



FACT SHEET

Info on Legislation:

House Bill 3007 Bill Language: 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. From Missouri Technology Investment Fund (0172) \$15,000,000

Definitions:

- ▶ **Active pharmaceutical ingredient (API):** “Any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product” (FDA, 2015).
- ▶ **Lomustine:** A chemotherapy drug used for the recurrence of glioblastoma, the most aggressive form of brain cancer.
- ▶ **Continuous manufacturing:** A fully integrated process that utilizes sequential flow unit operations to produce APIs.
- ▶ **Semiconductors:** The brains of modern electronics, enabling advances in medical devices and health care, agriculture, communications, computing, defense, transportation, clean energy, and technologies of the future such as artificial intelligence, quantum computing, and advanced wireless networks.



Statistics:

- ▶ According to the Food and Drug Administration (FDA), approximately 78% of active pharmaceutical ingredients (API) manufacturers are located outside of the U.S.¹
- ▶ United States Pharmacopeia (USP) identified Missouri as first in the nation with the most API manufacturers producing essential medicines.²
- ▶ Missouri currently ranks 7th in the nation in technology manufacturing growth and 8th in the nation for projected future technology manufacturing growth.³
- ▶ About 75% of global semiconductor manufacturing capacity is concentrated in China and East Asia, a region significantly exposed to high seismic activity and geopolitical tensions. 100% of the world's most advanced semiconductor manufacturing capacity is currently located in Taiwan (92%) and South Korea (8%). These advanced chips are essential to America's economy, national security, and critical infrastructure.⁴

Info on the "Lomustine Crisis":

Lomustine is a drug used to treat glioblastoma, the most aggressive form of brain cancer. There is currently no U.S.-source of lomustine. Recently, the sole foreign-sourced manufacturer of lomustine significantly increased the price of the drug, making clinical trials cost prohibitive. In 2021, the manufacturer pulled out of the federal discount program for Medicare patients, leaving many struggling to pay for treatment.⁵ According to the Society for Neuro-Oncology, "the field of neuro-oncology is in the midst of a crisis with lomustine."⁶ Continuity Pharma is working to resolve the lomustine crisis utilizing the advanced technologies of continuous flow manufacturing.

The Benefits of Continuous Manufacturing^{7,8}:

- ▶ Improves the quality and safety of essential medicines
- ▶ Rapidly scale manufacturing capabilities and competitiveness of the U.S.
- ▶ Shorten supply chains
- ▶ Increases US manufacturing resilience to supply disruptions
- ▶ Accelerate therapy development and time to market
- ▶ Improved efficiencies over current batch manufacturing
- ▶ Reduces manufacturing and labor costs while enhancing workplace safety
- ▶ Eliminates supply disruptions with on-demand production

REFERENCES

¹ FDA At a Glance. U.S. Food & Drug Administration. November 2021

² Medicine Supply Map. United States Pharmacopeia (USP). 2022

³ Technology 2030 Report. Missouri Chamber Foundation. 2018

⁴ Semiconductor Industry Association. 'Strengthening Trade And Our Supply Chain', February 15, 2022

⁵ Wall Street Journal. 'Costly Brain-Cancer Drug No Longer Covered by Medicare', June 17, 2021

⁶ Neuro-Oncology. The lomustine crisis: awareness and impact of the 1500% price hike. 21(1), 1-3, 2019

⁷ FDA website: Advanced Manufacturing. Link: <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing>

⁸ Fierce Pharma, June 1, 2021. "End-to end: Can pharma finally make the dream of continuous manufacturing a reality?"