PhysiciansAgainstDrugShortages

FACTS on Group Purchasing Organizations & Pharmacy Benefit Managers

A *$600 billion+* "pay-to-play" scheme, created by the misguided 1987 Medicare anti-kickback "safe harbor" statute, which exempted GPOs & later, PBMs, from criminal penalties for taking kickbacks and rebates from drug makers and other suppliers

DIAGNOSIS:

The anticompetitive contracting and pricing practices, self-dealing, and conflicts of interest 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, equipment and services. Four huge GPO middlemen—-Vizient, Premier, HealthTrust & Intalere—- control purchasing for most of the hundreds of billions in goods used by thousands of hospitals, clinics, and nursing homes. 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 shortages and skyrocketing prices of hundreds of mainstay generic and even branded drugs, notably sterile injectables, including antibiotics (e.g. penicillin), chemotherapeutic agents (e.g. methotrexate), basic IV solutions (e.g. sterile saline), anesthetics (e.g. propofol), and painkillers (e.g. fentanyl), resulting in needless patient deaths (including at least 76 from the 2012 fungal meningitis outbreak alone), complications, inferior outcomes, & longer hospital stays. A Feb. 2014 Government Accountability Office 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 several countries 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.

In 2003, the Dept. of Health & Human Services Inspector General extended the GPO safe harbor to the rebates drug makers pay PBMs, which distribute prescription drugs directly to consumers, inflating their prices by *at least* $130 billion as well. Three giant PBMs—-Express Scripts, CVS Caremark, and OptumRx —- whose total 2016 revenue exceeded $300 billion, account for about 80% of all outpatient prescriptions.

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

WATCH OUR NEW VIDEO!: NoMiddlemen.org. This is a rigged market that enriches these middlemen while denying millions of Americans access to affordable, effective healthcare. In contrast, the original GPO co-op business model worked well for more than 80 years. The first was established in 1910, when several New York City hospitals banded together to save money on supplies—-the sole purpose of a GPO—- by purchasing in bulk. Members paid dues to cover administrative costs. The unsafe safe harbor gave rise to perverse financial incentives that have dramatically inflated prices. That's because the kickbacks are based on a percentage of total contract volume, so higher prices generate more revenue for GPOs.

- Under the "pay-to-play" business model, which took effect in 1991, 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 and market makers. Instead of adding value to healthcare, they subtract it.

- GPOs circumvented the 3% cap on "administrative" fees (aka kickbacks) by creating "marketing" fees, "advance" fees, rebates, pre-bates, 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 circumvent 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 "share backs" (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 the GPO and PBM industries.

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

A bipartisan 2005 bill that would have done exactly that—and prevented the shortages and soaring drug prices— was drafted by the chairman and ranking member of the Senate Antitrust panel, but GPO lobbyists killed it. The bill was resurrected in 2017 by Rep. Mark Meadows (R-NC), but industry lobbyists killed it too.

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 *at least* $230 billion annually: $100 billion+ by eliminating GPO kickbacks, rebates, "fees," and monopoly premiums, as new competitors, entrepreneurs and investors enter the market and begin production, plus *at least* $130 billion by eliminating PBM rebates. 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: ***Physicians Against Drug Shortages*** is a non-partisan, *pro bono* patient advocacy group whose mission is to end the artificial shortages and soaring prices of medications. 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.112418]