NEUPUGEN consisted primarily of mild-to-moderal musculoskeletal symptoms These symptoms were

Buying Groups' Role in Drug Shortages Queried

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By Kristina Fiore, Staff Writer, MedPage Today







WASHINGTON -- Six members of the House of Representatives have called on the Government Accountability Office (GAO) to investigate whether contracting practices by hospital purchasing organizations are an underlying cause of ongoing shortages of generic drugs.

Specifically, the six want to know whether group purchasing organizations (GPOs) have designed exclusive contracts for drugs and devices that have had



detrimental effects on generic drugmakers -- potentially leading to drug shortages and an increased reliance on compounding pharmacies.

"Increased hospital reliance on compounded drugs should be a result of increased need, not unfair pricing," Rep. Ed Markey (D.-Mass.) said in a statement. "The investigation we are requesting will shed light on any possible linkages between drug shortages and reliance on compounding pharmacies, and help address gaps in our oversight of this industry."

The compounding pharmacy that made the contaminated steroid responsible for the ongoing bacterial meningitis outbreak is located in the Congressional district Markey represents.

When they were originally formed, GPOs were seen as a means of keeping healthcare costs down, enabling hospitals to band together to buy drugs and devices in bulk for lower prices.

But with the growth of these organizations -- almost all hospitals are now members of a GPO and more than 70% of all purchases are made through contracts with these companies, according to the letter -- some are concerned that their contracting practices may be quashing some generic drugmakers' incentives to keep producing their products.

According to the letter, the contracts involve fees that drugmakers pay to participate and to sell their products to hospitals. These fees are based on a percentage of the value of the purchase, and some have questioned whether this qualifies as a "kickback" -- the more a hospital pays for a product, the more the GPO makes.

Such fees also drive down generic drugmakers' profits on selling their drugs, diminishing incentives to continue production and potentially opening the door to shortages, according to the letter.

Angie Boliver, director of communications for Novation -- one of the largest GPOs in the U.S. -- told MedPage Today the drug shortage is complex and that the "notion that GPOs are responsible for drug shortages simply because they have negotiated prices too low is without logic or justification."

"The reality is that hospitals will, and do, pay whatever amounts they have to pay in order to get life-saving drugs," Boliver said in a statement. "It is important to note that GPOs are

negotiating against some of the largest and most powerful companies in the world. These companies are sophisticated businesses that are perfectly capable of negotiating contracts that will provide a reasonable profit margin."

When asked for comment, Premier, another top GPO, referred *MedPage Today* to its trade organization, the Healthcare Supply Chain Association. Organization president Curtis Rooney said 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."

"Drug companies regularly and quickly adjust pricing of GPO contracts when they experience shocks to production, and GPOs manage thousands of price changes annually, both increases and decreases," Rooney said, adding that "all hospitals can purchase off-contract."

Gregory Conko, executive director of the Competitive Enterprise Institute, a conservative think tank that champions economic freedom and was not involved in the GAO letter, said GPO contracting practices "scare a lot of manufacturers out of the market. It squeezes production capacity down to a point where you have only two or three manufacturers making a particular product."

But that "wasn't the intended result" of GPOs when they were formed: "Until the drug shortages, we saw them as a good thing," he said.

It's not that GPOs alone cause the drug shortages, Conko said, but they have set the stage for risk of shortages when disruptions in the supply chain — such as an inability to garner raw materials or problems with FDA-regulated good manufacturing practices — occur.

He added that pressure from public insurers such as Medicare and Medicaid to keep costs down also has hurt generic manufacturers and their ability to produce those drugs.

Joel Zivot, MD, director of the cardiothoracic ICU at Emory University Hospital Midtown in Atlanta, who has been researching the ethical issues surrounding drug shortages, said they are "a public health emergency that needs urgent attention."

"Although it sounds like an old-fashioned story about greed, drug shortages are really a story about individuals who suffer, some who have died, and some who will die. In that group, party politics means nothing," Zivot said. "I hope that members of government choose to think of this as the consequence born on the back of a real person who is being harmed, not simply on some company's balance sheet."

The letter was released on the second of two days of Congressional hearings about FDA oversight of compounding pharmacies that act more like drug manufacturers, such as the New England Compounding Center, which is at the center of the ongoing meningitis outbreak tied to one of its injectable steroid products.

That product, methylprednisolone, has indeed been in short supply during the outbreak.

Markey is currently championing the VALID Act, which calls for giving FDA greater authority to regulate such large-scale compounding pharmacies.

The letter to the GAO also was signed by Henry Waxman (D.-Calif.), John Dingell (D.-Mich.), Frank Pallone (D.-N.J.), Diana DeGette (D.-Colo.), and Anna Eshoo (D.-Calif.).

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