



PHARMACEUTICAL SUPPLY CHAIN

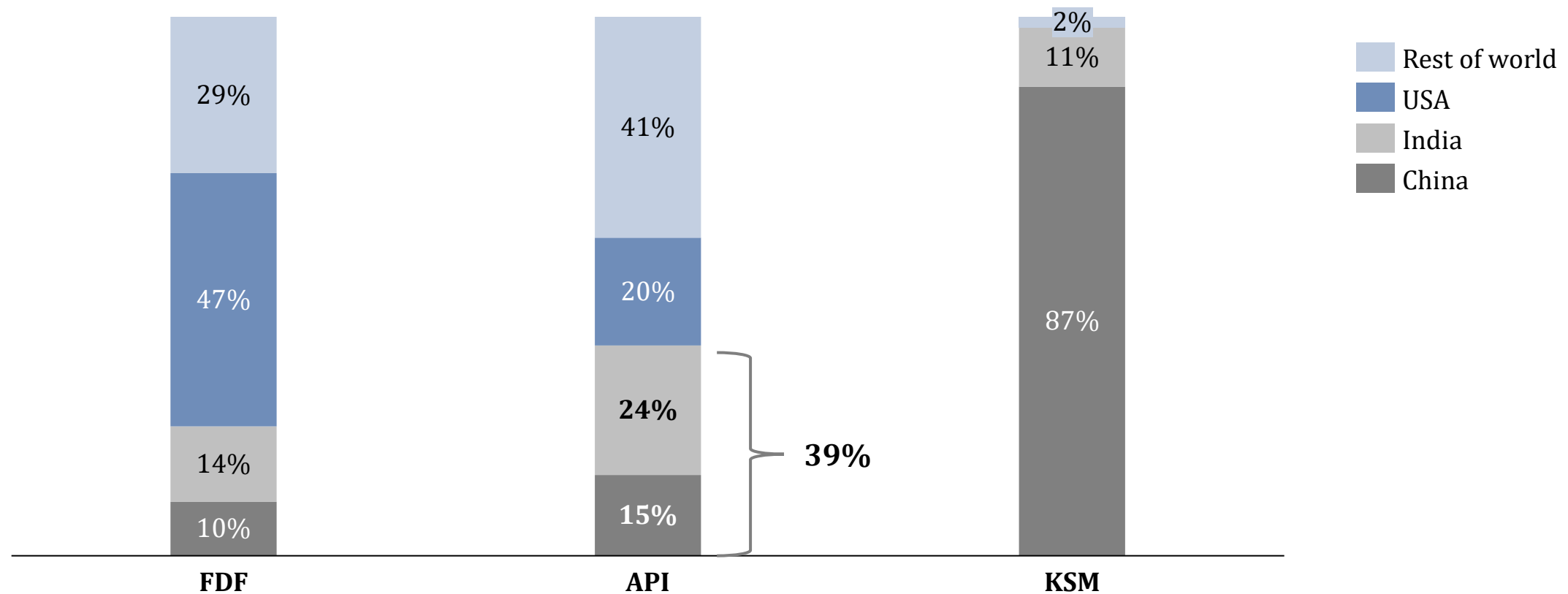
FOREIGN
DEPENDENCY

QUALITY



The U.S. Generic Supply Chain Relies on India and China for 39% of its APIs

¹Drugs imported into U.S. market by manufacturing countries, %



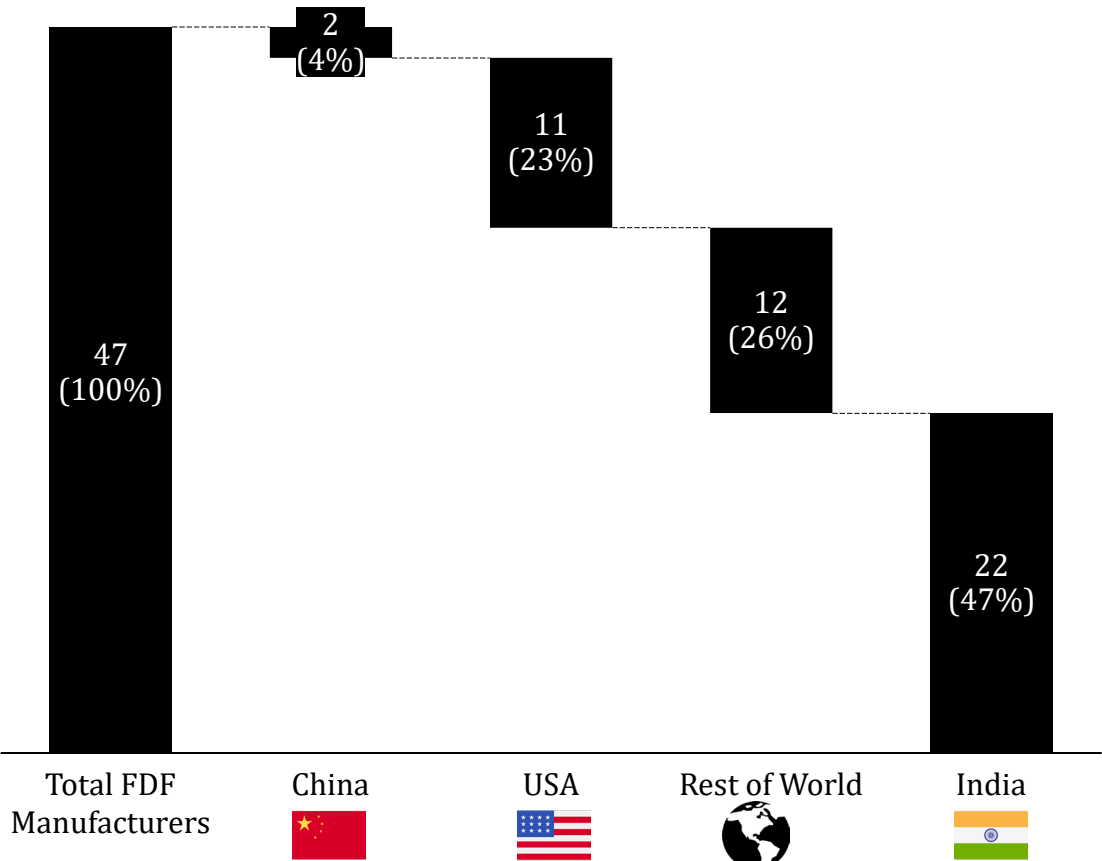
40 Prioritized Molecules* of National Importance are Overdependent on Foreign Sources for Inputs



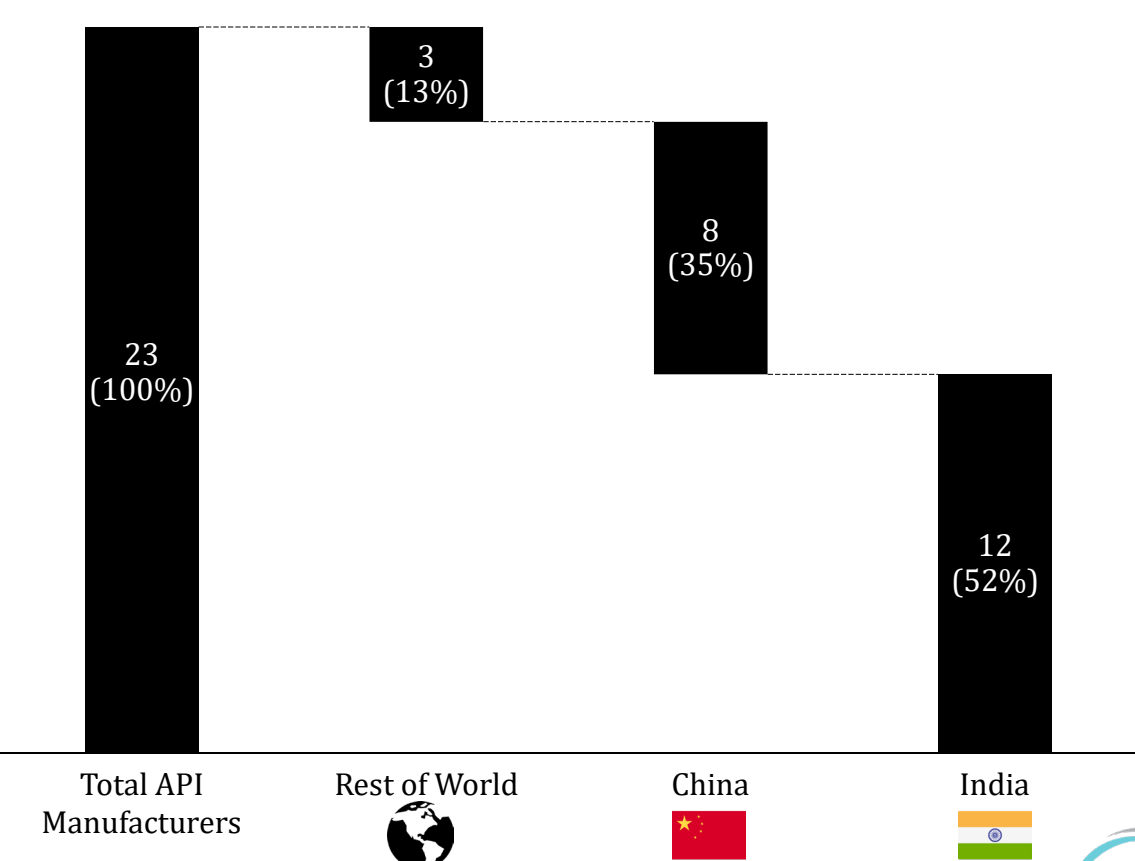
**Data retrieved from QYOB Database consisting of 40 APIIC identified drug molecules of national importance, October 14th, 2024.*

India Leads U.S. Trade in Fluoroquinolone¹ Antibiotics: 52% of API and 47% of Formulation Manufacturers are India-Based

FDF Manufacturers by country / region, # (%)



API Manufacturers by country / region, # (%)



¹The analysis is concluded including substances: Ciprofloxacin, Delafloxacin, Levofloxacin & Moxifloxacin.

Foreign Dependence by Therapeutic Class: API Vulnerabilities

The API Innovation Center's analysis of API sourcing by therapeutic category shows a consistent pattern of foreign dependence:

- **Cardiovascular, diabetes, and gastrointestinal drugs:** ~50% or more of APIs sourced from India.
- **Oncology medicines:** heavy reliance on both **India and China**.
- **Immunomodulators:** production concentrated in **Europe**.
- In nearly every category, **over 80% of APIs are manufactured abroad**.
- Critical areas — including **emergency, cardiovascular, and diabetes treatments** — are among the most exposed.

This dependence leaves essential categories of care vulnerable to foreign supply risks. For veterans and seniors, disruptions in these classes of medicines would affect treatments for heart disease, cancer, diabetes, and immune disorders — conditions that drive the highest rates of morbidity and mortality in the U.S. Over-reliance on foreign APIs not only threatens timely access, but also increases the risks of shortages, higher costs, and reduced availability for patients who can least afford disruption.

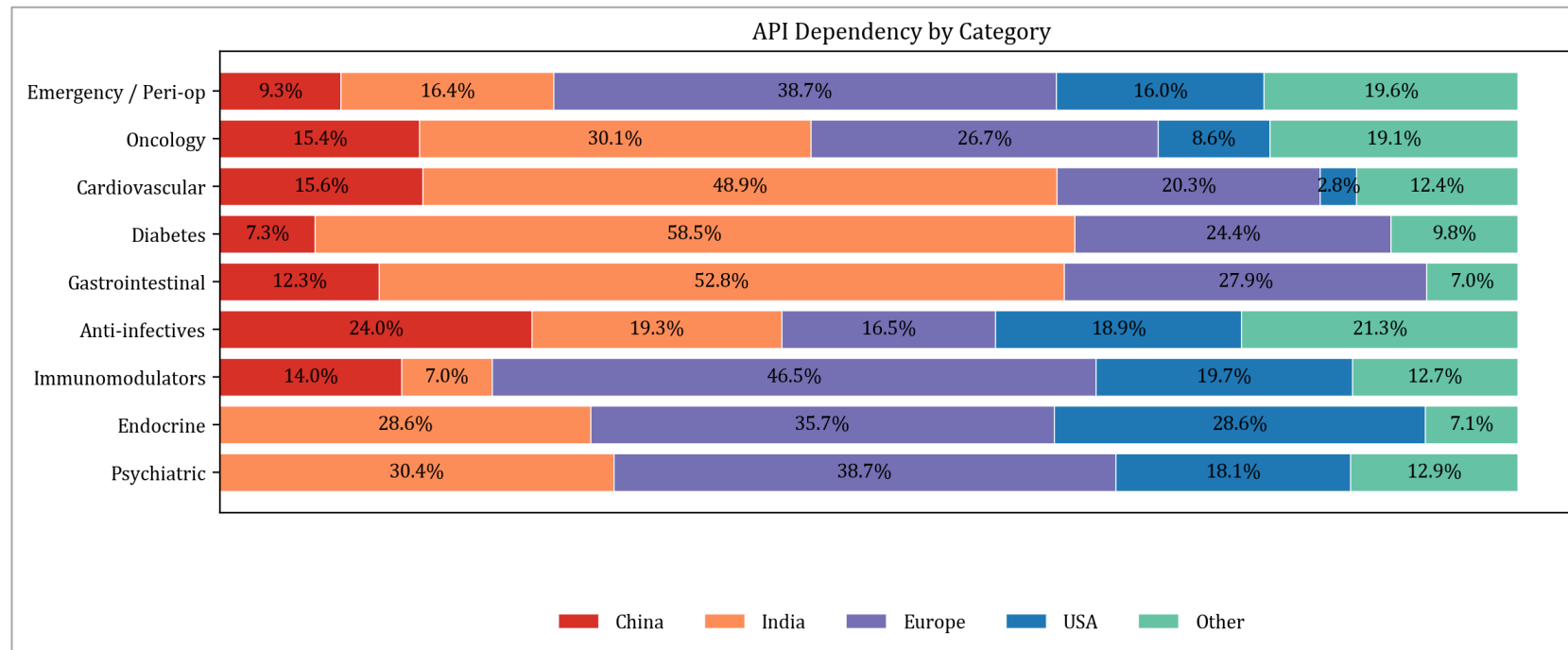


Figure 1: API Dependency by Therapeutic Class*

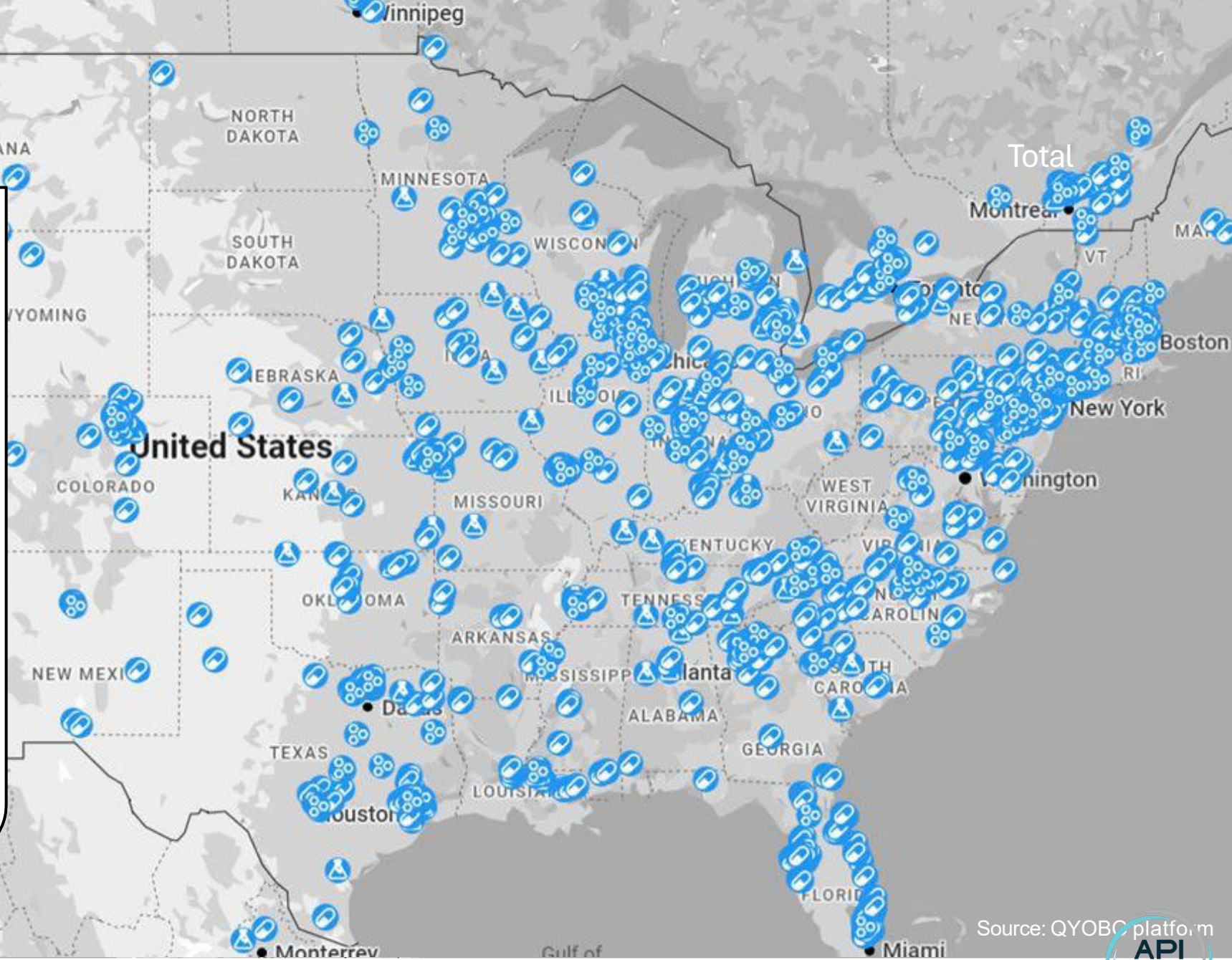
**This API dependency assessment includes 54 drugs for veterans and the elderly with available supply chain data.*



U.S. Pharma manufacturing sites



Total = 1,695 sites (API includes IPI, inactive ingredients)



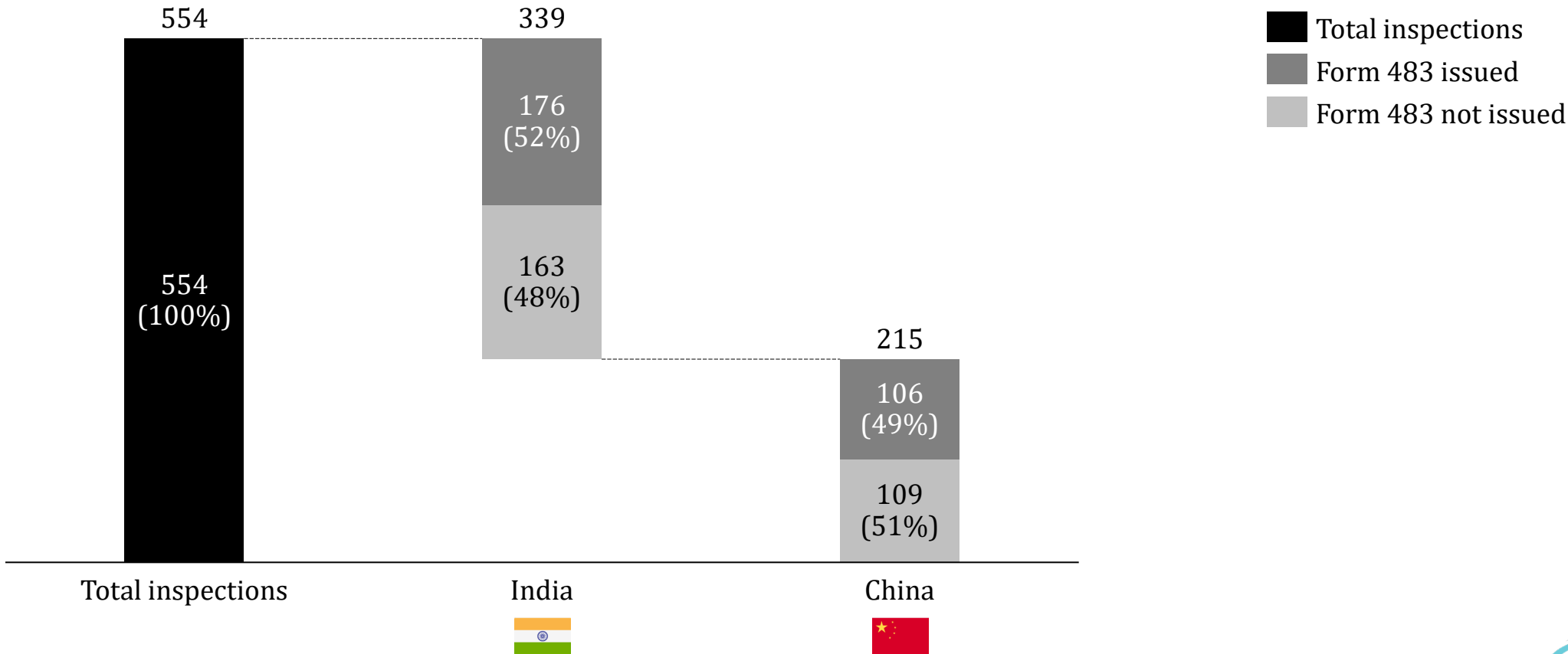
API FDF API + FDF

Source: QYOB platform



50% of inspections at API manufactures in India and China supplying US Generics have been issued a Form 483¹

Form 483s issued by U.S. FDA focusing the U.S. supply chain (2023–2025 YTD), # (%)

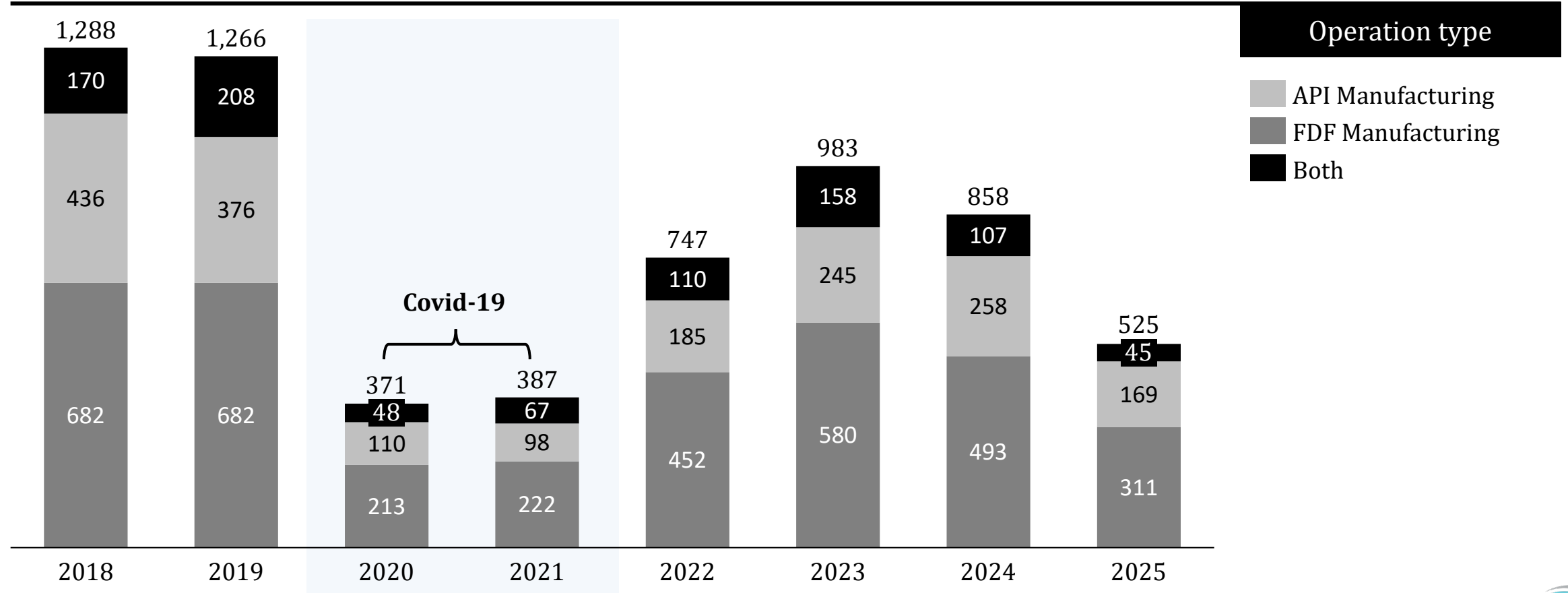


¹Focus on inspections at API and API+FDF manufacturing sites since 2023 to 2025 YTD



Post-COVID Strain on U.S. FDA: Inspection Activity Falls below Pre-Pandemic Levels

U.S. FDA Inspections by Manufacturing Type for U.S. Market (2018-2025 YTD), #



Defense Considerations

“You will not find it difficult to prove that battles, campaigns, and even wars have been won or lost primarily because of logistics.”

~ **Dwight D. Eisenhower**

