

COVER STORY PUBLICATION EXCLUSIVE

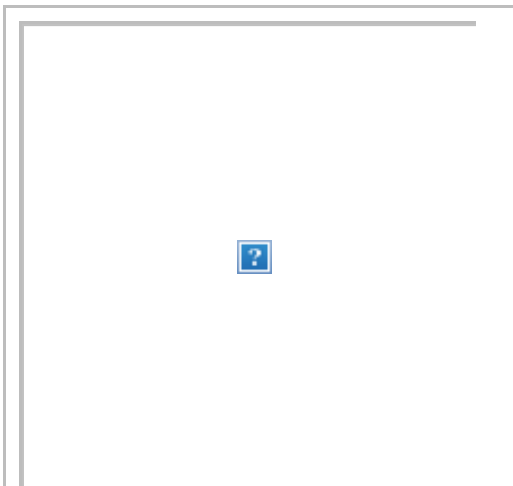
Expectation of drug shortages has become ‘new norm’ for cancer care

HemOnc Today, February 10, 2015

More than 230 drugs appeared on the American Society of Health-System Pharmacists’ drug shortage list as of mid-January.

The list — primarily comprised of generic, sterile injectables — included six oncology drugs and two hematology drugs.

The undersupply of one agent — doxorubicin liposomal (Doxil Janssen), an anthracycline chemotherapy used to treat metastatic ovarian cancer, Kaposi’s sarcoma and multiple myeloma — has been particularly troublesome.



Maintaining public awareness is critical to solving the problem of drug shortages, according to J. Leonard Lichtenfeld, MD, MACP, deputy chief medical officer for the American Cancer Society. “If we don’t constantly revisit this and make people aware of it, then this will become the status quo,” he said.

Source: Photo courtesy of J. Leonard Lichtenfeld, MD, MACP

“When we have patients with diseases such as ovarian cancer that require a specific drug that is no longer available, it impacts patients, physicians and anyone who is involved in the caregiving process,” **J. Leonard Lichtenfeld, MD, MACP**, deputy chief medical officer for the American Cancer Society, told *HemOnc Today*. “These issues create unneeded anxieties for patients, and barriers to physicians and hospitals caring for patients.”

In February 2012, the FDA allowed for a foreign supplier to augment the stock of Doxil. A year later, the agency approved a generic version of the agent to try to alleviate the shortage.

“There were alternatives, but they were not preferred alternatives,” Lichtenfeld said. “There were concerns as to whether the biological effect was equivalent. Being a cancer patient is difficult enough, and this just adds another layer of burden, whether it happens in a small practice, large practice or anywhere in between.”

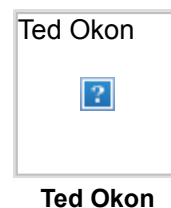
Drug shortages peaked in 2011, when 267 agents were in short supply. Since then, the FDA created its own drug shortage database, expedited generic approvals and began marketing foreign-manufactured drugs in hopes of minimizing the problem. Still, shortages of many agents continue, including some that have persisted for years.

HemOnc Today spoke with several key opinion leaders about how they have dealt with and tried to address oncology shortages, the extent to which the FDA's actions have helped, and what else must be done ensure sufficient supplies of critical therapeutic agents.

A lingering issue

A survey conducted by Goldsack and colleagues — published in 2014 in the *American Journal of Health-System Pharmacy* — showed 98% of pharmacy directors dealt with at least one injectable oncology shortage in the prior 12 months. Seventy percent of respondents said they had an insufficient supply to treat patients, and 63% reported running out of at least one injectable.

“Every time I speak, I ask everybody who is in the room to raise their hands if they have been impacted by drug shortages, and every hand goes up,” **Ted Okon**, executive director of the Community Oncology Alliance, told *HemOnc Today*. “This is especially important in the cancer realm, where when one regimen fails, oncologists move on to the next thing.”



The problem extends beyond injectable oncology drugs, according to **R. Brian Mitchell, MD**, president of the Virginia Cancer Institute.

“The drug shortage problem is hitting us again, and one of the biggest shortages having an impact right now is saline,” Mitchell said in an interview. “Plain old salt water is going to run out soon, and other IV fluids are close behind. We have to address this issue all the time by asking, ‘Can we use alternative fluids in certain situations? Can we use different size bags? Can we substitute injections or oral medication so that it does not have to be mixed in saline?’”

Goldsack and colleagues found clinicians employed several strategies to deal with drug shortages. Nearly two-thirds (62%) of respondents used alternative regimens, 46% altered dosages, 43% delayed treatments and 21% referred patients to other facilities.

One method of addressing shortages is to identify alternative medications that can be used. Unfortunately, determining that the alternative drug is equally effective and safe is not always clear-cut.

“During the shortage of mechlorethamine, we and others made a protocol change to substitute cyclophosphamide for mechlorethamine,” **William L. Greene, PharmD**, chief pharmaceutical officer at St. Jude Children’s Research Hospital, told *HemOnc Today*. “Unfortunately, we later determined that the

outcomes from treatment were not equivalent to what we had seen with mechlorethamine. In cancer, where dose intensity is such a critical part of outcomes, if you are not able to attain the amount necessary of the drug in shortage, you risk impairing the outcome goals.”

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