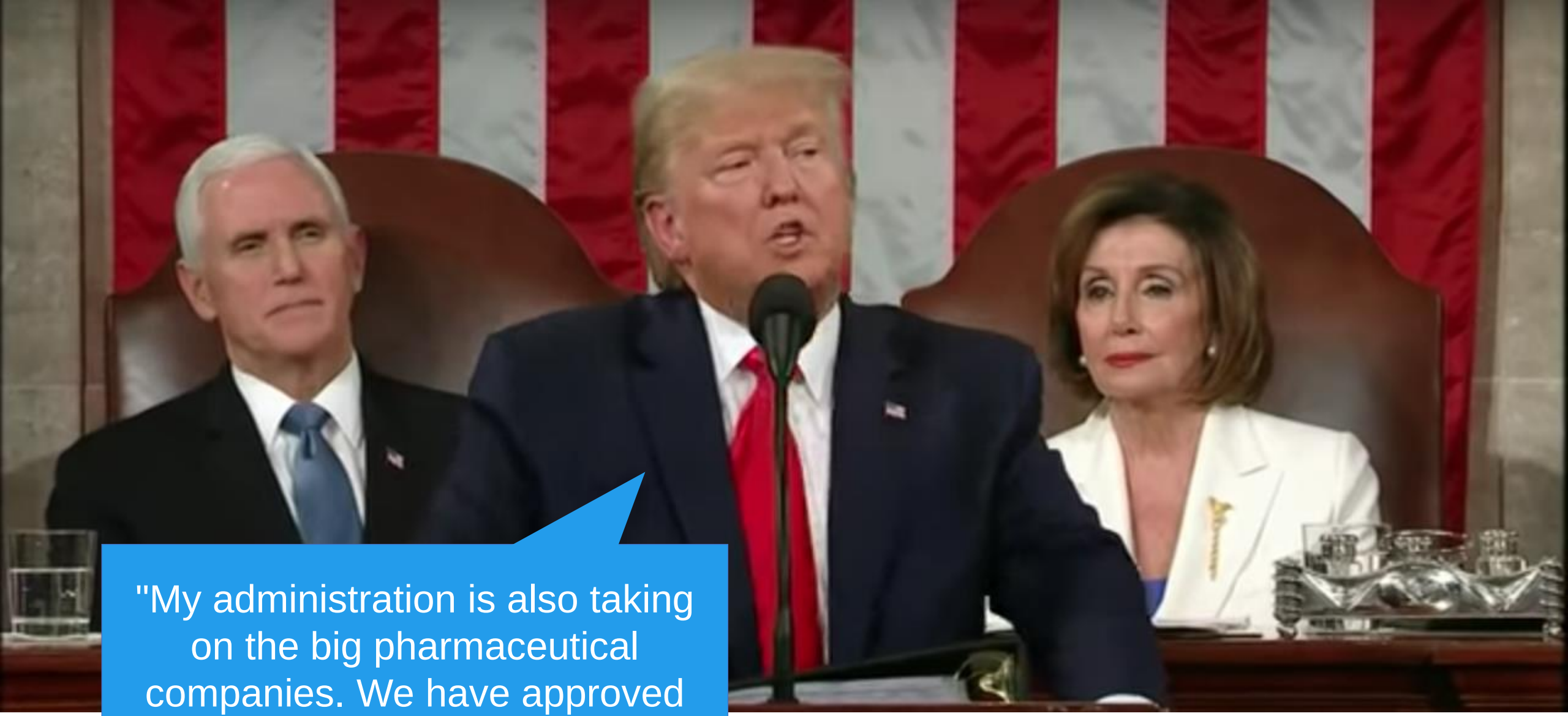
PRESCRIPTIONS FILLED IN THE U.S. ARE DISPENSED AS GENERICS

YET GENERICS ACCOUNT FOR ONLY

22%

OF ALL DRUG SPENDING

Source: IQVIA 2019



"My administration is also taking on the big pharmaceutical companies. We have approved a record number of affordable generic drugs."

President Donald Trump
State of the Union
February 4, 2020

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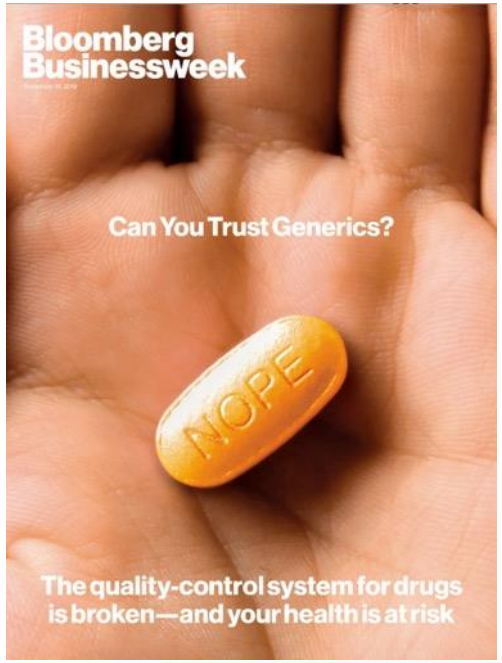
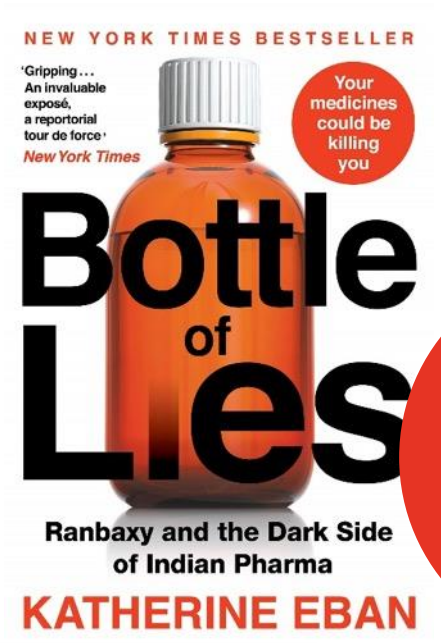
Quality & Overseas Manufacturing: A Growing Policy Storm in the U.S.

- Quality criticisms
- Alarmist headlines
- Federal & state
- Safety questions
- Right- & left-wing talk radio
- National security challenges
- Republican & Democratic concerns
- Presidential & local candidates

Quality & Manufacturing

Generics Are Under Attack





Your medicines could be killing you

THE HILL **Public health activist calls for country-of-origin labels on prescription drugs**

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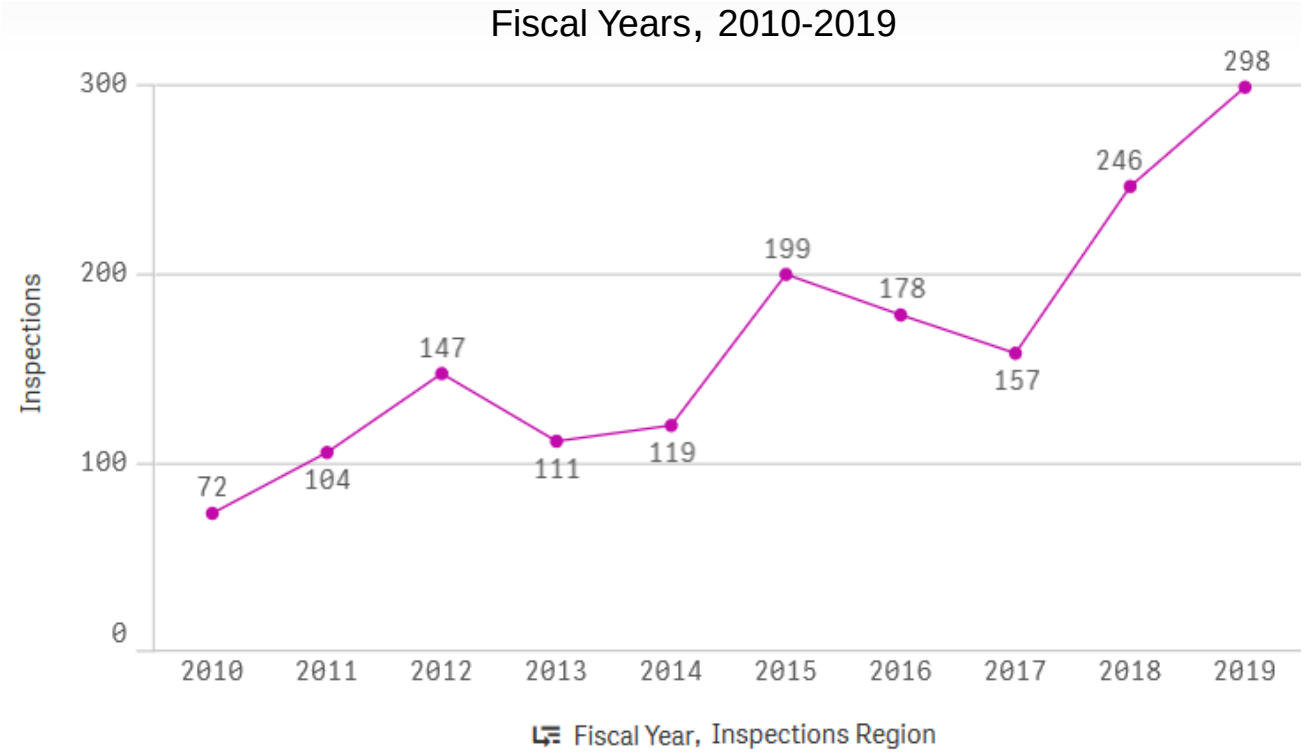
FDA Inspections in India



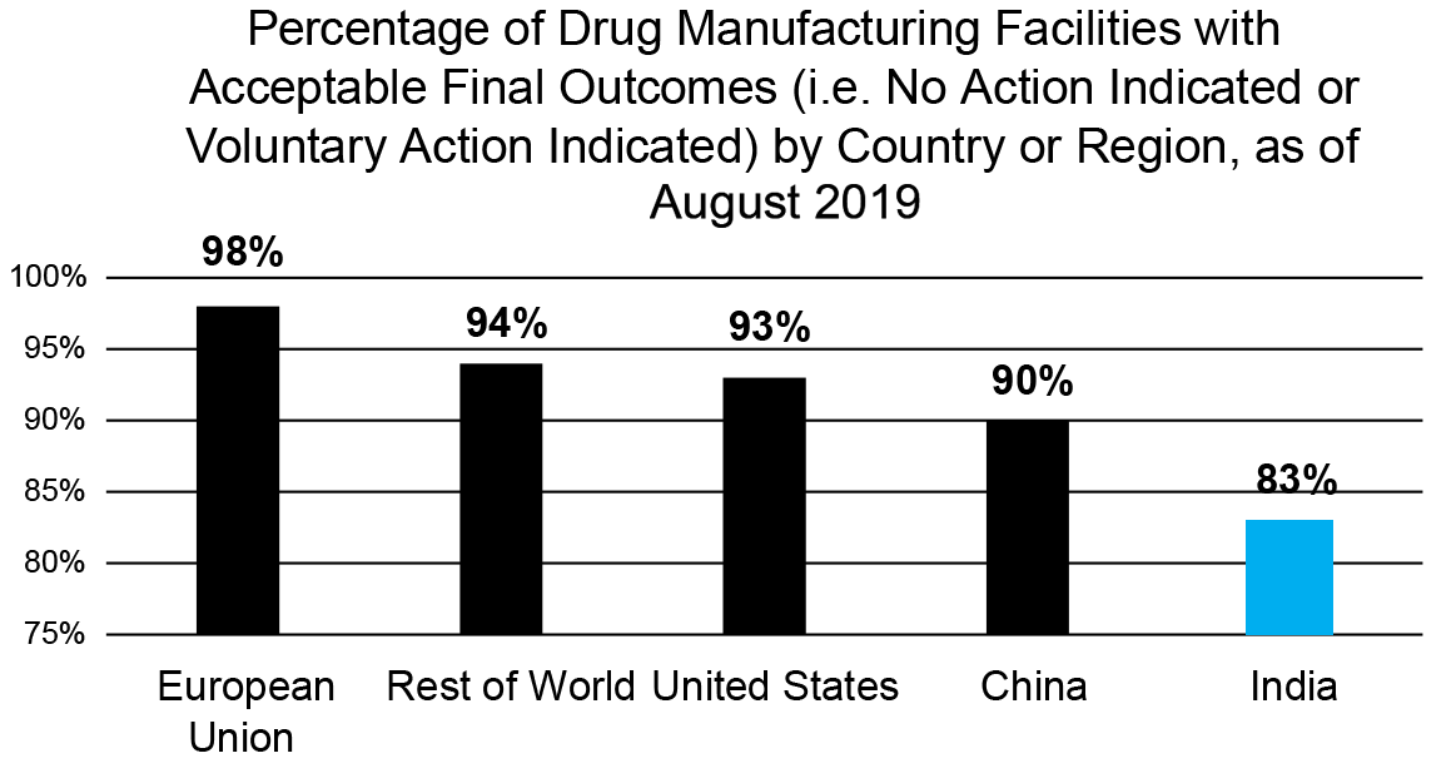
Source: U.S. FDA: https://datadashboard.fda.gov/ora/cd/inspections.htm

- The FDA has increased its inspections of overseas manufacturing facilities, particularly in India
- Warning letters have been issued to India's top firms
- India accounted for nearly one-third of total foreign inspections by the agency between October 2018 and June 2019

Congressional Hearing on Foreign Inspections

December 10, 2019

WOODCOCK: “However, India had a lower percentage of acceptable outcomes than other countries and regions.”



Overseas Manufacturing: A Target for Policymakers

"We need to think of pharmaceuticals as what they are for millions of Americans: a critical good that we literally can't live without. **It's unacceptable to become fully dependent on any single foreign country for those goods — all the more so when it's China**."

Representatives Anna Eshoo & Adam Schiff
Washington Post (Sept. 10, 2019)

Overseas Manufacturing: A Target for U.S. Policymakers

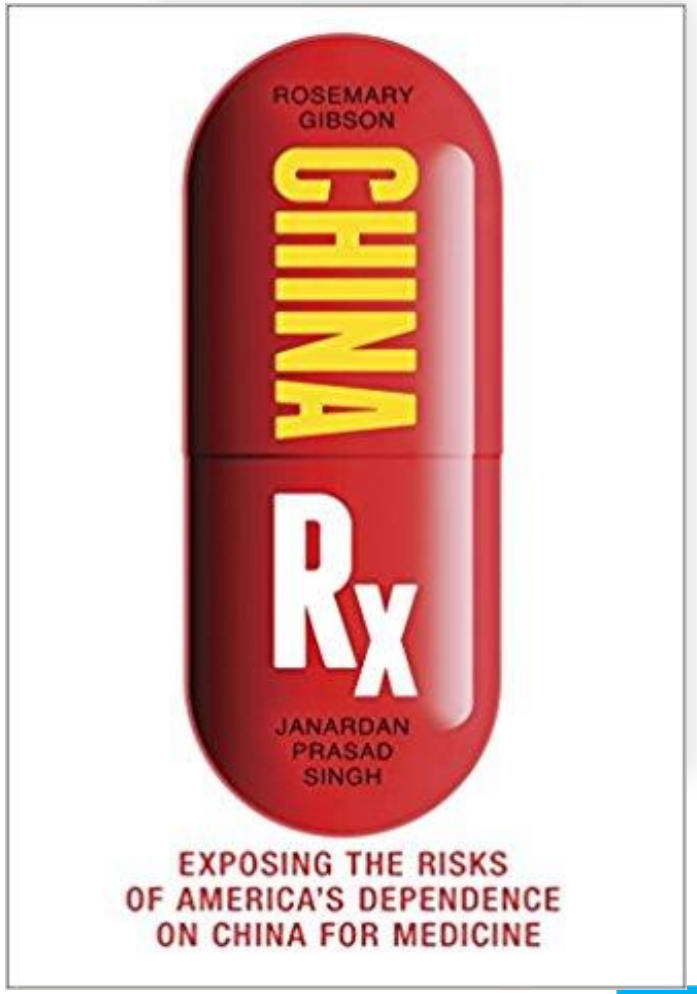
US-China Economic and Security Review Commission Hearing July 31, 2019

"The national security risks of increased Chinese dominance of the global active pharmaceutical ingredient (API) market cannot be overstated."

Christopher Priest, acting deputy assistant director for health care operations and Tricare, DHA.

National Security Risks of Dependence on China

Christopher Priest, DHA



Policy Risks and Potential Impact

Possible Policy Proposal
DoD and VA to “Buy American”
FDA demands additional funding
Improperly-designed finished dose rating system
Greater reliance on private testing by pharmacies or purchasers
Greater company disclosure to FDA of API source, likely product discontinuation
Country of origin labeling transparency (API / finished dose)

AAM-FDA Cooperation on Quality

- Through GDUFA II, the generic industry will have contributed approximately $4 billion to the FDA
  1. With GDUFA funding, FDA has been able to hire approximately 1500 employees to improve the ANDA review and approval process, which includes inspections of all facilities, U.S. and foreign
  2. Allowed FDA to stand-up the Office of Pharmaceutical Quality which has expanded the scope of quality oversight
  3. Allowed for a structured interaction between CDER and ORA
- Regular dialogue between AAM member companies and CDER leadership

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Access!

2020 Annual Meeting

May 11-13, 2020 | Washington, DC

Register Now

Find out more at access.accessiblemeds.org or contact Jennifer Soup at jennifer.soup@accessiblemeds.org.