Anatomy of a Drug Shortage

A long time has passed since I last gave chemotherapy, but I have not been immune to the news about the drug shortages in the past few years. Therefore, I wanted to explore what was behind the headlines like "U.S. facing cancer drug shortage: Ariz. doctors rationing supplies; FDA allowing India imports" in the February 22nd *Arizona Business News* (Alltucker, 2012). You may have been more directly involved in the stories behind these headlines. What dilemmas have you faced related to drug shortages?

Drug shortages are defined in Tyler (2002) as "a change in the drug supply that has the potential to compromise patient care" (p. 1). Two articles were published in the *New England Journal of Medicine* describing the multifactorial issues contributing to our current chemotherapy shortages (Chabner, 2011; Gatesman & Smith, 2011). Reasons cited for drug shortages cover the supply chain process (see Figure 1), including raw material supply, manufacturing issues and delays, product modification, market withdrawal[a], and increased demand (U.S. Food and Drug Administration [FDA], 2012). The cascade of events leading to these shortages has been linked to the 2003 changes in Medicare reimbursement for chemotherapy drugs, the majority of which are delivered in the outpatient or office setting. Prior to 2003, physicians' offices purchased chemotherapy at 66%–88% of the average wholesale price (AWP), and were reimbursed at 95% (consider AWP the manufacturer-suggested retail price of a car). The resulting profit margin was used to pay for chemotherapy nurses and practice costs associated with chemotherapy administration. Since 2006, Medicare now reimburses at average sales price (ASP) (consider ASP to be the dealer's invoice for a car), plus a 6% markup to pay for these expenses. For example, the reimbursement for a generic version of a chemotherapy drug may be so low as to not cover practice costs. When a company develops a drug, the right to market the drug is given exclusively as a way to recoup the research and development costs. When that exclusivity period ends (usually around seven years later), others can make generic versions of the drug that usually are much cheaper. Generic manufacturers also may be making business decisions about the financial viability of making generic drugs for sale in the United States. Prior to 2011, no requirement existed for the manufacturer to report a stoppage in production of a drug when such an action occurred.

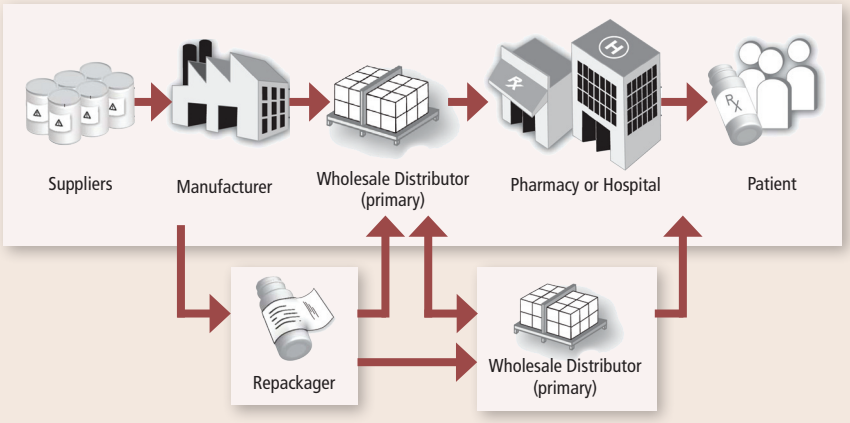

FIGURE 1. Drug Supply Change From Supplier to Patient

Note. From U.S. Food and Drug Administration, 2011.

According to Wagner (2011), drug shortages have been steadily rising every year since 2006, but have only recently been receiving media attention. Fifty-six drugs were reported to be in short supply in 2006. That number more than tripled to 178 in 2011. As of February 28, 2012, 110 drugs are listed on the FDA Web site, including at least 14 commonly used cancer chemotherapy drugs (e.g., bleomycin, cisplatin, daunorubicin, doxorubicin, doxorubicin liposomal, etoposide, fluorouracil, leucovorin calcium, leucovorin, methotrexate, mitomycin, mustargen, paclitaxel, thiotepa, vinblastine) and supportive care drugs. You can find more information and current drug shortage listings by accessing www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm.

In the fall of 2011, the Oncology Nursing Society (ONS) and the National Coalition for Cancer Research provided Congressional testimony about the impact of drug shortages on patient care and clinical research. On October 31, 2011, President Obama issued Executive Order 13588—Reducing Prescription Drug Shortages (WhiteHouse.gov, 2011), which directed the FDA "to take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines" (p. 1), require

[a] According to the U.S. Food and Drug Administration (FDA), market withdrawals are a firm's removal or correction of a distributed product that involves a minor violation that would not be subject to legal action by the FDA or which involves no violation.

drug manufacturers to give advance notice of manufacturing discontinuances, provide expedited regulatory review to ensure a safe and effective drug supply, and engage the Department of Justice in issues of drug stockpiling or price gouging. This has empowered the FDA to work with manufacturers outside of the United States to import and distribute some of these drugs to avert shortages. This measure, however, is temporary; the underlying causes of the shortages still need to be addressed to avoid longer-term deficiencies in the supply chain. Early notification to the FDA now is required, and that step has already been critical in averting some shortages. A number of bills have been introduced in the House and Senate to address this problem. You can follow the progress of these actions at the ONS Legislative Action Center (www.ons.org/LAC/Issues/DrugShortages).

In the meantime, oncology nurses and other healthcare professionals are left creating workarounds for scarce drugs. By anticipating shortages, practices can develop policies and teams to initiate short- and long-term strategies and keep staff informed and educated about changes to minimize errors (Mark, 2002).

Have you had to deal with drug shortages? What has it been like in your practice? What has your role been in dealing with the shortage? How have you been involved in the decision making about who gets access to these drugs? How have you dealt with patients and families concerning delays or change in treatments? Have there been financial concerns about staffing? Please tell me about your experiences by writing to CJONeditor@ons.org, and we will share responses in a future issue of the *Clinical Journal of Nursing*.

The author gratefully acknowledges Ann Reiner, RN, MN, OCN®, and Carl Brown, PhD, RN, AOCN®, for their suggestions and critique of this column.

References

Alltucker, K. (2012). U.S. facing cancer-drug shortage. Retrieved fromhttp://www.azcentral.com/business/articles/2012/02/22/20120222us-facing-cancer-drug-shortage.html

Chabner, B. (2011). Drug shortages—A critical challenge for the generic drug market. *New England Journal of Medicine, 365*, 2147–2149.

Gatesman, M., & Smith, T. (2011). The shortage of essential chemotherapy drugs in the United States. *New England Journal of Medicine, 365*, 1653–1655.

Mark, S. (2002, December). *Challenges posed by drug shortages. Understanding and managing drug shortages.* Proceedings from the 37th ASHP Meeting, Atlanta, GA.

Tyler, L. (2002, December). *Drug shortages. Understanding and managing drug shortages.* Proceedings from the 37th ASHP Meeting, Atlanta, GA.

U.S. Food and Drug Administration. (2011). A drug supply chain example. Retrieved from http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm277626.htm

U.S. Food and Drug Administration. (2012). FDA current drug shortages. Retrieved from http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm

Wagner, N. (2011). Historic drug shortages across the United States continue to get worse. Retrieved from http://www.theatlantic.com/health/archive/2011/09/historic-drug-shortages-across-the-us-continue-to-get-worse/245883/

WhiteHouse.gov. (2011). Executive Order 13588—Reducing prescription drug shortages. Retrieved from http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages

The author takes full responsibility for the content of the article. No financial relationships relevant to the content of this article have been disclosed by the editorial staff. Deborah K. Mayer, PhD, RN, AOCN®, FAAN, can be reached at CJONEditor@ons.org.

Digital Object Identifier: 10.1188/12.CJON.107-108