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No shortage of blame

Congress refocuses on gray market in drug shortfalls

By **Jaimy Lee**

Posted: July 28, 2012 - 12:01 am ET

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Frustrated lawmakers are seeking to assign blame to the organizations, regulatory policies and business practices that they say have caused or exacerbated drug shortages.

A report released in June by the House Committee on Oversight and Government Reform attributed the record number of drugs in short supply to the Food and Drug Administration's stepped-up enforcement actions. It also cited the Medicare Modernization Act's impact on generic drug pricing and the market structure of group purchasing organizations as contributors to drug shortages.

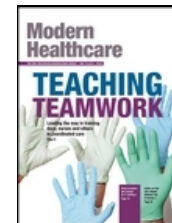
Now, some of the same lawmakers have turned their attention back to the so-called gray market, a secondary drug distribution chain that has often served as the only source of some scarce drugs for providers in need.



A pharmacy buyer holds a tray of magnesium sulfate—a drug that remains on the FDA's list of drugs in short supply.

Photo credit: AP PHOTO

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Rep. Elijah Cummings (D-Md.) launched an investigation into secondary drug distributors last year, alleging that some of the closely held distribution companies are engaged in drug speculation.

Last week, Cummings, along with Sens. Jay Rockefeller (D-W.Va.) and Tom Harkin

(D-Iowa), released a report providing information about the secondary drug distribution market and participated in a Senate Commerce Committee hearing about the gray market.

"Gray-market drugs leak out of authorized distribution chains, often through pharmacies that sell to wholesale distributors, and are sold to end users at aggressively marked-up prices," the report's authors wrote. "The questionable business practices of the distributors and pharmacies engaged in gray-market sales result in higher healthcare costs and potential risks to patients."

The report analyzed 300 drug pedigrees and found that distributors acquired nearly 70% of drugs sold into the gray

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market from pharmacies.

The California State Board of Pharmacy reached a similar finding after an investigation last year. Virginia Herold, the pharmacy board's executive officer, testified during the Senate hearing that the investigation was prompted by a pharmacist who inquired about the legality of buying drugs in short supply with the sole intention of selling them to a distributor.

The board found that 55 pharmacies in California had purchased drugs in short supply and sold them to Priority Pharmaceuticals, a San Diego-based secondary distributor,

more than 500 times. The board cited and fined the pharmacies and pharmacists. Some of the pharmacies and pharmacists have appealed. Although Priority is listed in the citations, the board's investigation into the company is ongoing.

Patricia Earl, an industry analyst for the National Coalition of Pharmaceutical Distributors, a trade group that represents secondary distributors, argued during the hearing that secondary distributors are a valuable part of the supply chain, in part because they provide drugs to healthcare providers during off hours and to remote regions. Secondary distributors also serve as a backup source for pharmacies, according to the National Community Pharmacists Association.

As drug shortages have gained attention from lawmakers, so have the gray-market practices of some distributors. Several members of the Senate committee expressed concern about distribution chains that show a drug being bought and sold multiple times, each time with a markup in price.



Earl said that the NCPD does not support multiple transactions within a pedigree or price-gouging.

However, two of the coalition's board members listed on its most recently available Internal Revenue Service Form 990, from 2010, are executives of Atlantic Biologicals and Reliance Wholesale, both of which are cited on multiple-transaction pedigrees in the July 25 congressional report. The owner of

Priority Pharmaceuticals is also listed as a member on the Form 990. A spokeswoman for the NCPD declined to comment when asked whether those executives remain part of the board.

Secondary distributors aren't the only organizations under scrutiny in Washington. On July 23, the FDA sent a letter to Cummings, stating that the agency is not the "root cause" of drug shortages and that the long-term commitment of drug manufacturers is necessary to solve the shortages.

The House report, which was released in mid-June, recommended that the FDA allow facilities to make improvements under its supervision rather than shut down manufacturing lines. About 30% of total manufacturing capacity at the four largest generic drug manufacturers in the U.S. has been shut down.

The same report cited the market structure of the group purchasing industry, which drives down prices for its members but can lead manufacturers to exit the market.

Curtis Rooney, president of the Healthcare Supply Chain Association, responded in a statement that GPOs "do not have the ability—nor would it be in our interest—to force manufacturers into contracts that undermine their ability to deliver product."

Despite an executive order in October 2011 that led to the prevention of at least 114 shortages and the addition of a provision in the recent FDA user-fee legislation that will require manufacturers to warn the FDA about potential shortages in certain instances, some say drug-shortage problems are not getting any better.

"We haven't seen a lot of improvement," said Michael Cohen, president of the Institute for Safe Medication Practices. "It's really disheartening." He noted that medication errors have been reported because of a clinician's unfamiliarity with an alternative product and hospitals are now hiring full-time staffers to handle the shortages. Propofol, the anesthetic that was in short supply two years ago, is again scarce.

"The point is it's still happening," Sen. Mark Begich (D-Alaska) said during last week's hearing. "We could argue the degree (that) it's happening but we need to figure this out because supply chain of pharmaceutical goods for health is critical."

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