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

The COVID-19 pandemic has exposed a troubling truth – the United States relies heavily on foreign countries for its supply of critical drugs. The United States imports nearly 80% of the active pharmaceutical ingredients (APIs), the requisite component of drugs, used in generic drugs that millions of Americans rely on. 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 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 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 produce the drugs, APIs, and starting materials included on the "critical drugs" list in the United States. These companies will use advanced manufacturing techniques that will allow for higher quality drugs to be produced more efficiently.

- **Creates a market for domestically-produced pharmaceuticals by requiring DoD, VA, HHS, and BOP to purchase American-made drugs and providing funding to subsidize the purchase of these drugs.** These agencies will be given an additional $1 billion over their current budgets procurement budgets to purchase drugs that utilize ingredients produced exclusively in the United States.

- **Boosts supply chain transparency** by requiring drug makers 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 drug makers to report to any federal agency that it supplies drugs with information on the foreign manufacturers that produce those drugs and components; 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.

- **Require the FTC 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.