



Do GPOs Play a Role in Drug Shortages? Long-Standing Allegations Disputed by The GPOs

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Shortages of injectable generics continue to bedevil hospital pharmacies. The Food and Drug Administration (FDA), which set up a task force last summer to attack the problem, has made some progress but much more needs to be done. At a meeting in Washington on November 27, 2018, co-sponsored by the FDA and Duke University's Margolis Center for Health Policy, there was much discussion of many of the well-known causes, such as manufacturing problems, the domination of individual product categories by a single manufacturer, and the roadblocks companies face trying to obtain FDA approval for new generic injectables.

One potential cause was not mentioned by any of the many speakers, nor has it ever been examined by any administration or Congress: group purchasing organizations (GPOs). But Phil Zweig, Executive Director of Physicians Against Drug Shortages (PADS), peppered those on the dais with questions and statements underlining his view that the GPOs are nefarious actors. PADS has been making that claim for years. (Audience applause for his somewhat cantankerous performance can be heard on the webcast.)

Zweig says: "If the GPOs/PBMs [pharmacy benefit managers] hadn't rigged this marketplace, if there were free, open competitive markets where prices were able to adjust without interference from these middlemen, there would be no shortages."

GPOs obtain rebates from drug manufacturers for including the manufacturers' products in their catalog. If rebates

are juicy enough, the GPO may issue a sole source contract. Hospitals pay GPOs membership fees and receive administrative fees back. Those fees, sometimes called sharebacks, are a percentage of total purchases, generally below 3%. But the higher the drug cost, the higher the GPO rebate, and the higher the hospital administrative fee. At the FDA-Margolis meeting, Todd Ebert, President and CEO of Healthcare Supply Chain Association (HSCA), the GPO trade group, said that GPOs are obligated to disclose all fees to the Department of Health and Human Services (HHS) upon request. But HHS has never asked for that information.

The GPO model is greased by an exclusion from the anti-kickback statute granted by Congress in 1997. The Office of the Inspector General at HHS administers that exclusion and is considering changes to its exclusion policy. However, it would probably take a congressional law to end or change the GPO exclusion. While the Trump administration is considering changing how rebates are passed from manufacturers to PBMs to pharmacies (see *Lowering the Boom on High Drug Prices*, page 122), no changes have been proposed to the similar GPO model.

HSCA argues that GPOs, some of which are owned by hospitals, get hospitals the lowest prices for drugs. Hospitals can purchase from more than one GPO, and from manufacturers directly. Ebert says, "The FDA and all other relevant stakeholders have repeatedly identified quality control problems, manufacturing issues, and barriers to getting new suppliers on line as the primary causes of drug shortages. There is no evidence that GPOs are a cause of drug shortages. PADS is a small fringe group with no apparent supply chain experience that promotes conspiracy theories to try and provoke undue scrutiny of GPOs."

Erin Fox, PharmD, Senior Director of Drug Information and Support Services at

the University of Utah Health, agrees with Ebert. "If you look at the major issues for drug shortages right now, we still have repercussions from Hurricane Maria in Puerto Rico," she says. "The majority of other shortages are due to problems at Pfizer's McPherson Kansas and Rocky Mount, N.C. factories."

There is no question that manufacturing problems are a key cause of drug shortages. The *Wall Street Journal* carried the latest horror story on January 19, 2019 about huge price increases on valsartan since "safety related recalls of the drug by other manufacturers began last summer." The story referenced 120 drugs on or recently on the FDA shortage list and said: "...one-third had price increases after the shortages started..."

But are PADS and Zweig conspiracy mongers, as the HSCA alleges? One example of where GPOs thwart efforts to cure specific drug shortages is their attitude toward 503B outsourcing facilities, drug compounders inspected by the FDA and allowed to sell drugs in bulk to hospitals. Lee Rosebush, a partner at Baker Hostetler and Chairman of the Outsourcing Facility Association, says, "According to many of my members, GPO exclusive contracts are hurting patient access to drug shortage products. Many of my members have products available on the FDA drug shortage list; however, they cannot sell these products to hospitals or clinics or providers because of the GPO exclusive contract."

One pharmacy director of a West Coast hospital, who does not wish to be named, concedes that the GPO model can lead to shortages, not for nefarious reasons but because GPOs force down the price of generics. Sometimes, prices are so low that multiple manufacturers leave the market, which then becomes vulnerable to disasters such as Pfizer's major manufacturing problems at its Hospira plants.

The hospital pharmacy director acknowledges that hospitals do get pay-

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ments from the GPOs to which they belong, and that those administrative fees to hospitals and rebates to GPOs from manufacturers, if subtracted from the equation, might lead to higher prices for generic drug makers, making them less likely to quit the market.

Neither successive Congresses nor successive administrations have looked into the role that GPOs play—if any—in drug shortages. Maybe they should. ■