U.S. Pharmaceutical Supply Chain Defense and Enhancement Act

U.S. Senator Elizabeth Warren (D-MA) and U.S. Senator Tina Smith (D-MN)

Background

Troublingly, the United States relies heavily on foreign countries for its supply of critical drugs. 77% of the facilities that manufacture active pharmaceutical ingredients (APIs) used in drugs consumed by Americans are located overseas.[1] This overreliance is an alarming national security and public health risk. Foreign manufacturers could restrict or completely cut off the supply of pharmaceutical products during a period of heightened geopolitical tensions, during a future pandemic, or after a natural disaster. Bad actors could tamper with drugs or APIs, rendering them ineffective, or even weaponize them. A lack of available information has prevented the federal government from adequately addressing these problems. The United States must take steps to counter this overreliance and ensure that reliable and high-quality drugs can be produced at home.

The Pharmaceutical Supply Chain Defense and Enhancement Act

The *Pharmaceutical Supply Chain Defense and Enhancement Act* is comprehensive legislation that takes bold steps to reinvigorate the United States' manufacturing capacity and end the nation's reliance on foreign countries for critical drugs used by millions of Americans. This bill:

- **Requires the U.S. Food & Drug Administration (FDA) Commissioner and the Secretary of Defense to develop a confidential list of "critical drugs" essential for public health and national security.** The list shall include the name of the drug, as well as all APIs and starting materials necessary to develop it and will be updated every two years to reflect the nation's shifting needs.

- **Lowers the cost of domestic production by providing $1 billion a year for 5 years to the Biomedical Advanced Research and Development Authority (BARDA), to dramatically upgrade our national capacity to manufacture "critical drugs**." Funding will be used to contract with U.S. nonprofits and companies to help them invest in the facilities, manufacturing techniques, and drug development processes needed to domestically produce the drugs, APIs, and starting materials included on the "critical drugs" list.

- **Creates a market for domestically-produced pharmaceuticals by requiring the Department of Defense, Veterans Affairs, Department of Health and Human Services, and Federal Bureau of Prisons to purchase American-made drugs and providing funding to subsidize the purchase of these drugs.** These agencies will be given an additional $1 billion to purchase drugs that utilize ingredients produced exclusively in the United States.

- **Boosts supply chain transparency** by requiring drugmakers to annually report to the FDA information about the source of APIs and starting materials used to make drugs consumed in the United States; requiring drugmakers to report information on foreign manufacturers in their supply chain to any federal agency to which they supply drugs; and requiring the FDA to issue both public and classified reports to Congress on the strength of the U.S. supply chain. This section provides $20 million to the FDA to update its technological capabilities and establish an API/key material database to track U.S. reliance on foreign manufacturers.

- **Requires the Federal Trade Commission and the Treasury Department to study the role of foreign investment in the U.S. pharmaceutical industry** within one year of the Act's passage.

[1] U.S. Food & Drug Administration, "FDA at a Glance," October 2024, https://www.fda.gov/media/182749/download.