

## Chemotherapy Drug Shortages Result in Access Challenges and Difficult Choices

BY NICOLE TAPAY, JD



Over the past 6 months, shortages of several anti-cancer drugs have jeopardized the quality of cancer care and placed the lives of some patients with cancer at risk. These shortages are occurring across treatment settings and geographies, including community cancer centers, hospital-based cancer programs, and private physician practices. In some cases, clinicians are being forced to choose who gets treatment between and among patients eligible for curative versus palliative intent. In addition to the alarming effects on patient treatment, these shortages pose risks to cancer research in the near and longer term.

Patients with cancer and oncology programs have been facing scarce supplies of a number of key chemotherapy agents, and there has been a particularly dire shortage of platinum-based chemotherapy agents (eg, cisplatin and carboplatin).<sup>1</sup> These two medications (individually or in combination) treat a wide range of cancers, including but not limited to gastric, pancreatic, colorectal, esophageal, cervical, and ovarian. Platinum drug shortages were first reported to the U.S. Food and Drug Administration (FDA) on February 10, 2023.<sup>2</sup> In a survey by the National Comprehensive Cancer Network (NCCN) released on June 7, 93% of NCCN centers surveyed reported a shortage of carboplatin and 70% reported a shortage of cisplatin.<sup>3</sup>

In certain cases, cancer programs and the clinicians who work there have been faced with the prospect of only being able to treat some of their patients. This past summer, “[A]n ACCC member program shared how drug shortages were essentially forcing oncologists to ‘prioritize’ patients receiving curative treatment over those receiving palliative care,” said ACCC


Chief Medical Officer and Deputy Executive Director, Leigh Boehmer, PharmD, BCOP. “That is not a decision any cancer care provider wants to—or should need to—make.”

Fortunately, some providers have been able to alleviate the shortages by coordinating within their own networks,<sup>1</sup> or with other practices or hospitals. Some have also benefited from strong drug procurement management by their pharmacy teams. Furthermore, alternative treatment options are available for some but not all anti-cancer therapies on shortage.<sup>1</sup> In some cases, providers have adjusted the dosing or intervals of the drugs.<sup>4</sup> Finally, certain oncology professional societies have issued recommendations regarding how to conserve and allocate the limited supplies.<sup>2</sup>

Cancer research and clinical trials are also affected by the shortages. Depleted supplies and uncertainty about the availability of certain drugs in the future affect researchers’ ability to enroll patients in certain clinical trials. The National Cancer Institute (NCI) has reported that at least 174 of its 608 trials may be affected by the drug shortages.<sup>5</sup>

These shortages reflect broader challenges with prescription drug manufacturing integrity in the US, stemming from production delays, unavailability of raw ingredients, and/or quality deficiencies, among other factors. In the late spring, the FDA worked with Qilu Pharmaceutical Co. Ltd. (Qilu) and its distributor Apotex Corp. to allow for the temporary importation of cisplatin during the shortage. Only Qilu and Apotex Corp. are allowed to import or distribute Qilu’s cisplatin injection in the US. Qilu issued a “Dear Healthcare Professional” letter that highlights some labeling changes and clarifies certain safety questions that may arise from

the importation and distribution of its product in the U.S.<sup>6</sup>

While this step by the FDA provided some near-term relief, additional changes will be needed to address the systemic issues that have led to these and other drug shortages. For example, some clinicians are calling for legislation to incentivize more domestic manufacturing of generic drugs.<sup>1</sup> It is critical that policymakers, patients, providers, and other experts continue to work on long-term solutions to the drug shortages challenge. To this end, ACCC is working key stakeholders to help educate providers and patients on the issue, share best practices, and help develop policy solutions that recognize the many complex factors that have contributed to the current situation. 

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