

National Cancer Drug Shortages: Policy Response and Potential Solutions

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Introduction

- In the United States, there has been an ongoing issue with the supplying the demand for generic prescription drugs.
- Low-cost generic drugs are more susceptible to shortages and many chemotherapy agents utilized to treat urologic conditions are affected.
- Currently there is a severe shortage of two commonly used chemotherapy drugs, carboplatin and cisplatin, with 86% of surveyed cancer centers reporting a shortage of at least one chemotherapy drug¹.

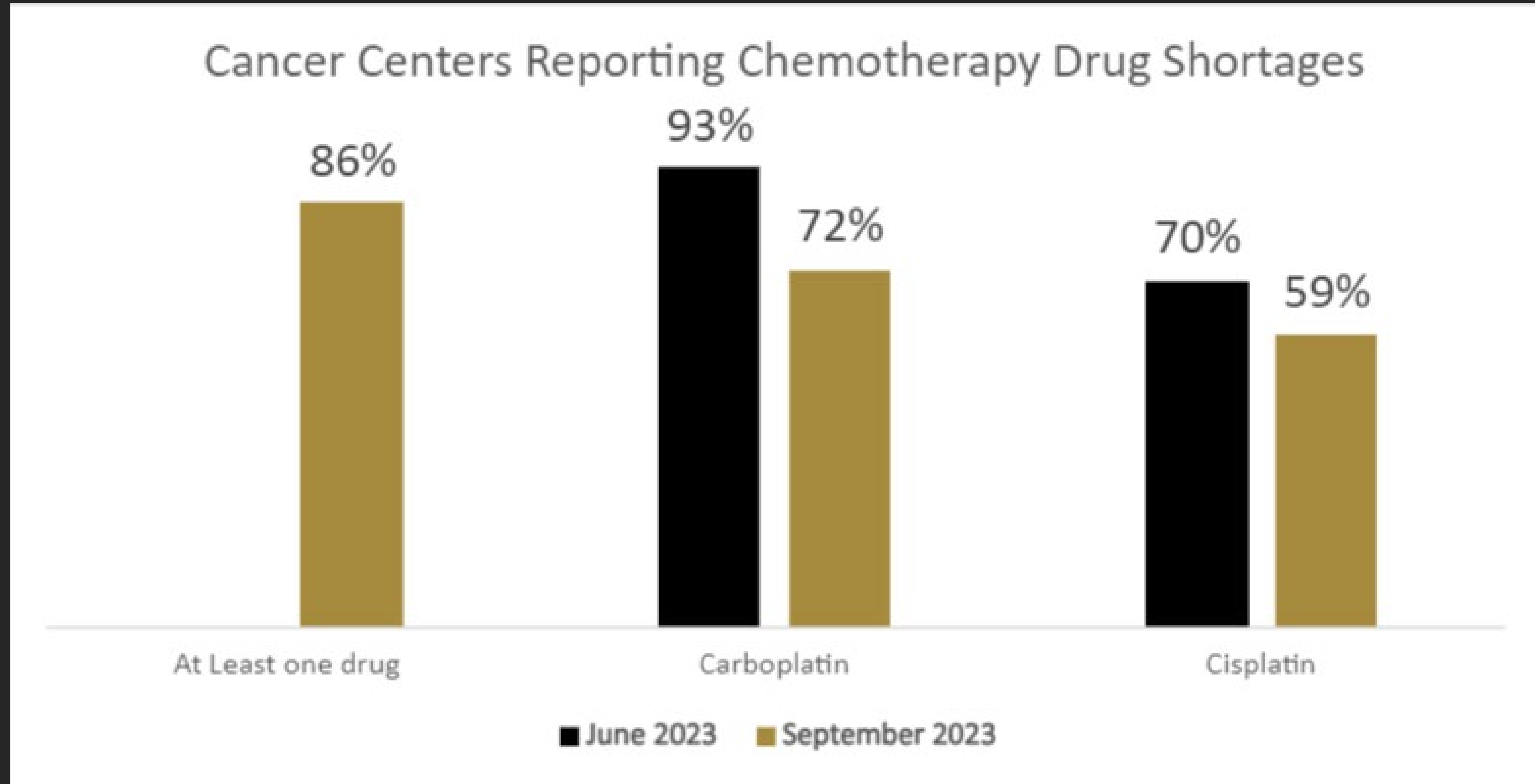
Objective

- To identify proposed legislative and federal agency policy changes to address and prevent cancer drug shortages and work to bring these matters to the attention of the Urologic community as targets for future advocacy efforts

Population Affected

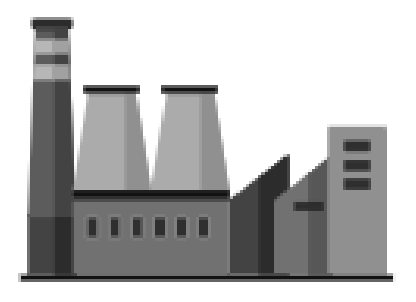
- Generic drugs make up approximately 90% of prescriptions filled by US consumers and the average generic drug shortage lasts for about 1.5 years².
- Chemotherapy agents are a key component of treating nearly all malignancies. Specifically, within the field of urology, carboplatin and cisplatin are utilized when the metastatic, adjuvant and neoadjuvant treatment of urothelial carcinoma and testicular malignancies. These cancers affect men and women of all ages, races and socioeconomic status.

Policy changes are necessary to effectively address current chemotherapy drug shortages and prevent future crises.



Derived from NCCN Best Practices Committee drug shortage follow-up survey results. Available at: www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortages-Survey-Update.pdf. Published Oct. 5, 2023.

Potential FDA Solutions



- Enforcing FDA policies which require drug manufacturers to provide advanced notice if a disruption in production of a specific drug is anticipated.



- Increased transparency into generic drug quality assessments and manufacturing capacity.



- FDA fast track approval of new manufacturing facilities as shortages emerge.
- Modifying expiration dates during times of acute shortage will help avoid wastage of medications in short supply.

Potential Policy Solutions

- H.R. 3810 "Drug Origin Transparency Act of 2023": Requires drug manufacturers to report supplies of active ingredients to the FDA and on drug labels.
- H.R. 3008 "Drug Shortage Prevention Act": Requires drug sponsors to notify the FDA in the event of an unanticipated spike in demand.
- H.R. 3793 "Ensuring Access to Lifesaving Drugs Act of 2023": Aims to improve the FDA's ability to safely, based on sound data, extend the shelf-life dates of drugs that are experiencing shortages.
- Tax incentives or other incentive programs for generic drugmakers to invest in these low-cost medications, and temporary drug importation measures from countries such as India and China.

Discussion

- During times of acute drug shortages, pharmaceutical companies have a moral and ethical obligation to prioritize the manufacturing of generic life-saving drugs.
- Similarly, insurance companies must reduce regulatory burdens for physicians to allow alternative agents to be used during drug shortages.
- Urologists can play an active role through advocacy and lobbying in helping drive these changes forward for the benefit of our patients.