Frustration Over Gray-Market Drugs Lingers Throughout Nation

By Eric T. Rosenthal

Although President Obama issued an executive order last October directing federal agencies to deal with the ongoing drug shortage and to look into the price gouging taking place in the so-called gray market (see J. Natl. Cancer Inst. online Jan. 23, 2012), frustration continues to build among oncology professionals trying to meet patients’ needs. Meanwhile, little coordination seems to exist among federal agencies (see sidebar).

JNCI interviewed various pharmacists, oncologists, and cancer center directors about their experiences with the drug shortage and the gray market. Although anecdotal and not necessarily representative of all situations, these interviews provide selective snapshots of the difficulties of obtaining drugs in short supply.

One such expert is David B. Wilson, R.Ph., oncology pharmacy manager and oncology pharmacy residency director for St. Luke’s Mountain States Tumor Institute, which consists of seven nonprofit hospitals in Idaho and is part of the NCI Community Cancer Center Program. As a Disproportionate Share Hospital, the institute is eligible to purchase medications at the same cost as government entities, such as the Veterans Administration.

Wilson said the ongoing drug shortage is routinely discussed with St. Luke’s purchasing group and executive leadership, and he has found that manufacturers have been trying to stop the shortage and meet patient demand.

“When we are getting down to our last few days’ supply of cisplatin, leucovorin, or Taxol [paclitaxel] and are faced with having to start calling patients and cancel their appointments, we contact the manufacturers, and they’ve been able to come through for us.”

Wilson said that for ordering by computer, the drug may be listed as on backorder, but following through with contacts can often help uncover a stash to meet patients’ needs. He recalls that the hospital’s purchasing agent had once been contacted by a gray-market distributor offering paclitaxel at 10 times the market cost, but St. Luke’s decided not to buy it because the drug’s pedigree could not be established.

George W. Sledge, M.D., Ballve-Lantero Professor of Oncology and professor of medicine and pathology at Indiana University’s Simon Cancer Center and immediate past president of the American Society of Clinical Oncology, told JNCI during the recent San Antonio Breast Cancer Symposium that he had been successfully treating a metastatic breast cancer patient with liposomal doxorubicin (Doxil).

“It was the only drug that was keeping her in remission, and then one day I had to tell her that the drug was no longer available,” he said, adding that he actually had received a call from his institution’s pharmacist while in San Antonio to let him know that a single dose had been located.

Sledge admitted that he had no idea about the drug’s cost but was glad to have it for his patient.

Shifting Paradigm

Nicholas J. Petrelli, M.D., Bank of America Endowed Medical Director of the Helen F. Graham Cancer Center at Christiana Care in Wilmington, Del., also part of the NCI Community Cancer Center Program, said the gray market reminds him of going to Madison Square Garden and seeing scalpers trying to sell tickets at excessive prices that he could buy for less in the lobby.

“The real paradox is that in the past some of these drug vendors would advertise drugs with prices than were less [expensive] than [they would be] through normal, legitimate distribution channels, and now they’re selling drugs in short supply with inflated prices.”

Petrelli said it’s troubling that gray-market distributors can get drugs that aren’t otherwise available. He’s bothered mostly about the quality and integrity of the drugs being sold.

“If they are diluted, counterfeited, mislabeled, [or otherwise compromised], they could pose a danger to patients and practicing physicians,” he said.

Petrelli said that at times it’s been difficult to get 5-FU, also known as 5-fluourouracil, which is used to treat many types of cancer. Petrelli added that sometimes several patients have needed the same type of chemotherapy that was in short supply.

“How do you make that decision who gets it? We’ve had several situations where we couldn’t place patients on clinical trials because we didn’t have a drug, and a few times we’ve had to place patients on trials to receive certain drugs.”

At Top Cancer Centers

At the University of Texas M. D. Anderson Cancer Center in Houston, a drug shortage team meets weekly to monitor shortages and look for proactive solutions to problems, according to Wendy Heck, Pharm.D., B.C.P.S., clinical pharmacy manager of drug information and drug use policy.

Heck said that M. D. Anderson is susceptible to the same shortages as other institutions but has been able to meet most patient needs, except for doxorubicin, which has been in short supply because of manufacturing problems.

“Our pharmacy purchasing department receives [gray market] solicitations every day, but we disregard them all. We have a very conservative, black-and-white approach and will not use any drugs that come from outside our regular wholesalers or manufacturers,” she said.

Heck’s pharmacy also gets requests from other hospitals needing drugs in short supply and tries to help out when possible, but that can be a tricky proposition when it...
might mean giving up doses that may not become readily available again.

Heck said that hospitals cannot sell drugs to other hospitals, and when drugs are borrowed, return payment is made in the monetary equivalent of that same drug or another of equal value.

“There have been times when we’ve been blindsided and just ran out of drugs, and then we’re approached by folks in the gray market saying they have this drug, do we need it?”

At Methodist Hospital, M. D. Anderson’s neighbor in the vast Texas Medical Center, pharmacy director Daniel Metzen, Pharm.D., said he tries to gauge three things when looking into the drug shortage: the therapeutic significance scale dealing with standard oncology drugs that have no substitute; the patient safety scale; and the operational impact, meaning the additional work, energy, and expenses related to coming up with viable solutions for patients.

“There have been times when we’ve been blindsided and just ran out of drugs, and then we’re approached by folks in"
the gray market saying they have this drug, do we need it?” he said, adding that Methodist doesn’t obtain drugs from questionable sources.

“Our purchasing guys are our signals and sometimes alert us about gray marketers offering drugs at higher prices, which we will then hoard ourselves.”

However, Metzen said that although pharmacists may stockpile drugs in the best interests of patients, he is concerned about how many of these drugs can expire or not be used at all.

And about the integrity of drugs, he reminds himself of a situation about 10 years ago when certain staff at prestigious Houston hospitals were stealing oncology drugs and selling them on the gray market to third-party vendors.

“The drugs were later found in a parked [unrefrigerated] U-Haul truck,” he said, adding that despite knowing the drugs’ pedigree because they came from hospitals that had acquired them through legitimate channels, a major question of safety remained because of how they had been stored.

Jonathan Adams, Pharm.D., chief of pharmacy services and assistant vice president at Buffalo’s Roswell Park Cancer Institute, said that RPCI has been monitoring several drugs—including bleomycin, doxorubicin, and leucovorin—and buys them whenever they become available, but doing so has involved working closely with manufacturers instead of responding to gray-market solicitations.

“We’ve gotten some calls from local health care agencies facing shortages, and in some cases we’ve been able to call around and find other agencies who have been able to share [drugs],” he said, adding that there was a reluctance to lend drugs out when you don’t know whether you can replace them for your own patients.

When asked what would he do if an RPCI patient needed a particular life-saving drug not available through normal channels and then was offered the drug at an inflated price from a gray-market dealer, Adams said, “We’d want as much information as possible about the distributor and the drug’s source, including its pedigree, and then we’d discuss it with the clinician who prescribed it and make a decision based on clinical information.”

RPCI CEO and President Donald “Skip” Trump, M.D., said he had to suspend a phase II prostate cancer trial because of a shortage of 1,24-dihydroxyvitamin D₃ (tacalcitol), an analogue of vitamin D. He then reopened the trial when a small supply of the drug became available, but he was concerned about completing the trial because of the uncertainty of future supplies.

Trump said his clinical nightmare would involve having to tell a 20-year-old kid with advanced testicular cancer that he couldn’t receive the potentially curative bleomycin because it wasn’t available.

Margaret Clapp, M.Div., M.S., chief pharmacy officer at Massachusetts General Hospital in Boston, had to deal with a similar situation when a patient needed a drug that wasn’t available until a single dose was found at another institution. Clapp said Mass General had denied the request because, even if the manufacturer could be verified as legitimate, there was still a number of safety issues involved dealing with how the drug had been handled since leaving the manufacturer and having the drug administered to the patient at another institution.

“We also had a shortage of thiopeta, and the FDA made an allowance to purchase the drug from Italy. What had cost $900 per gram was now $1,200 per gram, and that was raised to $2,600 per gram within a year and with a $5,000 shipping charge,” she said.

Clapp added that her department disregards notices from gray-market vendors but can sometimes face pressure to buy drugs from questionable sources.
At Smaller Practices
At Century Medical Associates, a six-member oncology practice also located in Buffalo, founder Kandala K. Chary, M.D., said that his office has the same issues and concerns as larger practices or institutions, but with even more frustrations because it doesn’t have as many contacts and often relies on working with other independent oncology groups.

“We are requesting that our practice manager get drugs from whatever source, hopefully at cost... and that they are from respectable vendors. We hope these sources are legal.

“We’ve been losing money on lower-end drugs and we’ll plead with insurance companies if there is a small markup, but we just can’t afford to subsidize very expensive drugs. We are always struggling.”

Chary also said that patients have sometimes purchased their own doxorubicin and gotten the green light from their insurers to have it administered by his practice, even without knowing about the drugs’ pedigree.

Noting that he and his fellow oncologists are often working to exhaustion, Chary said that for buying drugs, “We let our office manager decide what to do. She uses common sense and judgment, and if it is very expensive she’ll bring it to the attention of one of the physicians.”

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