

Drug Shortages: What Can Be Done?

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It is estimated that a total of 1,596,670 new cancer cases will occur in the United States in 2011 (Siegel et al., 2011). New treatment regimens and new oncology drugs have contributed to longer survival and better outcomes for specific tumor types. But what happens when oncology agents are just not available?

If you care for oncology patients, the oncology drug shortage is not new to you. Advanced practitioners (APs) have been struggling with the shortage of needed drugs for almost a year. The effects of the drug shortage continue to be a factor for many hospitals in the United States. Recently, a clinical nurse specialist described the problems her institution had in providing the appropriate chemotherapy for a patient newly diagnosed with leukemia (personal communication, 2011). An acute shortage of cytarabine led to a critical lack of availability, potentially interfering with continuity of patient care. This patient received an altered form of the standard chemotherapy regimen for acute leukemia. As a caregiver, this concerns me.

Reasons for the drug shortage are varied, but some of the availability problems may be due to the fact that there is no incentive for drug manufacturers to make low-cost generics with minimal profit margins. Additionally, specific generic chemotherapy drugs are also in limited supply. Manufacturing or capacity constraints have also been quoted as contributing to the problem (Slama, 2011). Some of these agents are standard drugs used in multiple regimens, including cisplatin, doxorubicin, and leucovorin. These agents are critical in the treatment of many different and common tumor types. Although there may be similar agents that might be substituted for an unavailable agent (such as the substitution of a novel anthracycline for doxorubicin), substitu-

tion may not be appropriate for all tumor types or patients (Bath, 2011). Toxicities may differ. Subsequently, cycles of therapy may be held or delayed until the appropriate drug becomes available.

Late last year, a Drug Shortages Summit convened by the American Society of Clinical Oncology (ASCO), the American Society of Anesthesiologists, the American Society of Health System Pharmacists, and the Institute for Safe Medication Practices—some of the many organizations affected by the shortages of oncology drugs—was held. One of the points made at the summit was that the drug shortages are not just in oncology, but in other fields such as critical care (Chustecka, 2011). The group made several recommendations: improved communication among stakeholders, removal of barriers faced by the FDA and drug manufacturers, exploration of expanded FDA authority to require manufacturer notification of market withdrawals, and requirement of FDA notification if there is a single manufacturing source or any interruption in the supply of raw material or manufacturing process (Chustecka, 2011).

Get Involved

The American Society of Hematology (ASH) is also calling for clinicians to join their advocacy efforts by asking their senators to support new legislation regarding the drug shortage. This is supported by ASCO as well and is called the Preserving Access to Life-Saving Medications Act. This act would address the important shortages of specific hematology-related chemotherapy and other agents as well as the other factors identified by the Drug Shortages Summit. ASH recommends that each health-care clinician send a letter outlining the critical points regarding drug shortages, adding specifics about his or her own experience with patients and unavailable drugs.

To send a letter by email, visit www.hematology.org. From the homepage, click on “Advocacy–Take Action!” on the right-hand side of the screen. You will be taken to a page that lists Legislative Alerts and Updates. Click on the red button that says “Take Action” under the heading Contact Your Senators to Support the Preserving Access to Life-Saving Medications Act. From there, the site will guide you through the process of crafting a letter to your senators. You can customize the letter, but there is a template available as well.

You can get information on current drug shortages from the FDA, including reasons for the shortage and release dates if available (FDA, 2011). This information is provided voluntarily by manufacturers. The FDA also requests that clinicians report shortages and updates by notifying drugshortages@fda.hhs.gov

I encourage all advanced practice clinicians to get involved in the drug shortage crisis. Writing to your senator and reporting specific clinical examples will help convey the depth of this problem. The drug shortage has the potential to affect the quality of care for oncology patients. As advanced practitioners, we should be on the front lines, communicating the impact drug shortages are having on the patients we care for every day. New legislation may improve and preserve treatment strategies for our patients with cancer.

Inside This Issue

In this issue of the *Journal of the Advanced Practitioner in Oncology (JADPRO)*, we are proud to launch our new series of review articles focusing on treatment-related adverse events. In the first installment of the series, Anecita Fadol and Tara Lech present a discussion of cardiovascular toxicities seen in patients receiving various therapies. In another comprehensive review article, Heather Kasberg and Autumn Diligente explain what the AP needs to know about nutritional management of patients in the adult hematopoi-

etic stem cell transplant setting.

Nicoletta Campagna shares her experiences with a patient with hereditary breast and ovarian cancer syndrome in her *Grand Rounds* article. In *Practice Matters*, Patrick Horne and Roniel Cabrera show us how their clinic at the University of Florida manages patients with hepatocellular carcinoma and its common comorbidity, cirrhosis.

In a pair of complementary articles in our *Translating Research Into Practice* section, Georgia Litsas and Peg Esper share their explanation and interpretation of the key trials that led to the FDA's accelerated approval of bevacizumab for metastatic breast cancer in 2008, and its subsequent recommendation for the indication's removal in late 2010. In *Prescriber's Corner*, Vivian Tsang and Jennifer Kwon give us an overview of the drug denosumab, which has two different brand names and two different indications. Finally, don't miss our *Tools & Technology* offering—Anya Prince introduces us to the Cancer Legal Resource Center and explains how we can guide our patients to take advantage of this valuable support system.

Also be sure to take advantage of the smartphone QR barcodes you'll find throughout the journal. See page 268 for a lesson on how to use them to access supplemental information.

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Use your smartphone to access the ASH website's template for writing to your senator about the oncology drug shortage.

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