The high cost of low-priced cancer drugs

By Dawn Holcombe, FACMPE | Oncology Network of Connecticut, South Windsor, CT

Dangerous Doses: How Counterfeiters are Contaminating America's Drug Supply

By Katherine Eban Harcourt Press 480 pages. \$25

ith a gripping novelistic flair, Dangerous Doses chronicles the investigations launched over the past 4 years in Florida to identify and prosecute criminal activity in the secondary drug wholesaler market. These outrageous crimes included adulteration, contamination, and counterfeiting of drugs-especially high-priced cancer drugs ripe for undetected substitution. Ms. Eban details how a vast web of fly-by-night wholesalers and profiteers was uncovered. She movingly tells the painful stories of people whose lives were affected by the phony drugs. I followed this saga in the Florida press as it was unfolding, and used many of the stories in discussions on brownbagging of cancer drugs.

Extreme change, extreme risk

Ms. Eban's account of the risks to the quality and integrity of the American supply of cancer drugs has a special resonance now. We are in an era of extreme change for cancer treatment. The Medicare Modernization and Improvement Act of 2003 created an average selling price (ASP) for cancer drugs and a new distribution system for those drugs. The distribution system, popularly known as CAP (for Competitive Acquisition Program), is encouraging national feeder networks of suppliers and distributors. The program relies on existing state licensing to validate the legitimacy of the vendors. But that licensing is seriously flawed.

Currently, Florida has—on paper at least—the most stringent regulations in the country. However, the execution and oversight of those regulations are so underfunded that major loopholes still exist. Given the speed at which questionable vendors fled Florida to set up unchecked drug wholesale businesses in other states, one can only imagine the tractor trailer-sized loopholes that must exist elsewhere.

Dangerously flawed system

A recent study by the Medicare Payment Advisory Commission found that the costs of acquiring and handling cancer drugs in the hospital setting exceed purchase price by up to 28%. The ASP-based program itself sets up a market dynamic whereby buyers serving Medicarebe they doctors, pharmacies, or CAP vendors-are scrambling to find those elusive low prices that allow them to survive under this artificially low price point. As spotlighted by the author, the major dynamic driving proliferation of the illegal market originating in Florida is the fact that there were always buyers for products priced lower than manufacturers' list. But as the adage goes, you get what you pay for, and in this case the stakes are so much higher: a low price can buy an inferior, useless, even harmful product.

This suggests that continuing to rely on ASP, and expanding the ASP concept to hospital and CAP vendors, will drive the cancer drug system ever faster toward the precipice. There's a growing incentive for bad products to enter the system as more buyers try to beat the mandated reimbursement maximum of ASP. Underground and illicit vendors will find that their bargain basement prices for questionable drugs are in demand. One could argue that ASP will come to mean "A Suspect Product."

Dangerous Doses will leave you disturbed and angry that such crimes occurred and were allowed to proliferate. We need to channel that anger and use it, as many already have, to better protect the patients who depend on quality drugs for their care. Regulatory improvements must be made so that wholesalers cannot cross state borders and resume their nefarious business without challenge. Inventory control and packaging measures must be undertaken at the manufacturer and distributor level. Payment and pricing policies must be crafted to minimize the chance that adulterated drugs enter the mainstream drug system. It means asserting a strong political will.

© 2005 Elsevier Inc. All rights reserved.