■ CNE Article/Journal Club

Drug Shortages and the Burden of Access to Care: A Critical Issue Affecting Patients With Cancer

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Pharmaceutical drug shortages are multifaceted and complex problems that affect all aspects of health care, including patients, caregivers, healthcare providers, third-party payers, the pharmaceutical industry, and regulators. Drug shortages have increased significantly since 2000, which cause increases in healthcare costs and compromised patient care. New government regulations have led the U.S. Food and Drug Administration to focus efforts on updating policies and improving regulation of the pharmaceutical industry to limit and avoid drug shortages. This article discusses the current issues surrounding the pharmaceutical drug shortage and the implications for patients and healthcare providers. A review of the literature presents the multidimensional impact of the pharmaceutical drug shortage, and the analysis shows patients who are most burdened by drug shortages and have experienced substandard care, increased cost of care, and compromised quality of health care.

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A 42-year-old woman named L.M. was diagnosed with recurrent papillary serous ovarian cancer. Following 12 weeks of treatment with the chemotherapeutic agent doxorubicin hydrochloride (HCl) liposome injection, she received notification from her healthcare provider that the U.S. Food and Drug Administration (FDA) announced that the drug was unavailable because of manufacturing issues. L.M.'s healthcare provider informed her that her chemotherapy protocol would need to be altered midtreatment. She, like other patients with cancer, would be offered a different treatment regimen that potentially had increased side effects and was less effective. L.M. followed recommendations to begin an alternative treatment regimen. Unfortunately, after three treatments with the alternative regimen, L.M.'s CA-125 level increased and a computed tomography scan of her abdomen and pelvis demonstrated disease progression. L.M.'s story exemplifies a common finding in the care of patients with gynecologic malignancies, supporting the evidence that drug shortages have a significant negative impact on patient care and disease outcomes.

Despite advances in oncology, shortages of chemotherapeutic agents have become routine at the point of care, affecting the quality of healthcare delivery, patient outcomes, and adherence to research protocols (Chabner, 2011; Gatesman & Smith, 2011). Inconsistent access to those sustaining, life-saving therapies places the greatest burden on patients as well as their caregivers and healthcare providers. Drug shortages affect chemotherapy agents as well as anesthetics, analgesics, antibiotics, sedatives, and parenteral nutritional feeding agents (Alspach, 2012). The shortages have caused delay or cancellation of treatment (e.g., surgery), increased length of acute-care hospital stay, increased cost of health care, and compromised patient safety (Alspach, 2012; Kaakeh et al., 2011; Larkin, 2011). All members of the healthcare team (e.g., pharmacists, physicians, nurse practitioners, physician assistants, nurses) must be informed of the impact of shortages on quality of care, patient safety, and patient outcomes. The purpose of this article is to inform nurses about the issues surrounding the pharmaceutical drug shortages in the United States and provide implications for nursing practice.

Overview of Drug Shortage

A drug shortage occurs when the total supply of all clinically interchangeable versions of an FDA-regulated drug fails to meet the current or projected demand for the estimated patient demand level (Alspach, 2012; Carter, 2011; Golembiewski, 2012). Drug shortages in the United States began in the 1990s, but the problem continues to worsen with time. When an inadequate supply of a drug exists, pharmacies alter how they stock and order medications, which directly affects patient access to necessary treatments. A survey of hospital pharmacies demonstrated unnecessary waste of pharmaceuticals that were in short supply because of drug manufacturers' shelf-life recommendations. Those outdated requirements on shelf life from the Centers for Medicare and Medicaid Services (CMS) are contradicted by evidence-based literature (Golembiewski, 2012; Mayer, 2012).

According to the FDA (2013), the United States is plagued with record numbers of pharmaceutical shortages, particularly those involving sterile injectable drugs (e.g., chemotherapy agents, anesthetics), causing a national public health crisis and limiting access to cancer care (Gatesman & Smith, 2011). In five years, the number of drugs in short supply has tripled from 61 pharmaceutical agents in 2005 to 178 in 2010. Of those, 132 included sterile injectable agents. Those numbers continue to rise with 251 drugs reported in 2012, 183 of which involved sterile injectable agents. Many of those agents are used in the standard treatment of many oncology protocols for childhood, breast, hematologic, and gynecologic malignancies (FDA, 2013) (see Table 1). The shortage of chemotherapy agents creates a huge burden. Patients with cancer who are undergoing treatment cannot be switched to another chemotherapy agent without repercussions. Equivalent dosing for substitute regimens often is absent, and substitutions are not based on evidence gathered from previous randomized clinical trials.

The American Hospital Association reported that 99.5% of hospitals experienced pharmaceutical drug shortages (Gatesman & Smith, 2011). In addition, the American Society of Health System Pharmacists reported that drug shortages are at the highest level in more than a decade and that the shortages are by far the worst in 30 years (Gatesman & Smith, 2011). The most commonly reported pharmaceutical shortages are injectable and infusion agents, antibiotics, and chemotherapy agents (Larkin, 2011).

Medication Errors

Another adverse health outcome from drug shortages is medication error. Larkin (2011) attributed at least 15 deaths to pharmaceutical drug shortages during a 15-month period, which included a case where sepsis resulted from tap water being substituted for sterile water when flushing feeding tubes prior to and after medication administration. Other deaths occurred when medications were substituted during intubation and the patients developed fatal laryngospasms. In addition, patients suffered chemotherapy complications or fatal side-effect toxicities when delays or cancellations in treatment or drug substitutions were instituted because of the shortages of chemotherapy agents (Alspach, 2012; Gatesman & Smith, 2011; Jensen & Rappaport, 2010; Larkin, 2011).

To capture the danger of these shortages, the Institute for Safe Medication Practices is attempting to track near misses of medication errors from drug shortages (Larkin, 2011). From July to September 2010, data revealed that 35% of healthcare providers reported a near miss of a medication error, and 25% of clinicians reported that medication errors occurred while attempting to substitute or replace a drug as a result of a drug shortage (Alspach, 2012; Beeson, Lehrfeld, Fowler, & Manifold, 2012; Doyle, 2011; Gatesman & Smith, 2011). Clinicians also have noted that, of the errors reported, inexperience with replacement pharmaceuticals was cited as the most common reason for medication errors (Gatesman & Smith, 2011). Alspach (2012) reported in an analysis of 228 hospital and pharmacy professionals that 80% of those evaluated had experienced pharmaceutical shortages that led to patient treatment delays or cancellations. Chabner (2011) cited that the risk of medication error increased with the use of substitutions in alternative treatment regimens. For example, Chabner (2011) reported that patient safety was compromised when chemotherapy agents were substituted or replaced and

TABLE 1. Chemotherapy Drug Shortages

Drug	Use for Drug	Reason for Shortage	Date of Last Noted Shortage
Daunorubicin hydrochloride	Chemotherapy agent	Increased drug demand; manufacturer shortage	August 20, 2013
Doxorubicin hydrochloride liposome injection	Chemotherapeutic agent; primary and secondary treatment of reproductive cancers	Manufacturer shortage (Sun Pharma Global FZE); solved by a temporary importation of Lipodox (doxorubicin hydrochloride liposome injection)	April 10, 2012
Doxorubicin lyophilized powder	Chemotherapeutic agent	Discontinuation of drug production	April 10, 2012
Leucovorin (calcium lyophilized powder for injection)	Folic acid analog; used in conjunction with methotrexate; high risk of dosing error with substitute (levoleucovorin)	Drug manufacturer discontinuation (Bedford Laboratories); regulatory delay (Teva Pharmaceuticals, APP Pharmaceuticals, and Sagent Pharmaceuticals)	August 20, 2013
Vinblastine sulfate	Chemotherapy agent	Increased drug demand	December 7, 2012

Note. Based on information from U.S. Food and Drug Administration, 2013.

when dosing regimens were altered with substitute pharmaceuticals to meet replacement drug protocols. Standardized treatment guidelines evolve from randomized, controlled trials that evidence the best health outcomes for various malignancies. Once the treatment is altered in any way from the regimen tested in the trial, the patient no longer receives evidence-based treatment. When healthcare providers are forced to select alternative chemotherapeutic agents because of unforeseen shortages and choose alternative protocols based on availability rather than evidence, patient safety and care are compromised, which creates substantial ethical and legal issues as well as risk for future refinement of cancer treatment (Chabner, 2011; Gatesman & Smith, 2011; Link, Hagerty, & Kantarjian, 2012).

Drug Shortage Etiology

Since 2005, manufacturers discontinued production of many drugs for reasons that included pharmaceutical mergers, limited profit margins, increased cost of pharmaceutical drug manufacturing, shortages of raw materials for drug development, contamination of raw materials for drug development, increased pharmaceutical drug demand, increased regulatory processes that delay drug manufacturing, and the use of older manufacturing plants that are less efficient for drug development (Carter, 2011; Gehrett, 2012; Golembiewski, 2012; Holcombe, 2012; Mayer, 2012). The high cost of production for many of the chemotherapy agents may make it nearly impossible for community and hospital pharmacies to keep a sufficient supply on hand when a steep financial risk exists of discarding the drugs if they expire before they are used.

Limited Profit Margins

To keep the cost of chemotherapy drugs low for third-party payers (e.g., insurance companies) and to eliminate incentives for overuse because of high profit margins, drug profit margins have been severely reduced since 2005 when legislation changed Medicare's pricing policies (Gehrett, 2012; Holcombe, 2012). With low fixed reimbursements from third-party payers such as Medicare, a pharmaceutical company's ability to manufacture drugs is challenging. Limited profit margins prohibit pharmaceutical companies from making vast profits when drugs move off patent and become generic and less profitable to develop and distribute. When a pharmaceutical drug is available as a generic, the net profit margin for the company is limited, and often the company is not interested in manufacturing the drug. In addition, fixed Medicare legislation and increased drug demand have caused many companies to seek cost-containment measures (Golembiewski, 2012). Once cost-containment measures take effect, companies use older, less efficient manufacturing facilities; use less expensive raw materials for drug development; and decrease the employee base (Chabner, 2011; Gehrett, 2012). Several pharmaceutical companies (e.g., Bedford Laboratories, Hospira) have experienced issues (e.g., contamination of drug vials, manufacturing delays) because of cost-containment measures (Alspach, 2012; Gatesman & Smith, 2011; Larkin, 2011). Teva Pharmaceuticals, one of the largest generic-producing pharmaceutical companies, has experienced drug shortages as a result of limited resources of raw materials to manufacture drugs, microbial contamination during drug development, and an increase in drug demand (Gatesman & Smith, 2011).

Gray Market Systems

Pharmaceutical drug shortages also have produced a secondary gray market, a system where middlemen from nontraditional manufacturers sell pharmaceuticals that are in short supply at premium prices (Larkin, 2011). Gray market concerns include pharmaceutical drug safety, interruption in the pharmaceutical supply chain to hospitals and pharmacies, lack of reputable distributors, and the legal and ethical issues of paying inflated prices to middlemen (Larkin, 2011).

Legislative Mandate

Reimbursement for pharmaceuticals has decreased significantly since the Medicare Prescription Drug, Improvement, and Modernization Act (enacted in 2003 and implemented in 2005) substantially reduced payment rates for chemotherapy drugs and other high-cost injectable and infusion agents (Gehrett, 2012; Jacobson, Earle, Price, & Newhouse, 2010; Kaakeh et al., 2011). The Medicare Modernization Act set the chemotherapeutic drug agent reimbursement restriction to a maximum of a 6% markup. Prior to this act, oncology practices purchased chemotherapy drugs at 66%–88% of the average wholesale price and were reimbursed at 95%, which resulted in a profit margin large enough to cover the cost of the chemotherapy nurse, chemotherapy administration, and practice cost for in-office administration. Medicare currently reimburses physician practices and healthcare systems for the average sales price (ASP) for the drug, which covers the cost of the drug itself plus a 6% markup (CMS, 2013; Jacobson et al., 2010; Mayer, 2012).

Although the Medicare guidelines that limit the pharmaceutical markup to 6% of the ASP may seem reasonable, the reduction in the reimbursement for healthcare systems and private independent healthcare providers fails to allow a profit margin for the maintenance of professional staff and facilities to deliver the drug safely and efficiently (Jacobson et al., 2010). If healthcare providers are not reimbursed adequately to maintain the staff and facilities needed to deliver the drug, they are unable to afford to sustain administration (Havrilesky, Garfield, Barnett, & Cohn, 2012; Jacobson et al., 2010). In addition, the drug may cost more than the ASP plus the 6% markup reimbursement for the healthcare provider if, for example, the cost of a pharmaceutical changes from the time of administration to the time of reimbursement. Healthcare providers also may pay for the drugs on credit, incurring interest charges that could exceed the allowable 6% profit margin. Many healthcare systems and private providers purchase the pharmaceutical agent and are not reimbursed by Medicare or third-party payers for 3–6 months after drug administration. The delay, suspension, or absence of adequate reimbursement for pharmaceutical purchases poses significant financial risk to healthcare institutions, burdening the provider and institution (Havrilesky et al., 2012; Jacobson et al., 2010). As pharmaceutical costs rise for specific agents because of shortages of generic pharmaceuticals that are less expensive, healthcare providers and facilities may not be able to sustain the financial risk of purchasing and administering a more expensive agent, which would increase generic drug demand. Although the priority of healthcare systems and providers is to deliver consistent, high-quality evidence-based care,

the cost of purchasing and delivering this level of care must be balanced with reimbursement to maintain sustainable, high-quality service (Havrilesky et al., 2012; Jacobson et al., 2010).

Impact of Drug Shortages on Patient Care

Traditionally, healthcare providers have relied on pharmaceutical agents to treat patients under the guidelines and recommendations of evidence-based standards of care regulated by the FDA (Burr, 2012). Inadequate and inconsistent drug supply has altered clinical care. Depending on pharmaceutical availability, patients may not be treated based on evidence-based practice, which has affected patient care (Alspach, 2012; Burr, 2012; Gatesman & Smith, 2011; Larkin, 2011). The lack of authority and autonomy of healthcare providers to render evidence-based care has delayed treatments and increased unanticipated side effects or toxicities, medication errors, and healthcare costs for patients and providers (Gatesman & Smith, 2011).

Ethical and Legal Issues of Drug Shortages

Ezekiel Emanuel, MSC, MD, PhD, oncologist and professor of medical ethics and health policy at the University of Pennsylvania, stated, "Most shortages appear instead to be the consequence of corporate decisions to cease production, or interruptions in productions, caused by money or quality problems, which manufacturers do not appear to be in a rush to fix" (Emanuel, 2011, para. 5). Drug shortages are caused, in part, by manufacturers' preference to produce more profitable brand-name drugs rather than generics that do not generate as much profit.

Although the FDA does not dispute that significant ethical and legal implications are present in widespread pharmaceutical shortages, much of the argument lies in the hands of the pharmaceutical industry. Pharmaceutical companies have an ethical and legal responsibility to safely manufacture and distribute pharmaceuticals to patients, providers, and healthcare systems. Pharmaceutical companies argue that they are able to determine drug cost based on profit margin, cost of raw materials, and cost of maintaining drug development facilities and personnel for research and distribution, and they must maintain sufficient profit margin to sustain manufacturing and distribution (Havrilesky et al., 2012; Thompson, 2009).

Healthcare providers contend that delivery of care is influenced by profit margins of those pharmaceutical companies and third-party payers who decide drug cost and reimbursement. Many patients have received second- and third-line pharmaceuticals, have experienced treatment protocol interruptions with delays and cancellations, and have experienced unnecessary side effects and toxicities from substitute or alternative drug protocols, all of which affected the quality of their care (Thompson, 2009).

Since 2008, obtaining leucovorin, a drug used to prevent harmful effects of methotrexate, has posed a challenge for healthcare providers (Kaakeh et al., 2011). The National Cancer Institute sent instructions to cancer centers on how to address the national shortage. Although pharmacists did not admit to stockpiling the drugs, many ordered large quantities when they received notice that their manufacturers were in short supply. The American Society of Health System Pharmacists has advised healthcare organizations to refrain from stockpiling drug products since 2001

because of the risk of increasing cost to healthcare organizations (Kaakeh et al., 2011). Physicians, pharmacists, and healthcare administrators argue that planning is essential when considering patient needs. Establishing committees for deciding which patients take priority when drug shortages occur and communicating with patients and providers on distribution and administration of drugs would ease confusion and prevent the urge to stockpile. Figure 1 shows a sample action plan for drug shortages.

Until healthcare providers and pharmaceutical companies agree on a systematic process of how to handle a drug shortage when it occurs, they are left to decide how best to protect their own interests, sometimes to the detriment of patient safety and quality of care. Healthcare providers argue that stockpiling may be more effective and ethical because, ultimately, patient safety and providing quality care to patients are compromised during a shortage. Although research for future drug treatment protocols is important, issues at the point of care take precedence for healthcare providers.

Interventions to Decrease Drug Shortages

After Congress began to address pharmaceutical drug shortages, the FDA was responsible for regulating drug safety and preventing and resolving drug shortages, particularly those drugs that are medically necessary (Alspach, 2012). When pharmaceutical companies experience manufacturing and quality issues, the FDA must work closely with the company for swift resolutions to prevent patient harm (FDA, 2011, 2013). In addition, the FDA is responsible for monitoring drug production to help avert drug shortages. When the American Society of Clinical Oncology (2011) realized the scope of the national drug shortage, they hosted a summit to address the issue. In response, the FDA's Cen-

Prioritize patients according to disease severity, and engage ethics committee and risk management for a patient priority policy.

Identify current drug shortages, and research drugs in short supply.

Establish ongoing communication with staff about the priority drugs (e.g., short supply, on shortage, on hand), and assess drug inventory.

Establish reliable alternative drug suppliers.

Inform patients to seek potential programs to buffer financial burden of chemotherapy costs (i.e., drug manufacturer or local health systems may have special programs).

Develop plans to handle adverse events related to drug shortages.

Identify potential therapeutic alternatives.

FIGURE 1. Sample Action Plan for Pharmaceutical Drug Shortages

Note. Based on information from Costerison & Graham, 2008; De Oliveira et al., 2011; Dorsey et al., 2009; Hunnisett-Dritz, 2012.

Identify which team members are responsible for ordering required drugs and monitoring drug shipments.

Identify which patients are a priority when drugs become unavailable.

Identify which team members are responsible for communicating to patients when drugs fail to arrive, when treatments must be altered or delayed, and when the patient-care team must be notified of a change in treatment when a drug shortage occurs.

Identify whether substitute drugs are covered by third-party payers.

Implement a log-tracking system for receipt, administration, billing, and reimbursement of drugs and drug substitutes.

Create a list of reliable distributors that would be potential chemotherapy drug sources to healthcare institutions.

FIGURE 2. Priority Needs for Drug Shortage Protocol Requirements

ter for Drug Evaluation and Research (CDER) began collecting information on drug shortages, increased inspection of pharmaceutical manufacturing facilities, and loosened requirements for pharmaceutical drug importation (FDA, 2013). CDER also was responsible for enhancing communication with manufacturers and healthcare providers to increase availability and usability of drug shortage information and collaborations within the FDA (2011, 2013). In addition, President Obama issued an executive order to address the national pharmaceutical shortage. Executive Order No. 13,588 (2011) directed the FDA to review existing regulations for outdated, ineffective, and insufficient guidelines that may contribute to drug shortages (FDA, 2013; Stone, 2012).

Executive Order No. 13,588 (2011) mandated that the FDA work with pharmaceutical manufacturers to provide advance notice when drug discontinuances are forthcoming, expand the current effort to expedite FDA regulatory drug reviews, and communicate to the U.S. Department of Justice any findings that pharmaceutical shortages have led market participants to stockpile drugs that would or could cause price gauging (FDA, 2011; Stone, 2012).

In response to Executive Order No. 13,563 (2011), which addressed drug shortages, the FDA approved a temporary importation of doxorubicin HCl liposome injection from India. The FDA also approved the manufacturer of methotrexate to increase drug supply. In addition, Pfizer began to market two chemotherapy drugs previously on patent (Larkin, 2011). Because of Executive Order No. 13,588 (2011) and the development of the CDER office, the FDA has received a six-fold increase in voluntary and mandatory drug shortage notifications and was able to prevent 128 pharmaceutical drug shortages (FDA, 2013; Stone, 2012).

Implications for Practice

Nurses should be aware of the issues that surround the pharmaceutical drug shortage, as it directly affects patient care. Clear implications exist for nursing action at the policy level and at the point-of-care level. At the policy level, nurses could be strong advocates for preventing drug shortages. The patient stories from nurses could be told to policy makers and journalists. Nurses, more than any other group of healthcare professionals, are privy to some of the most poignant situations of how cancer affects patients and families. Nurses can consider encouraging patients with cancer to articulate how the drug shortage affected their treatment. Potential options for patients and nurses include calling legislators, the FDA, and local newspapers. Advocacy among nurses includes developing educational programs for interdisciplinary healthcare providers. Because a collective voice is more powerful than individual voices, nurses could use national organizations as a medium to communicate with others on the issue of drug shortages.

Nurses also are in key positions in the clinical setting to act as leaders and ameliorate the issues associated with drug shortages. Nurses are responsible for identifying gaps in care and assisting to resolve them. Nurses are an important part of the healthcare team, and they have the ability to take charge and implement reliable and efficient protocols that will help secure reliable sources of pharmaceuticals. Figure 2 provides a list of potential nursing actions to address the drug shortage.

Conclusions

Access to evidence-based care for patients with malignant diseases depends on the availability of necessary pharmaceutical agents. The drug shortages create difficulties for patients as well as the healthcare team caring for them. The issue of drug shortages is multifaceted, and it affects all aspects of health care from patients, caregivers, and healthcare providers to third-party payers, the pharmaceutical industry, and regulators. Drug shortages have grown significantly since 2000, increasing healthcare costs and compromising patient care. Nurses are important members of the healthcare team who have the opportunity to assist in patient advocacy efforts to address the issue of drug shortages.

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Implications for Practice

▶ All healthcare providers must work together to identify and manage the shortage and its potential impact to patient care outcomes.

▶ Nurses should take leadership roles in the development and implementation of policies and procedures at the point of care to address drug shortages in healthcare institutions.

▶ Nurses play an important role in education, patient advocacy, and policy development to address issues surrounding drug shortages and their impact on patient care.

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