



APIIC Releases Recommendations to Combat Rising U.S. Drug Shortages and Ensure Access to Life-Saving Medications

Pharmaceutical makers, patient advocates agree: Public-private collaboration, advanced manufacturing technologies, supply-chain transparency all vital to meeting Biden Administration's five-year goal for strengthening American biomanufacturing

ST. LOUIS – (Jan. 24, 2024) – The rising rate of drug shortages demands immediate formation of a public supply-chain entity to drive the programs, policies and transparency required to protect our nation's health security, the [Active Pharmaceutical Ingredient Innovation Center](#) (APIIC), a consortium of biotechnology industry, policy and academic leaders, said today in a whitepaper, outlining recommendations for reshoring the manufacture of essential, life-saving pharmaceuticals.

Developed with unfiltered input from leading manufacturers, patient advocates and other public health stakeholders, the report, [A Bold Goal: Reshoring 25% of Small Molecule API to the U.S. in Five Years](#), urges the public and private sectors to work together to overcome the price erosion, industry consolidation and manufacturing offshoring dynamics challenging Americans' reliable access to essential medications.

"The collaboration necessary to develop a paper of this caliber is impressive," said Tony Sardella, chair of the API Innovation Center. "Continued collaboration with industry stakeholders and the organizations represented in this paper will be instrumental in tracking progress and implementing the recommendations."

At least 83% of the nation's top 100 generic drugs have no U.S.-based source for the small-molecule active pharmaceutical ingredients (APIs) found in today's medications, and 90% of the most frequently prescribed antivirals and antibiotics rely on APIs manufactured offshore, according to researchers at the [Olin Business School at Washington University](#).

The APIIC report encourages pharmaceutical manufacturers and policy makers to address these vulnerabilities to national health security through the adoption of advanced biomanufacturing technologies and public incentive programs designed to reignite idle capacity at U.S. manufacturing facilities.

Specifically, the report explores:

- The state of the workforce, technology adoption and capacity in U.S. biomanufacturing;
- Approaches for defining and prioritizing essential small-molecule selections for API production, with considerations on geographic, materials availability and more; and

- The barriers and opportunities for mitigating health risk by diversifying the U.S. manufacturing base through the domestic reshoring of API production.

“For more than 200 years, U.S. Pharmacopeia has brought healthcare professionals, scientists, and regulators together to ensure quality and trust in our drugs,” said Dennis Hall, vice president, Advanced Manufacturing Technologies at U.S. Pharmacopeia. “This work is another example of what a group of experts can do to solve the issue of drug supply chain surety.”

Developed in response to the Biden Administration’s bold goal to re-shore 25% of small-molecule APIs within five years, the APIIC report is the result of a 15-member working group of subject matter experts from the pharmaceutical supply chain, representing U.S. Pharmacopeia, Pfizer, Thermo Fisher Scientific, Angels for Change, Duke-Margolis Center for Health Policy and other industry leaders who gathered at a plenary event in November 2023 at the API Innovation Center in St. Louis.

“By continuing to convene and facilitate connections with key organizations and stakeholders in the industry, the industry members that came together for this paper and event can continue to work to support the development of investment to secure supply chain resilience within the United States,” said Kurt Karst, Hyman, Phelps & McNamara, P.C., co-founder of the [FDA Law Blog](#).

It follows developments and reports from the [White House Office of Science and Technology](#), the National Economic Council (NEC) Director and the National Security Advisor (NSA), calling for a new approach aimed at guaranteeing Americans reliable access to essential medications.

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About APIIC:

The API Innovation Center (APIIC) is a 501(c)(3) non-profit public benefit organization headquartered in St. Louis, Missouri, dedicated to delivering market-competitive commercial supply of U.S.-made Active Pharmaceutical Ingredients (APIs) to address national health security. By fostering collaboration among a network of companies, academic and research institutions, and startups, APIIC stewards innovations in advanced manufacturing and enables solutions for drug supply chain fragility. The Center also works to create a diverse talent pipeline by partnering with local educational and apprenticeship programs that target underrepresented communities. APIIC is supported by the State of Missouri through a grant awarded by the Department of Economic Development and the Missouri Technology Corporation. To learn more about APIIC, visit: www.apicenter.org