Ensuring a Stable Supply Chain of Necessary Medicines in the US

Alaska Representative Geran Tarr, Treasurer, Women In Government Board of Directors (Moderator)

Sean Grove, Director of Government Affairs, Mallinckrodt Pharmaceuticals

Kevin Webb, Vice President of External Engagement,
API Innovation Center







API Innovation Center @ CORTEX

Kevin Webb, Chief Operating Officer

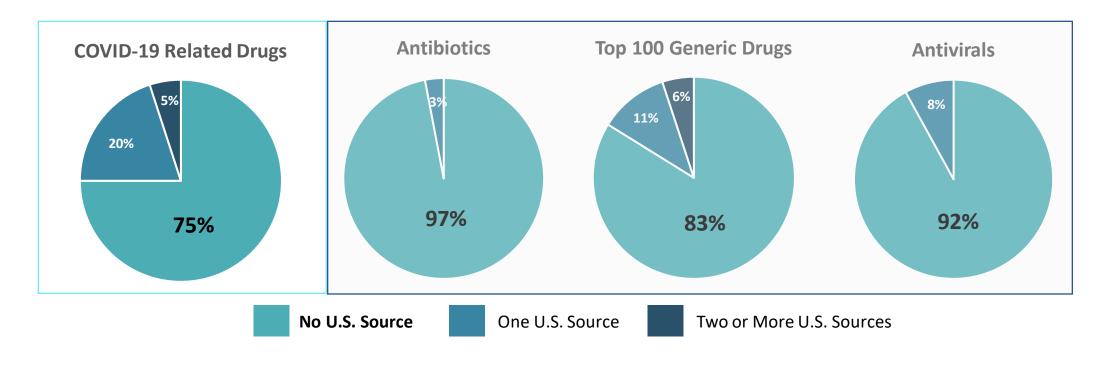




The U.S. Drug Supply Chain Is Vulnerable

We are over-reliant on foreign-sourced drug API

Our dependence on foreign countries for pharmaceuticals and API has created both a public health and national security risk.







Federal Government: Supply Chain Security

"Keeping the nation's drug supply chain secure, robust, and resilient is essential for the national security and economic prosperity of the United States."

The White House Report: Building Resilient Supply Chains June 28, 2021

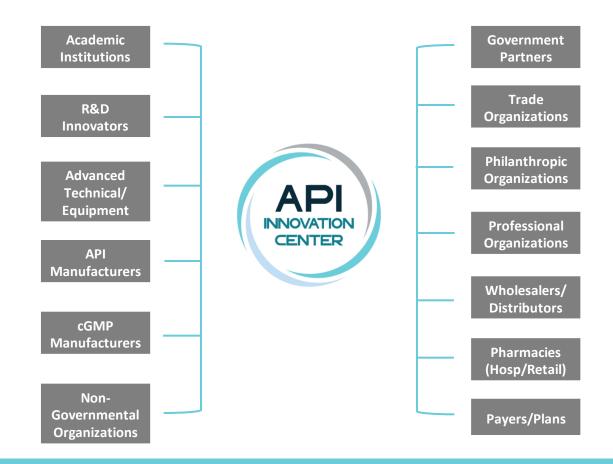
- <u>Inspector General Department of Defense</u>: "A disruption of the supply of foreign-made API to domestic manufacturers could cause a drug shortage that affects every level of the U.S. health care system, which is a public health and national security risk."
- President Biden Executive Order: "Improve and expand domestic biomanufacturing production capacity."
- <u>US Treasury's Committee on Foreign Investment in the United States (CFIUS)</u>: blocks sale of Snapdragon to a Chinese pharmaceutical and research company.
- <u>US Congress</u>: Introducing legislation to support advanced manufacturing: Endless Frontiers Act; US COMPETES Act.
- <u>FDA Report</u>: Adoption of advanced manufacturing techniques would reduce production costs and increase resilience of US production.





APIIC: Accelerate Domestic Biomanufacturing

Center of Excellence Ecosystem:
Commercialize Advanced Manufacturing Technologies





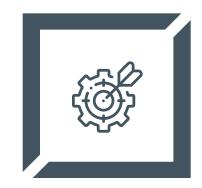


The API Innovation Center @ CORTEX: De-Risking the Innovation Process



PARTNERSHIPS

Fostering collaboration among a network of companies, academic and research organizations, and startups spanning the API advanced manufacturing supply chain.



INVESTMENTS

Collaborates with public entities to de-risk/fund investments assuring viability of US-made APIs



RESEARCH

Develop solutions for shared emergent challenges that leads to new technologies and methods.



INNOVATION

Through a coordinated approach, enable the commercialization of advanced manufacturing technologies in cGMP facilities to produce essential and critical medicines within 24 months.



WORKFORCE

Create a diverse talent pipeline by partnering with local educational and non-profits that engage under-represented communities and support DEIA.





APIIC Model: Begin with the End in Mind

OUR DECISION PROCESSES



Demand/Volume Regional Job Growth No US Source Profitable Profile Technically Feasible Patient Impact Technical Readiness Strategic Business Fit Competency/Expertise Excess Capacity Matching Investment



Invest in new technologies and advanced manufacturing

- De-risk investment for companies to expand manufacturing capabilities
- Put idle manufacturing capacity to work

Workforce Development

- Advanced manufacturing advanced degrees
- Create accelerator hubs located in the communities (not the campus)

Medicaid reimbursement

- Increase Medicaid reimbursement, not to exceed federal upper limit
- Establish a higher dispensing fee (to pharmacist) for US-sourced drugs (i.e. specialty drug)





Missouri – Funding Advanced Manufacturing

HOUSE BILL NO. 3007

101ST GENERAL ASSEMBLY

For the purpose of providing grants to state based organizations creating infrastructure for industries that are fundamental to the national security of the United States where the manufacturing of essential products have become reliant on production outside of the United States which potentially jeopardizes a reliable supply chain for domestic consumption. Furthermore, grants shall focus on such manufacturing where Missouri has an inherent connection or advantage creating an environment for significant growth in Missouri's economy. Relevant investment sectors shall include but not be limited to advanced and innovative manufacturing of active pharmaceutical ingredients and semiconductors. Grants shall provide for investment and infrastructure focused on creating a hub of such industries in Missouri



Gov. Parson (R-MO) HB3007 Bill Signing

