'Gray Market' Not Such a Gray Area Anymore

Why Hospitals Are Paying Exorbitant Drug Prices

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If you are a hospital pharmacy director and wonder why some secondary drug distributors offer you a drug in short supply at an exorbitant price when your regular wholesaler or government purchasing organization can't find it, here is one answer.

In July, the Senate Commerce Committee released an intriguing report on the "gray market" in drugs.[1] Apparently, some retail "pharmacies" across the country exist solely to buy drugs that are in short supply from authorized distributors. They then shove them into a long, gray market pipeline, and the price is marked up at each juncture. The initial pharmacy that gets the ball rolling, although licensed by the state, never sells a single drug to a single patient.

Ginny Herold, Executive Officer at the California State Board of Pharmacy, added context to the committee's report. California, the "Golden State," conducts its own investigations of the gray market. One investigation yielded details about a wholesaler, unnamed by Ms. Herold, who convinced 55 California pharmacies to buy short-supply drugs and then sell them to that wholesaler. Key to this investigation was the fact that most of the drugs involved would have been used by hospitals and rarely would have been needed by community pharmacies. Moreover, California's first electronic pedigree (e-Pedigree) law in 2004 made it illegal for pharmacies to sell more than a nominal quantity of drugs to a wholesaler.

Not surprisingly, the California pharmacies, which were the subject of the state's investigation, never sold the short-supply drugs that they purchased at the wholesaler's behest to any retail customers; they sold them only to the rogue wholesaler. All of the pharmacies and their pharmacists-in-charge have been cited and fined in various amounts up to $70,000 for violation of California law. Appeals of these citations and fines are pending. The wholesaler has not yet had discipline completed; therefore, none of these actions or investigations has been concluded. Ms. Herold added that three other investigations are under way.

The Senate's investigation included the example of the shipment of 25 vials of a chemotherapy drug, fluorouracil, in September 2011. Priority Healthcare, a Maryland pharmacy owned by Marianna Pesti, purchased the vials from McKesson and sold them to a New Jersey distributor, Tri-Med America, which was owned by Ms. Pesti's husband, Gabor Szilagyi. The drugs were sold five more times before they reached the end-user, Sonora Regional Medical Center in California. Priority Healthcare paid $7 per vial. By the time those vials were sold to the hospital, it paid $600 per vial.

David Mayhaus, PharmD, MS, Chief Pharmacy Director of Cincinnati Children's Hospital Medical Center, told the committee that over the previous 12 months, the hospital purchased only nine out of 2,800 line-item drugs from these alternative wholesalers. In some cases, the price of those nine drugs exceeded 35 times the normal pricing. The additional costs incurred through those purchases totaled $100,000 in the previous year.

Given the hostile environment brimming with angry senators, one has to give some credit to Patricia Earl, an industry analyst for the National Coalition of Pharmaceutical Distributors. This trade group represents the secondary drug distributors often accused of constituting the gray market pipeline. Appearing before the damning-report-wielding senators (the equivalent of entering the lion's den just before dinner time), she explained that all members of her association are licensed by the FDA and the Drug Enforcement Administration.

She said, "We do not support bad actors."

She indicated that her members are usually involved in "pipelines," consisting of only a couple of sales, not the multiple sales found by the Senate's investigation.

We don't support multiple transactions," she emphasized.

Under questioning from the senators about the exorbitant markups exposed by the Senate report, Ms. Earl repeatedly explained that those additional costs reflected the inventory and transportation costs incurred by her members. She said that those costs could reach 100% in some instances.

Senator Amy Klobuchar (D-Minn.) was dubious. "I think we are paying for more than just the freight charges," she answered.

For all five drugs in the Senate investigation, units normally costing $10 to $20 were regularly marked up to $200 or more while they traveled through the gray market.

When Senator John Thune (R-S.D.) asked the panelists about solutions, Ms. Herold quickly jumped in to talk about California's e-Pedigree requirement, which will be phased in starting in 2015. Every unit-level sale will have to be recorded electronically. Patricia Earl endorsed that system. The Prescription Drug User Fee Act (PDUFA) reauthorization bill, passed by the Senate this year, included a national lot-level e-Pedigree requirement. However, the House bill did not, nor did the final bill signed by President Obama. John Gray, President and Chief Executive Officer of the Healthcare Distribution Management Association (HDMA), told the senators "that we got perilously close" to a national e-Pedigree system during the PDUFA negotiations.

But the HDMA did not support item-level tagging, nor did other members of the Pharmaceutical Distribution Security Alliance. Of course, they will all have to get comfortable with the idea by 2015 if they want to do business in California. But 3 years is a long time for hospitals to have to continue to put up with artificially exorbitant prices for chemotherapy agents and other intravenous drugs.

REFERENCE

1. Senate shining light on the 'gray market'. July 25, 2012. Available at: http://commerce.senate.gov. Accessed August 27, 2102. ■