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 hospital GPOs & later, PBMs, from criminal prosecution for taking kickbacks and rebates (post-sale kickbacks) from drug makers and other suppliers

DIAGNOSIS:

The anticompetitive contracting and pricing practices, self-dealing, conflicts of interest and kickbacks/rebates of giant buying cartels (a/k/a monopsonies) have undermined the law of supply and demand and free market competition in the *entire* healthcare supply chain, i.e., drugs, devices, supplies, including personal protection equipment (PPE) and services. Three for-profit GPO middlemen—-Vizient, Premier Inc., & HealthTrustpg—-control purchasing for most of the hundreds of billions in goods used by thousands of hospitals, clinics, & nursing homes. Overwhelming evidence, including four Senate Antitrust Subcommittee hearings, federal & 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 soaring prices of hundreds of mainstay generic and even branded drugs, notably generic sterile injectables, including antibiotics (e.g. penicillin), chemotherapeutic agents (e.g. vincristine), basic IV solutions (e.g. sterile saline), anesthetics (e.g. propofol), and painkillers (e.g. morphine), 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 & chemo agents from a contaminated plant in China; increased dependence on China for active pharmaceutical ingredients (APIs) and PPE has created national security risks.

- ***Blocked*** safer, better, cheaper devices & supplies, incl. masks, gowns & ventilators, from use in health facilities; purchasing agents, ***not*** clinicians, often decide which hip implants, pacemakers, syringes etc. are used for patients & 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: In 2018, a 10-vial box of propofol, an essential surgical anesthetic, cost $22 off-contract vs. $55+ on a GPO contract.

In 2003, the Dept.of Health & Human Services Inspector General extended GPO safe harbor protection to the rebates drug makers pay PBMs, which distribute prescription drugs directly to consumers, inflating their prices by *at least* $160 billion as well. Three huge PBMs—-CVS Caremark, Cigna/Express Scripts & OptumRx—- whose total 2021 revenue of $377 billion accounted for about 80% of all outpatient scripts.

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

WATCH 60 Minutes of 5/22/22 "In Short Supply." This is a rigged market that enriches these predatory middlemen while denying millions 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 NYC hospitals banded together to save money on supplies—the sole purpose of a GPO—by purchasing in bulk. Members paid dues to cover admin 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 profits for GPOs & their big hospital shareholders.

- Under the "pay-to-play" business model, which took effect in 1991, GPOs became the agents for vendors, not hospitals. These venal 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 destroy it.

- GPOs circumvented the 3% cap on "administrative fees" (a/k/a 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 annual revenue for a single drug, according to federal court documents.

- Exorbitant GPO "fees" have slashed 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, antitrust lawsuits and independent studies have exposed a laundry list of egregious GPO practices, self-dealing, & conflicts of interest, including: sole-source, long-term contracting, tying & bundling, and penalty pricing; taking equity stakes & "advance fees" (payola) from vendors in return for contracts; awarding stock and options in "captive" firms to top GPO executives; participating in vendor-underwritten slush funds/junkets.

- Since GPOs are owned by hospitals, CEOs of those facilities often get "share backs" (a percentage of the vendor kickbacks) for enforcing compliance with exclusive GPO contracts, so that they benefit *personally* from higher prices. This may explain why HHS & GAO studies 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 vehemently 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 for decades 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 via congressional REPEAL of the ill-conceived GPO/PBM anti-kickback "safe harbor" statute. Congress must CANCEL their "GET OUT OF JAIL FREE CARD!"

A bipartisan 2005 bill that would have done exactly that—and prevented the shortages & soaring drug/PPE prices— was drafted by the chair & ranking member of the Senate Antitrust panel, but GPO/AHA 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/supplies industries and end the artificial shortages and skyrocketing prices of drugs/PPE sold through GPOs to healthcare facilities, and through PBMs to individual consumers.

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

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

- ***Save*** our healthcare system *at least* $260 billion annually; an estimated $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* $160 billion by eliminating PBM rebates. Cartels raise prices. Competition lowers them.

For documentation, visit www.physiciansagainstdrugshortages.com. Contact: Mitchell Goldstein M.D.,M.B.A. chair; Phillip L.Zweig M.B.A., executive director/co-founder, plzweig@aol.com. DISCLOSURE: ***Physicians Against Drug Shortages Inc. (PADS)*** is a non-partisan, *pro bono* patient advocacy group whose mission is to end the artificial shortages and soaring prices of medications, devices, and supplies, incl. PPE. Members include physicians, pharmacists, attorneys, a journalist and concerned citizens. We have no financial conflicts of interest, no budget and cover expenses out of our own pockets. [Rev. 041023]