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frinter friendly $\mid \square$ email this article $\mid \square 0$ <u>Comment(s)</u> Doctor Group Claims Drug Purchasing Organizations Causing Chronic Shortages by Ted Agres

Frustrated with ongoing shortages of key drugs, a new grassroots group led by anesthesiologists is calling for the repeal of federal legislation that permits group purchasing organizations (GPOs) to engage in what they call collusive and anticompetitive activities. Several senior U.S. lawmakers have asked the Government Accountability Office (GAO), the investigative arm of Congress, to look into the allegations that GPOs are at

least partly responsible for the nation's drug shortages.

"We are convinced that the anticompetitive contracting and pricing practices, kickbacks and self-dealing of hospital GPOs are the root cause of this public health emergency," said anesthesiologist Robert A. Campbell, MD, co-chair of the new group, Physicians Against Drug Shortages (PADS). "We're launching a national campaign to build public awareness of these anticompetitive practices and press Congress to halt them," said Dr. Campbell, who also is vice president of the Pennsylvania Society of Anesthesiologists (ASA).



Dr. Campbell described PADS as "a small group of physicians who met at the recent ASA meeting. After a totally unsatisfactory panel on drug shortages we chose to exchange emails and explore an economic explanation for drug shortages. Our solution will save at first \$35 billion per year in health care costs. Once competitive forces are restored in the health care supply chain, even more savings will be realized."

Any attempt to link GPOs to drug shortages is an "irresponsible and dangerous distraction," countered Curtis Rooney, president of the Healthcare Supply Chain Association (HSCA), a trade association representing 14 GPOs, including the nation's five largest. "The true cause of drug shortages is manufacturing problems, disruptions and barriers to entry in getting new suppliers online when there is a disruption in supply. The fact is that GPOs are taking a variety of creative and innovative steps to reduce drug shortages," Mr. Rooney told *Anesthesiology News*.

Leveraging Purchasing Power

GPOs negotiate contracts with manufacturers and vendors of pharmaceuticals and other medical products on behalf of their customers, typically hospital groups and other large health care organizations. About 72% of all hospital purchases are made through GPO contracts. GPOs leverage their collective purchasing power in order to keep costs low for their customers. Vendors pay GPOs "administrative" fees, typically based on a percentage of sales and capped by law at 3%. GPOs have been allowed to collect these fees since 1986 through a "safe harbor" provision added to the Social Security Act's Anti-Kickback statute, which would otherwise prohibit the practice.

"By exempting GPOs from criminal prosecution for taking kickbacks from vendors, [the exemption] has given rise to monumental conflicts of interest and perverse incentives that have undermined competition and innovation and inflated costs in the health care supplies, devices and generic drug marketplace—with tragic consequences," said Phillip L. Zweig, MBA, executive director of PADS. Mr. Zweig worked for medical device companies between 1999 and 2008 but no longer has financial ties to the industry. His current work with PADS is pro bono, he said.

"Our goal is to end the generic drug shortage crisis by restoring integrity and free market competition to the broken generic injectable marketplace, and indeed, to the entire U.S. health care supplies industry," Mr. Zweig said. "To accomplish that, we're pushing for the repeal of the Medicare anti-kickback safe harbor provision, which created the GPO 'pay to play' scheme in the first place. As a result of this misguided legislation, the GPOs now exert a stranglehold on the entire hospital supplies marketplace. They've rigged the market. PADS intends to end their reign of terror."



PADS, Mr. Zweig added, does not want to abolish GPOs, but rather return them to the pre–safe harbor system —"which worked fine from the early 1900s to the early 1990s."

But Phil Johnson, oncology director at Premier Inc., the nation's second largest GPO by purchasing volume, said the accusation that GPOs have eliminated free market forces is "uninformed and wrong."

"In fact, GPOs encourage the free market by competitive bidding and multiple rewards for the best supplier performance," Mr. Johnson told *Anesthesiology News*. "Consider that Premier represents approximately 2,700 hospitals and more than 90,000 non-acute sites. Our members determine the acceptable drugs or medical supplies within a therapeutic category, and Premier obtains strong contracts ensuring multiple vendors and product choices. With GPOs, the best drugs within the category, as determined by our member providers—physicians and pharmacists—develop strong contracts with competitive pricing."

However, a June 2012 report by the House Committee on Oversight and Government Reform concluded that GPOs have contributed to the current shortage of generic injectable medications because of pressures that the purchasing organizations exert on manufacturers and suppliers. "Companies that cannot produce a drug at large enough output levels to take advantage of the economies of scale—often because they lack the guaranteed source of demand that GPOs provide—will stop producing the drug or will neglect to enter the market," the House report stated.

Congressional Probe

The controversy surrounding GPOs is not new. Over the years, hospital systems have claimed that GPOs have saved them billions of dollars annually in purchasing costs (*Anesthesiology News* July 2009), while lawmakers and others have worried about the anticompetitive or unethical practices of GPOs. The GPO industry has adopted voluntary codes of conduct and since 2005, many companies have participated in an annual survey of their contracting practices.

In November 2012, six senior members of the House of Representatives asked the GAO to investigate whether GPOs are a "driving cause" of drug shortages. The lawmakers—Democrats Edward J. Markey (Mass.), John Dingell (Mich.), Frank Pallone (N.J.), Diana DeGette (Colo.), and Henry A. Waxman and Anna G. Eschoo (Calif.)—also said that shortages of critical drugs have forced hospitals and other providers to rely on unregulated compounding pharmacies, such as the New England Compounding Center, the Framingham, Mass., firm that has been blamed for last year's deadly outbreak of fungal meningitis and other infections caused by contaminated epidural steroid injections.

"As Congress fully investigates all the causes of the tragic meningitis outbreak in an effort to protect patients in the future, we need to look at the role GPOs play in the occurrence of drug shortages that could lead to increased reliance on compounding pharmacies," Mr. Markey said in a statement.

Expert practitioners and academics concurred. "This broken generic drug market, which is the direct consequence of unethical GPO drug purchasing contracts legalized by Congress, must be fixed immediately," said Joel B. Zivot, MD, medical director of the cardiothoracic intensive care unit at Emory University Hospital, in Atlanta, in a statement.

"GPOs are a major, if not the primary, contributor to the market distortions in the health care industry in the United States," added S. Prakash Sethi, PhD, university distinguished professor at Baruch College, in New York City. "Through exclusive contracting, which has given GPOs effective monopolistic control of this industry, they have contributed to product shortages and disincentives for legitimate producers to manufacture and stock essential drugs. At the same time, they have given rise to unscrupulous manufacturers to produce and market substandard drugs and thereby expose the patient population to serious health risks."

But Thomas G. Moore, president of Hospira Inc., blamed shortages of injectable drugs on manufacturing problems and disputes any link between drug shortages and the meningitis outbreak or between drug shortages and GPOs. "The practice of hospitals contracting with a GPO in order to aggregate their purchasing power is not a factor in drug shortages," Mr. Moore wrote in a Nov. 19, 2012, letter to the lawmakers. "It has been

Hospira's experience that GPOs do not limit the manufacturers who can contract with the GPO, especially in the circumstance of a drug shortage."

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