PhysiciansAgainstDrugShortages

FACTS on HEALTHCARE GROUP PURCHASING ORGANIZATIONS (GPOs)

A *$300 billion+* "pay-to-play" scheme, created by the ill-conceived 1987 Medicare anti-kickback "safe harbor" provision, which exempted GPOs from criminal penalties for taking kickbacks from vendors

DIAGNOSIS:

The anticompetitive contracting and pricing practices, self-dealing, conflicts of interest and "legalized" kickbacks of giant buying cartels (a/k/a monopsonies) have undermined the law of supply and demand and free market competition in the *entire* healthcare supplies industry, i.e., drugs, devices, supplies and equipment. Four huge GPO middlemen—-Vizient, Premier, HealthTrust & Intalere—- control contracting for an estimated 90% of the goods purchased by about 5,000 health systems and thousands of non-acute care facilities. Overwhelming documentation, including four Senate Antitrust Subcommittee hearings, federal and state investigations, media exposés, antitrust lawsuits, independent research, even a 2009 book, "Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry," shows how they have:

- ***Caused*** unprecedented artificial shortages and skyrocketing prices of hundreds of mainstay generic and even branded prescription drugs, notably sterile injectables, including antibiotics (e.g. penicillin), chemotherapeutic agents (e.g. methotrexate), basic IV solutions (e.g. sterile saline) and anesthetics (e.g. propofol), resulting in needless patient deaths (including 64 from the 2012 fungal meningitis outbreak alone), complications, inferior outcomes, & longer hospital stays. A Feb. 2014 GAO drug shortage study, mandated by Congress, cited GPOs as a key "underlying cause."

- ***Decimated*** domestic generic drug production (and thousands of American jobs), forcing the FDA to allow "temporary" imports, including sterile saline from Spain, Norway and Germany and chemo agents from a contaminated plant in China; increased dependence on China for active pharmaceutical ingredients (APIs) has created potential national security risks.

- ***Blocked*** safer, better and cheaper medical devices and supplies from use in healthcare facilities; purchasing agents, ***not*** physicians, often decide which hip implants, pacemakers, syringes, and other devices are used for patients & by HC workers.

- ***Inflated*** healthcare supply costs (the 2nd largest health system expense) by 25-35%+, or up to $100 billion+ annually, including wastage of unexpired goods, nearly half of which are reimbursed by Medicare/Medicaid and other gov't programs. Ex: a 10-vial box of propofol, a key surgical anesthetic, costs $22 off-contract vs. $55+ on a GPO contract.

HOW COULD WE HAVE DRUG SHORTAGES IN A FREE MARKET ECONOMY?

This is a rigged market, a throwback to the disgraced ex-Soviet economic system. In contrast, the original GPO co-op business model worked well for more than 80 years. The first GPO was established in 1910, when several New York City hospitals, led by Bellevue, banded together to save money on supplies—-the sole purpose of a GPO—- by purchasing in bulk. Members paid dues to cover administrative expenses.

Then in 1987, hospital lobbyists sold Congress on the fiction that more money could be saved if suppliers, instead of hospitals, paid "admin" expenses. In 1991, the Dept. of Health & Human Services Inspector General issued the "safe harbor" rules, which set a 3% cap on "admin" fees. This gave rise to perverse financial incentives that have dramatically inflated prices. That's because fees are based on a percentage of total contract volume, so higher prices generate more revenue for GPOs. What's more, in 2003, OIG quietly extended the safe harbor to pharmacy benefit managers (PBMs), inflating their prices as well.

- Under the post-1991 "pay-to-play" business model, GPOs became the agents for vendors, not hospitals. These middlemen literally sell market share to vendors by awarding exclusive (sole-source) long-term contracts to the highest bidder. In the generic drug market, that has slashed the number of domestic suppliers to one or two or even none at all. They are the gatekeepers. Instead of adding value to healthcare, they subtract it. All they do is enrich insiders.

- GPOs circumvented the 3% cap on "admin" fees by playing a semantics game, creating "marketing" fees, "advance" fees, rebates, prebates, private labelling and other price-gouging gimmickry—-so that *total* fees have sometimes exceeded 50% of a drug maker's total annual revenue for a single drug, according to federal court documents.

- Exorbitant GPO fees have cut profit margins on many generics to razor-thin levels, forcing drug makers to halt production or curtail investments in quality control and plant and equipment, causing plant shutdowns and shortages. According to *Modern Healthcare*, hospital pharmacists have had to do end runs around these middlemen to find drugs for patients.

- Senate hearings, gov't and media investigations, lawsuits and independent studies exposed a laundry list of egregious GPO practices, self-dealing, and conflicts of interest, including: taking equity stakes and "advance fees" (payola) from vendors in return for contracts; awarding stock and options in "captive" firms to GPO execs; setting minimum purchase levels for hospital members; participating in vendor-underwritten slush funds/junkets; and tying and bundling, to name a few.

- GPOs have made many hospital executives "partners," paying them "patronage" fees (a percentage of their own kickbacks) for enforcing compliance with exclusive GPO contracts, so that they benefit *personally* from higher prices. This may explain why a 2005 HHS study found that many hospitals have failed to report GPO payments and supplier rebates to Medicare as the law requires—-and why the American Hospital Association has steadfastly opposed repealing the safe harbor.

- HHS OIG has failed for years to properly oversee the GPO industry, according to a 2012 GAO report; the Justice Dept. Antitrust Division and Federal Trade Commission have failed in their duty to maintain a competitive marketplace. There is no required disclosure, accountability, regulation or viable oversight of this industry.

Restore market competition, innovation and integrity to the healthcare supplies marketplace by repealing the GPO/PBM anti-kickback "safe harbor" provision.

A bipartisan bill that would have repealed the safe harbor—-and prevented the drug shortage debacle—- was drafted in 2005 by former Senators Herb Kohl (D-WI) and Mike DeWine (R-OH), who presided over four Senate Antitrust hearings on GPO abuses. Unfortunately, it died in the Subcommittee.

PROGNOSIS: Excellent—-If Congress repeals the "safe harbor." Repeal would:

- ***Resurrect*** the moribund U. S. generic drug industry and end the artificial shortages and skyrocketing prices of generics sold through GPOs to healthcare facilities, and through PBMs to individual consumers.

- ***Repatriate*** well-paying manufacturing jobs to the U. S. that have been lost as a result of generic drug imports.

- ***Eliminate*** deaths, complications, and poor outcomes resulting from shortages and high prices of vital drugs.

- ***Save*** our healthcare system an estimated $30 billion annually in the short-term, and as much as $60 billion to $70 billion in the long-term (GPO "fees"+ monopoly premium), as new competitors, entrepreneurs, and investors enter the market and begin production. Cartels raise prices. Competition lowers them.

For documentation, visit www.physiciansagainstdrugshortages.com. Contact: Robert A. Campbell M.D., chair, rcampbellmd@comcast.net; Phillip L. Zweig M.B.A., executive director, plzweig@aol.com; Marion Mass M.D., co-chair, MRNMASS@aim.com.

Disclosure Statement: ***Physicians Against Drug Shortages (PADS)*** is a non-partisan, *pro bono* patient advocacy group whose mission is to end the artificial shortages and outrageous prices of generic prescription drugs. Members include physicians, pharmacists, attorneys, a journalist and concerned citizens. We have no financial conflicts of interest. We have no budget and receive no outside funding. [Rev.060617]