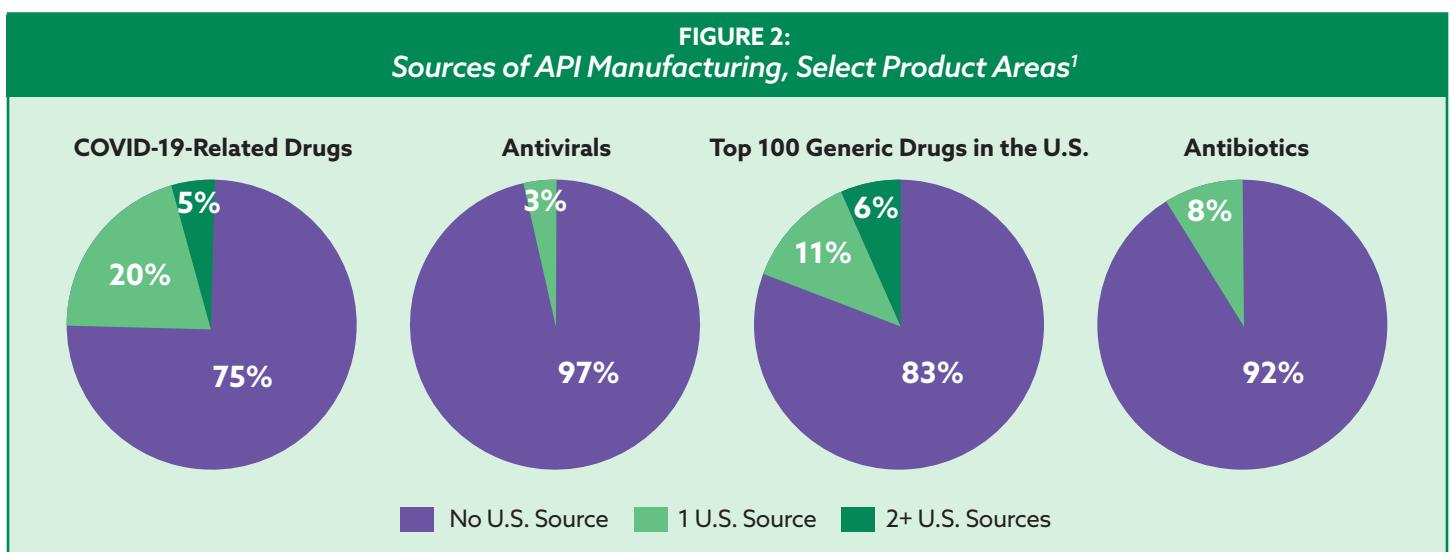
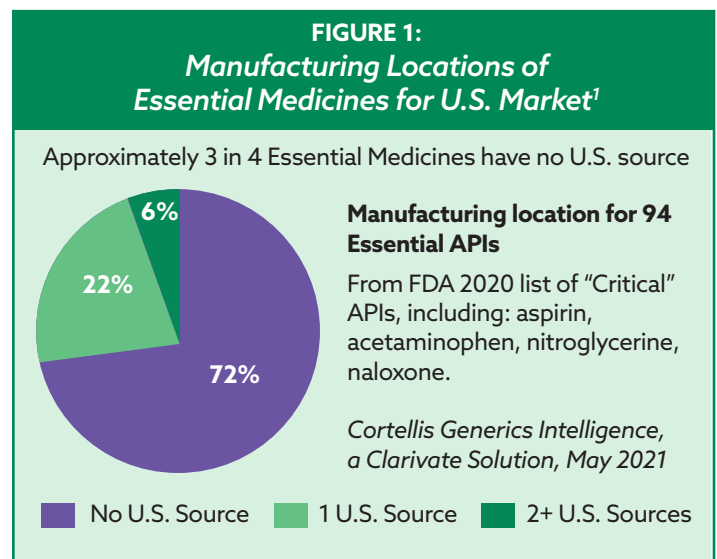


# REDUCE DEPENDENCE ON FOREIGN SOURCING OF PHARMACEUTICALS BY RETURNING MANUFACTURING TO THE U.S.

Active Pharmaceutical Ingredients (API) are the components of a medicine that deliver the therapy and chemical and biological compounds formulated and manufactured into finished dosage forms (e.g., tablets, capsules, solutions, creams, etc.).

## The U.S. is Heavily Reliant on Foreign Sources of API

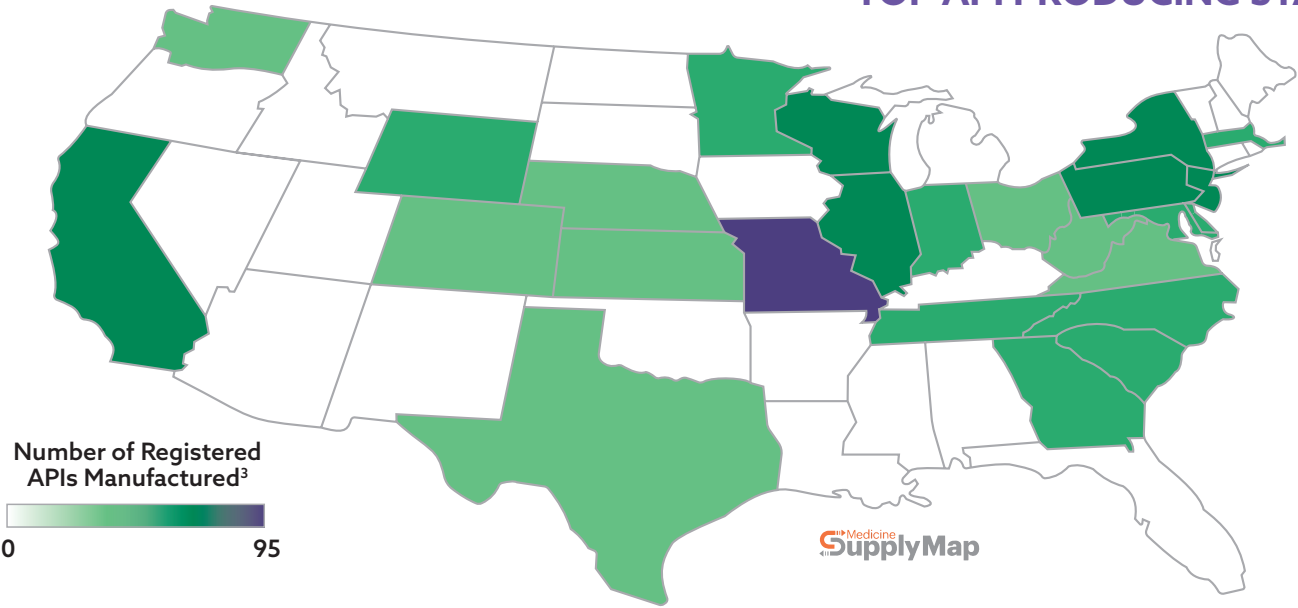
- ▶ The majority of API provided to the U.S. market are from overseas factories.
- ▶ With only 4% of the world's high-volume API sites<sup>1</sup>, domestic API manufacturing is at **sub-critical scale to meet U.S. needs.**
- ▶ 72% of the FDA Essential Medicines<sup>2</sup> have no U.S. source of API.
- ▶ Beyond essential medicines, many COVID-19 related and other **critical medicines have no U.S. source of API supply.**<sup>2</sup>



### Sources

1. A. Sardella, "The U.S. Active Pharmaceutical Ingredient Infrastructure: The Current State and Considerations to Increase U.S. Healthcare Security," Olin Business School, Washington University (St. Louis, MO), Aug. 2021
2. Cortellis Generics Intelligence, formerly known as Newport. Copyright Clarivate 2021
3. "Medicine Supply Map." USP, <https://www.usp.org/supply-chain/medicine-supply-map>
4. Woodcock, Janet, "Safeguarding Pharmaceutical Supply Chains in a Global Economy." U.S. Food and Drug Administration, 30 Oct. 2019

# TOP API PRODUCING STATES



## The Importance of **STRENGTHENING** U.S. Pharmaceuticals Manufacturing

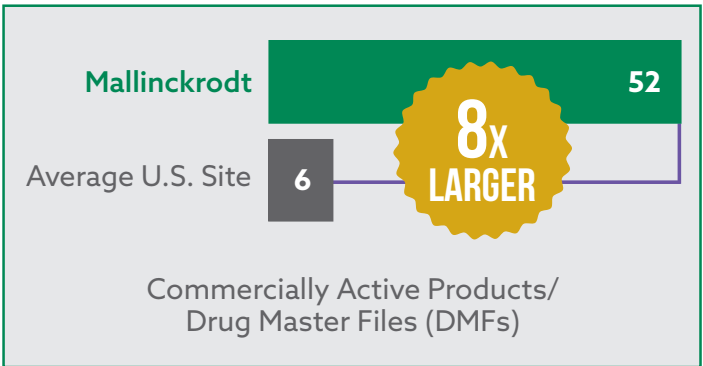
- ▶ *A critical mass of U.S. API manufacturing in essential medicines is necessary to address emerging threats*
- ▶ Domestic manufacturing will provide a more secure pharmaceutical supply chain and decrease the dependence on foreign sources
- ▶ As U.S. API production ramps up, substantial jobs will be created

## **ESSENTIAL MEDICATIONS** Can Be Re-Shored Within 2-3 Years

- ▶ *Collaborative partnerships between technology companies, established cGMP\* manufacturers and governmental agencies can accelerate speed to market*
- ▶ Significant existing and idle domestic API manufacturing capacity is available now<sup>4</sup>
- ▶ Investing in new, innovative manufacturing capabilities can reduce reliance on overseas suppliers

## Mallinckrodt Specialty Generics is the **PARTNER OF CHOICE**

- ▶ *150+ year-old U.S. based manufacturing network with five FDA-approved sites and over 1,500 U.S. based employees*
- ▶ Founding member of API Innovation Center – an advanced manufacturing non-profit engaging universities, technology innovators and API leaders to solve this challenge
  - ▶ <https://www.apicenter.org>



\*cGMP = Current Good Manufacturing Practice