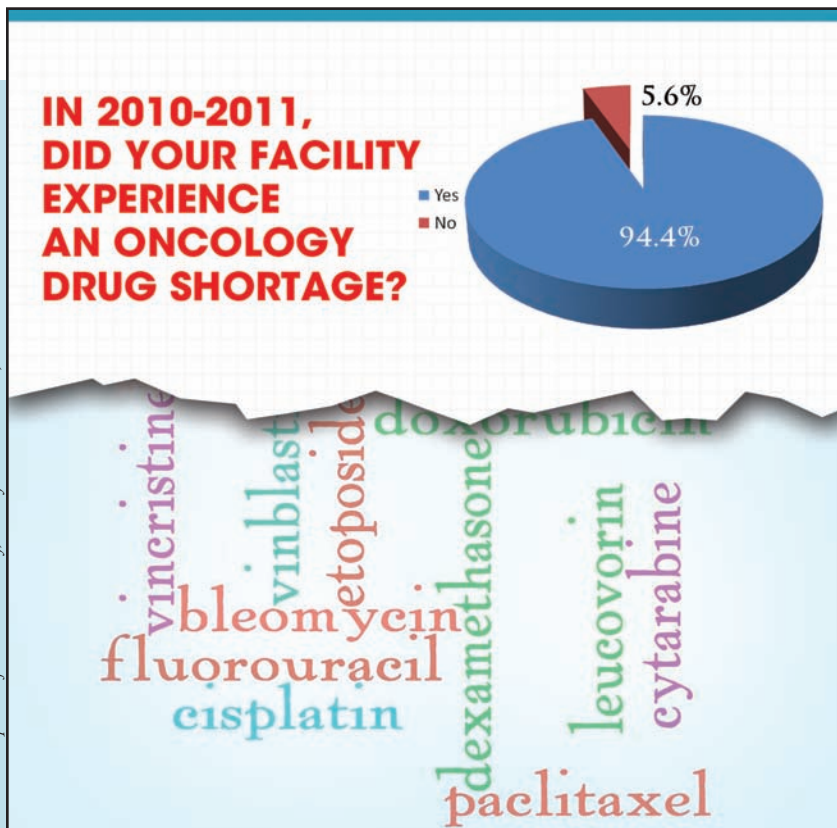


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Pie chart and question from ACCC survey, courtesy Manheh Farber, MA

Oncology Drug Shortages Worsening

BY PEGGY EASTMAN

The problem is fast reaching crisis proportions, a new survey shows, endangering or delaying patient care, putting oncologists in difficult positions, threatening clinical trials, and fueling a grey market of imported drugs that are of unknown purity and typically available only at high markups.

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Oncology Drug Shortages Worsening, Threatening Patient Care

BY PEGGY EASTMAN

The briefing was sponsored by the ACCC, ASCO, ONS, the Leukemia & Lymphoma Society, the Community Oncology Alliance, the Children's Cause Cancer Advocacy, AOSW, ASHP, and US Oncology.

WASHINGTON, DC—A new survey released at a Capitol Hill briefing here shows that the problem of oncology drug shortages is fast reaching crisis proportions, endangering or delaying patient care, putting oncologists in difficult positions, threatening clinical trials, and fueling a “grey market” of imported drugs that are of unknown purity and available typically only at high markups.

The briefing was sponsored by the Association of Community Cancer Centers, the American Society of Clinical Oncology, the Oncology Nursing Society, the Leukemia & Lymphoma Society, the Community Oncology Alliance, the Children's Cause Cancer Advocacy, the Association of Oncology Social Work, the American Society of Health-System Pharmacists, and US Oncology.

The most frightening aspect of the worsening drug shortage problem is that many of the drugs in short supply are part of the standard of care in oncology, said Matthew Farber, MA, the ACCC's Director of Provider Economics and Public Policy. These include doxorubicin, leucovorin, cisplatin, paclitaxel, etoposide, dexamethasone, cytarabine, bleomycin, fluorouracil, vinblastine, and vincristine, among others.

Bills have now been introduced in both the House and the Senate to try to combat worsening drug shortages (*see box*).

The new survey data show that 94.4%

of contacted facilities—ranging from hospital outpatient departments to oncology private practices to academic medical centers to freestanding clinics—that saw cancer patients in 2010 through the first half of 2011 experienced an oncology drug shortage.

Fully 84% of those responding said that due to a drug shortage, they had to modify or temporarily suspend a chemotherapy regimen or provide a substitute drug. Institutions reported that their staff has had to spend more time on drug shortages, and 43% said they had been contacted by grey market suppliers offering to sell drugs currently in short supply.

The crisis is fueling a grey market of imported drugs of unknown purity and that are available typically only at high markups.

“Just about every cancer across the board has been affected by these drug shortages,” said Mr. Farber. Because of drug shortages, he said, chemotherapy regimens have had to be changed for patients with colon cancer, leukemia, breast cancer, Hodgkin lymphoma, lung cancer,

testicular cancer, prostate cancer, esophageal cancer, ovarian cancer, pancreatic cancer, and colorectal cancer.

Accelerating

“This is an accelerating problem, and it is getting to be a critical problem,” said ASCO President Michael P. Link, MD, the Lydia J. Lee Professor of Pediatrics at Stanford University School of Medicine. “The problem does not seem to be going away.”

Shortages for oncology drugs are part of a larger US shortage of drugs overall, some of which affect cancer patients, he noted, citing antibiotics and anesthesia drugs as examples.

At the current pace, he said, more than 300 drugs will be in short supply for 2011; and of particular concern for oncology is that 77% of shortages in 2010 were of sterile injectables. There were shortages of 23 chemotherapy drugs last year, and 11 so far in 2011.

“There are no alternatives to these drugs for most indications,” Dr. Link emphasized. “Manufacturing issues are not resolving.”

The suspected causes, he said, are manufacturing difficulties and/or compliance issues, corporate decisions and discontinuations, market concentration and limited capacity, and shortages of raw materials. For example, with older sterile injectables, there are fewer firms making these products, they have a complex manufacturing process, and are generally not economically attractive.

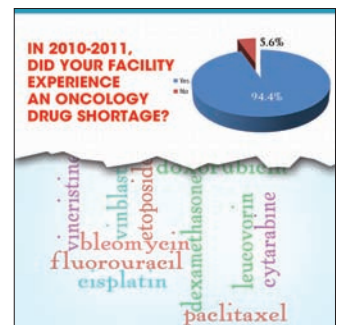
“We're hoping there will be more investigation into what the true causes are,” he said. “When one firm has problems or discontinues [a drug], a shortage almost always occurs.”

Among the adverse psychological effects for cancer patients and their families is increased anxiety. “We can now cure 80% of all children that we treat,” said

“Just about every cancer across the board has been affected by these drug shortages.”
—Matthew Farber, MA

Dr. Link, citing acute lymphoblastic leukemia, the most common childhood cancer, and osteosarcoma. “But if you're in my shoes...you might as well close your doors if you don't have these drugs.”

When a pediatric oncologist must talk to a parent about a drug shortage, “that's a conversation you don't want to have.”



Proposed Legislation to Alleviate Drug Shortages

There are proposed bills in both the House and the Senate to address drug shortages. The Senate bill is sponsored by Sen. Amy Klobuchar (D-Minn.) and Sen. Robert P. Casey, Jr. (D-Pa.), while the House bill has been introduced by Rep. Diana DeGette (D-Colo.) and Rep. Tom Rooney (R-Fla.).

“We recognize that these bills won't solve all the problems, but they will help,” said the ACCC's Matthew Farber, MA. The House bill, for example—the Preserving Access to Life-Saving Medications Act—would expand current statutory language related to reporting of information to FDA regarding manufacturing interruptions that could result in drug shortages. The bill also calls for increased communication from FDA regarding drug shortages, including providing shortage information to health-care providers.

While the bill would not allow FDA to publish proprietary pharmaceutical information, it does call for the FDA to develop evidence-based criteria for identifying drugs that could be vulnerable to shortages and to work with manufacturers to create “continuity of supply” plans that include processes to address drug shortages. The bill also requires the Government Accountability Office to study the causes of drug shortages, and requires the FDA to provide an annual report on drug shortages to Congress.

At the Capitol Hill briefing, Lynn Magrum, CRNP—a member of the Oncology Nursing Society—asked what she and other oncology nurses could do to help alleviate the cancer drug shortage problem. Speakers urged her and other stakeholders concerned about the welfare of cancer patients to contact their members of Congress and urge them to support the pending legislation.

Financial Impact

Ali McBride, PharmD, MS, BCPS, Clinical Pharmacist for Hematologic Malignancies and Stem Cell Transplants at Barnes Jewish Hospital in St. Louis, warned that the clinical consequences of drug shortages for patients can result in preventing appropriate care, withholding or delaying medical treatments (which could be fatal), reducing the dose for efficacy with unknown results, and the potential for an increase in medication errors.

There are delays in transplants for patients who need them, and there is a potential for medication errors in dosing conversion in patients with IV to oral chemotherapy.

Ali McBride, PharmD, MS, BCPS, estimated that drug shortages cost US hospitals at least \$200 million a year, and that health care providers are having to pay an average of 11% more for drugs in short supply.

Dr. McBride also noted that drug shortages have a harmful financial impact. He estimated that drug shortages cost US hospitals at least \$200 million annually, and that health care providers are having to pay an average of 11% more for drugs in short supply.

Grey market drugs are expensive—up to 10 to 1,000 times the usual cost, he said. “The grey market is a big issue and

“There are no alternatives to these drugs for most indications.

Manufacturing issues are not resolving.”

—Michael Link, MD

will get worse as time goes on,” said Dr. McBride. And he noted that drug shortages lead to indirect costs, such as added

labor to manage the shortages and find alternatives.

Thomas Kornberg, PhD, a Hodgkin lymphoma survivor in remission, who is a scientific researcher and patient advocate in San Francisco, described how he was faced with a vinblastine shortage when on a regimen of doxorubicin, bleomycin, vinblastine, and dacarbazine. Dr. Kornberg said that although after calling around, he was able to obtain the drug from another source, but that the shortage did indeed affect his therapy. ■



‘That’s Capitalism’

Asked by *OT* why—given the aging of the baby boomers and the expected growth in cancer patients—pharmaceutical companies would make decisions not to meet the demand for cancer drugs, ASCO President Michael Link, MD, said, “That’s capitalism”—meaning that firms have to make marketing decisions that take profit into account, and that current Medicare regulations and reimbursement policies probably act as a disincentive to drug companies.

Asked by several people at the briefing about the role of the FDA, Dr. Link said the agency is doing what it can within the scope of its authority; and Ali McBride, PharmD, MS, added that the FDA is examining a possible avenue for importation of drugs for which there are shortages in the United States.