

Strengthening the Supply Chain for Cancer Drugs

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Ensuring every American has access to the tools and interventions that exist today to prevent, detect, and treat cancer—and to the breakthroughs we are advancing in the Biden-Harris Administration—is essential to achieving the Biden Cancer Moonshot goal of ending cancer as we know it.

Unfortunately, the United States is currently experiencing a shortage of 15 cancer drugs due to manufacturing and supply chain issues. Three of these drugs—cisplatin, carboplatin, and methotrexate—are widely used generic drugs and have been staples of cancer treatment for decades. Several generic oncology drug manufacturers have discontinued products over time for economic reasons. And, in the last year, manufacturing site closures cut the U.S. supply of these three drugs nearly in half. These supply issues have had serious impacts on patients in the form of delayed and altered treatments.

The Biden-Harris Administration has been closely tracking these issues and taking action. Over the last several months, the Food and Drug Administration (FDA) has taken a number of important steps to tackle cancer drug supply issues and to help mitigate and prevent impacts to patients:

- For generic carboplatin and cisplatin, the FDA worked closely with cancer drug manufacturers to help identify opportunities to increase manufacturing capacity and bring companies that had stopped producing those drugs back to the U.S. market. Additionally, after a rigorous evaluation of the availability of other sources of these drugs in terms of safety and quality, the FDA exercised enforcement discretion for a manufacturer to import 14 lots of cisplatin from an FDA-registered facility outside of the United States. Cumulatively, these actions brought the cisplatin supply back to nearly 100 percent of the pre-shortage levels and are greatly alleviating the shortages of carboplatin.

- The FDA worked closely with the five manufacturers of generic methotrexate for injection to help increase supplies during the shortage.
- Close cooperation among the FDA, the manufacturers, and health care systems is helping to ensure approximately 400,000 patients per month receive their treatments. While meaningful progress has been made for patients across the United States, shortages have not been fully resolved and the FDA continues to work with drug manufacturers and health care providers to help restore access to essential cancer treatments and other medicines that are currently in short supply.

There is more work to do. To advance the Administration's efforts, on July 28, the Cancer Moonshot and White House Office of Science and Technology Policy convened leaders from across the generic oncology drug supply chain, patient advocates, caregivers, and health care providers to hear directly from those who are working on the ground to resolve these supply chain disruptions, and to get medicines to patients.

During this meeting, White House officials underscored President Biden's commitment to ensuring patients have access to the treatments they need. In addition to the FDA's work, broader Administration efforts to strengthen supply chains for pharmaceuticals and medical products will continue.

The participants and organizations represented in this productive conversation all agreed that these supply chain issues cannot be fixed solely through government action. They identified key areas where industry, nonprofits, public-private partnerships, and government can work together to change the status quo and implement ongoing efforts led by nonprofit organizations to help assure patient access to needed medicines. Each committed to continue working with the Administration to execute on a roadmap to end shortages for cisplatin, carboplatin, and methotrexate. There was also broad agreement that the increased use of data related to supply capabilities and patient needs at a local level can support supply chain resilience and lessen the economic and patient costs of shortages.

The Administration will continue to work through the FDA, the Department of Health and Human Services, and other agencies to address and prevent drug shortages and mitigate impacts to people facing a cancer diagnosis.

[This announcement](#) was published by the White House on September 12, 2023.