Price Gouging: A Black Mark On Gray-Market Distributors

By: Bruce Buckley

Gray-market distributors are taking advantage of long-term critical drug shortages to demand exorbitant payments from hospital pharmacies that run out of options for obtaining lifesaving treatments from regular wholesalers, according to a recent Congressional report.

Investigators who compiled the report found numerous instances in which short-supply medications changed hands multiple times across a chain of buying and selling, with each transaction adding a fat markup until the products reached hospital pharmacies at prices at least 30 times higher than typical contract amounts.

Several pharmacy directors from top health systems say that in the months since the report was issued, they have continued to feel the sting of steep price hikes. “Just last week, I paid about 10 times what it used to cost me for propofol,” said Tom Van Hassel, RPh, MPA, of Yuma Regional Medical Center, in Yuma, Ariz. “If I am truly out, I really have no choice; I have to buy whatever I can. It doesn’t matter if it’s $27 a bottle or $300 a bottle. I can’t close my hospital surgery down because I don’t have a crucial induction agent.”

Mr. Van Hassel said he buys most pharmaceuticals direct from the hospital’s primary wholesaler under a group purchasing organization contract. However, he noted, if an essential product is not available from his regular source, as in the recent propofol shortage, he will turn to alternate suppliers.

“There are some bad apples that are in business purely looking for short products,” he said. “They don’t sell a legitimate line of products. They really only deal in hard-to-find pharmaceuticals.” Mr. Van Hassel does do repeat business with selected secondary suppliers. “It’s not that they’re all bad. That’s the hard part of this. The good ones get lumped in with the bad ones.”

The Good and the Bad

The Congressional report, *Shining Light on the "Grey Market,"* acknowledged that duality. Although it focused a harsh light on the practices of a group of pharmacies and distributors operating "outside of authorized distribution networks," it also told how the mainstream drug distribution system, including the legitimate secondary market, works to ensure safe passage of medications from manufacturers to patients.

Most of the report, however, was devoted to the bad actors. One scenario described a 25-vial shipment of fluorouracil with an original $7 per-vial wholesaler price that was ultimately sold, after six separate transactions, to a California regional medical center at $600 per vial, a markup of 8,471%.

At a July Congressional hearing on the report, David Mayhaus, MS, PharmD, chief pharmacy director at Cincinnati Children's Hospital Medical Center, in Ohio, told senators and others in attendance that his hospital sometimes had to pay alternative wholesalers many times the normal contract price to obtain a critical drug in short supply. He cited one instance when the usual pipeline for cytarabine dried up and hospital inventory became perilously low. Cincinnati Children's Hospital had little choice. "After careful consideration [and] due diligence," he said, the hospital "did in fact purchase this drug from alternative wholesalers. Because of this purchase, we did not run out of this important drug and all the patients received all the appropriate doses."

Dr. Mayhaus told *Pharmacy Practice News* that the price paid for the essential leukemia therapy was "greater than 35 times" the hospital's regular contract amount. And these are not isolated cases; similarly steep markups continue to hit his pharmacy budget "and remain a real challenge," he said.

How High Is Too High?

Dr. Mayhaus, who sits on the pharmacy executive committee of the Children's Hospital Association, said hospitals generally were not opposed to paying somewhat higher prices for products they were unable to obtain from regular sources. "We know these secondary wholesalers are not buying it for prices that our big wholesalers pay," he said, but he questioned why prices were "30, 40, 50 times more than our acquisition costs."

In response to the report's critical findings, Patricia Earl, a consultant to the National Coalition of Pharmaceutical Distributors, told hearing attendees, "I cannot emphasize enough the value that small or secondary pharmaceutical distributors bring to the health care system." She said there were "thousands of small distributors that work with hospitals across the nation. To remain competitive they must comply with laws, follow pedigree and handling regulations to the letter and still offer an economical price point that allows for only a modest profit margin. If they do anything else, they run the risk of permanently losing a customer."

Most hospitals have strict policies about acquiring drugs outside normal channels. Some make it a rule not to buy in the gray market. Others will do so only as a last resort, and then only after

scrupulous pedigree checking. Multiple transactions for a single drug almost always raise a red flag and lead a hospital to forego the purchase.

“No law says [a drug] can’t pass through several hands, but if there are an excessive number of wholesalers touching the product, we’ll shy away from it,” Dr. Mayhaus told *Pharmacy Practice News.*

He said Cincinnati Children’s Hospital does use “a small group of secondary wholesalers,” but only ones licensed by the Ohio Board of Pharmacy. The pharmacy board, he noted, “has a process to vet the legitimacy” of out-of-state wholesalers. “So if Joe’s Wholesaler contacts me and they’re not listed on the Ohio Board of Pharmacy Web site, we will not use them,” he said.

A Combined Coping Strategy

Roger Woolf, PharmD, administrative director at Virginia Mason Medical Center in Seattle, said his hospital “does not consider purchasing pharmaceutical products outside the traditional distribution channels,” meaning its primary wholesaler or direct from a manufacturer.

“Instead of alternate suppliers,” he said, referring to the gray market, “we use internal systems and regional relationships to manage specific shortages. This means working with our providers on the demand side of medication use and extensive communication with our wholesaler to manage product flows and obtain alternative dosage forms or therapeutic alternatives.”

One lesson learned in recent years, Dr. Woolf said, “has been that different wholesalers have access to different drug supplies. This means that the historical approach of having a single wholesaler for all drug purchases is probably not the optimal arrange- ment. This has led us to look at having more than one wholesaler agreement and in our case using regional care delivery arrangements with partner organizations to improve our overall access to product. This places a greater burden on us to ensure product custody, in that we have to understand our regional partners’ standards for drug control as well as our own.”

Because drug distribution laws vary from state to state, one solution to the gray-market problem might be a federal law governing the sale and shipment of drugs across state lines. Mr. Van Hassel, who currently serves as vice president of the Arizona Board of Pharmacy, said that such legislation may help. But another option—certification—should also be part of any solution to ensuring supply-chain safety. “One of the things we’re concerned about, and every other pharmacy board in the country is concerned about, is how do we control the drugs that come into our state to make sure they’re of the highest quality,” he said. “There is no way without having all wholesalers board-certified.”

He pointed to the National Association of Boards of Pharmacy’s Verified-Accredited Wholesale Distributor (VAWD) program as a potential model for a nationally required certification process.

“We need to be able to require that you are a VAWD-certified wholesaler,” he said, “and if you’re not certified and not following pedigrees, then you cannot sell those products.”

Multiple sales of the same product also have to be barred, he said. “We need to stop all these inter-wholesaler sales. We can’t allow product to be sold six and eight and 10 times before it gets to the end user. The only way that can be done is on a national level.”