Homeland Security News Wire

DRUG SUPPLY CHAINS

U.S. Policymakers Acting to Bolster Drug Supply Chains Amid Critical Shortages

By Mary Van Beusekom

Published 23 June 2023

Alarmed by persistent shortages of critically important drugs such as cancer medications, Adderall, and antibiotics, U.S. policymakers are taking steps to shore up the country's pharmaceutical supply chains. The American Society of Health-System Pharmacists has more than 900 drug and dose shortages on its drug shortage list, and the FDA lists more than 200. The number and length of supply disruptions has grown over the last 10 years.

Alarmed by persistent shortages of critically important drugs such as cancer medications (https://www.cidrap.umn.edu/resilient-drug-supply/life-threatening-cancer-drug-shortages-are-result-cascade-troubles), Adderall (https://www.cidrap.umn.edu/resilient-drug-supply/shortage-adhd-drug-adderall-likely-last-2023), and antibiotics, U.S. policymakers are taking steps to shore up the country's pharmaceutical supply chains.

Recently, Senators Gary Peters (D-Michigan) and Joni Ernst (R-Iowa) proposed legislation to identify the country's pharmaceutical supply chain weaknesses and reduce its reliance on China for drugs and drug ingredients.

The legislation, called the Pharmaceutical Supply Chain Risk Assessment Act, would require the Department of Homeland Security, the Department of Defense, the Department of Health and Human Services, and the White House Office of Pandemic Preparedness and Response Policy to conduct a risk assessment and create a plan to address long-standing drug-supply issues.

But reducing dependencies will be complicated. The Food and Drug Administration (FDA) said early this month that it had resorted to permitting the import of the chemotherapy drug cisplatin (https://www.nbcnews.com/health/cancer/cancer-drug-shortage-fda-will-allow-imports-cisplatin-china-rcna87751) from China, even though it is not approved in the United States. The FDA said it was also considering importing another platinum-based cancer drug, carboplatin, from China.

Import of Unapproved Drugs a "Temporary Relief"

David Margraf, PharmD, PhD, pharmaceutical research scientist at the Resilient Drug Supply Project (RDSP), said that the import of non–FDA-approved drugs to alleviate shortages is a temporary relief for strained drug supply chains.

"The legislation would require the Department of Homeland

> Security, the Department of Defense, the Department of Health and Human Services, and the White House Office of Pandemic Preparedness and Response Policy to conduct a risk assessment and create a plan to address long-standing drug-supply issues."

These drugs come from facilities that are not inspected by the FDA for quality control, so it is important to consider the potential risks to patients due to the increased likelihood of compromised safety and efficacy," he said. RDSP is part of the University of Minnesota's Center for Infectious Disease Research and Policy (CIDRAP), publisher of CIDRAP News.

According to Margraf, the underlying structural problems with the U.S. drug supply stem from market factors that favor low-cost production at the expense of quality and consistent availability. "Cost considerations of generic drug production play a significant role, which has led to a complex and convoluted global market," he said. "The pursuit of low-cost production has led to outsourcing manufacturing to countries with lower production costs and less stringent regulatory standards."

More Stories: