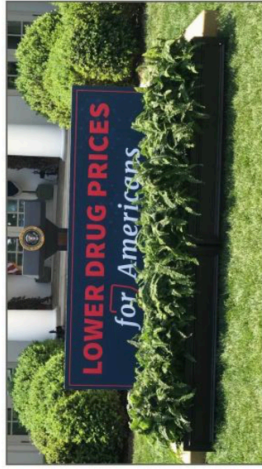


Drug Costs, Drug Shortages and Group Purchasing Organizations

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In 2018, history may be repeating itself. The healthcare marketplace is plagued by similar contracts of mass destruction promulgated by secretive middlemen. They are not really middlemen in the true sense of the word. They do not have capital at risk or inventory of any kind. They mostly write contracts for kickbacks. Why? Because in the healthcare supply chain, Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs) have a unique ability to do so. They have a Safe Harbor for kickbacks which allows them to do this without the usual criminal penalties. The GPO/PBM Safe Harbor is an unfortunate government inducement for good people to do bad things. Like Collateralized Debt Swaps of 2008 not many people know much about GPO or PBM contracts in 2018. Still physicians and patients would do well to learn about these things.

The author was fortunate to be invited to the White House Rose Garden for President Trump's long promised prescription to lower the cost of medications. He went off from the prepared teleprompter text one time when he said, "We are very much eliminating the middlemen. The middlemen became very, very rich right? Wherever these middlemen are. And a lot of people never even figured it out. They are rich. They will not be so rich anymore."

He is right. So now let's try to understand this slightly cryptic language. The Big Four GPOs are Vizient, Premier, Healthtrust, and Intalere. The Big Three PBMs are CVS Health, Express Scripts, and Optum RX. These companies never reveal their secret contract terms with suppliers, insurers, hospitals, and pharmacies. There are clues about the scale of the problem.

Pharmaceutical manufacturers which do research and create new patented medications have a trade group called PhRMA. They are the 35 largest research manufacturers. Their members pay "Rebates" to get through the GPO and PBM Middlemen. "Rebates" is an inside the beltway euphemism for legalized kickbacks. Legalized by one precious Safe Harbor for GPO/PBM Kickbacks. Apparently in the first survey of its kind they have discovered its members paid \$1.44B last year in Kickbacks...I mean "Rebates". That kind of yearly outlay could cure Alzheimers or Diabetes. Instead it simply is siphoned off and raises the cost of medications. 37% of patent medication cost is kickbacks. Patients pay them one way or another via insurance premiums, co-pays, or tax dollars for Medicaid and Medicare programs. In 2019 the projection is for 47% of the cost of patient medications to be kickbacks.

Generic medications are also profoundly affected. Pay-to-

play arrangements make it so only one or two companies are permitted to make certain drugs. So Mallinckrodt is the exclusive manufacturer for acthar which makes a \$40 1952 generic molecule cost \$40,000 per month. Baxter makes salt water for \$545 per bag and nitropruside is \$1,245 per dose. Mylan makes epi-pens with no competition for \$850 per dose. Sole source contracts compel companies to pay huge kickbacks. In return no competitor is permitted. Sole source contracts are the reason we have generic drug shortages. It is not really complex at all.

Restructuring the healthcare supply chain is the essential first step in any plan to make healthcare affordable again. The Big Four Group Purchasing Organizations GPOs write contracts for over 90% of hospital drugs, supplies and medical devices. They offer companies the opportunity to "pay-to-play" if the price is right for sole source contracts. Sometimes two companies are allocated market share. With only one or two manufacturers and only four buyers this creates a fragile supply chain resulting in pervasive shortages of hospital medications since 2006.

In 2017 there were 146 new drug shortages, mostly generics, and many vital. Generic medications should be inexpensive and plentiful. They are neither. Some drugs come off the shortage list because contractually permitted companies increase production. Other times the drug comes off the shortage list because the permitted companies discontinue manufacturing. Then the drug is gone altogether. This has happened frequently.

Prior to 1991 GPOs were small, low revenue companies that served hospitals and were not permitted to demand kickbacks from manufacturers. In 1991 GPOs experienced their Big Bang moment and received permission from Congress and Health and Human Services (HHS) to collect kickbacks. Suddenly the revenues of GPOs exploded. Healthcare costs soared.

The Big Three Pharmacy Benefit Managers (PBMs) also write secret contracts for over 80% of all outpatient prescriptions. They were modest-sized companies until their Big Bang moment in 2003 when the GPO Safe Harbor was inexplorably extended to PBMs. Now PBMs happily join GPOs in ruling over the healthcare universe controlling the entry and pricing for the healthcare supply chain for nearly all outpatient prescription drugs. Kickbacks are a percentage of revenue so inflationary incentives prevail. This explains how in 2000 Americans' prescription drug costs were \$12.1B and in 2017 \$360B. PBMs enjoy extraordinary profit margins. Thus, the rush to either buy one or be bought by one in the marketplace. Merger mania.

Generic pharmaceutical companies and medical device manufacturers have not disclosed just how much they

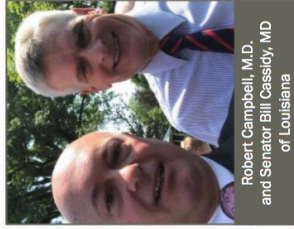
must pay to gain access to their customers on the other side of the GPO/PBM paywall. The cumulative evidence suggests well over \$200B in healthcare cost savings by cutting out the middleman kickbacks. This does not include the incalculable financial benefits of restoring freedom to the marketplace for suppliers to compete. If these funds were re-directed from the pockets of businesses and the campaign coffers of politicians and used instead for healthcare some interesting things would happen. The Association of Community Pharmacists projects outpatient prescription costs would fall by one third if rebates are eliminated. Hospital costs and insurance premiums would fall. Medical device and generic drug manufacturers would experience a renaissance in their businesses. Capital investment for new manufacturing plants in America would result in thousands of high paying American Jobs.

The middle class does not have to disappear. It is time for kickbacks to disappear and the American middle class to re-appear. Of course, all of these financial calculations do not include any calculation of the human toll exacted by the many hundreds of medications in short supply or not available at all. Cardiologists inserting temporary pacemakers because the hospital has no bicarbonate. Bad care. No spinal anesthetics. Bad care. Out of Fentanyl. Bad care.

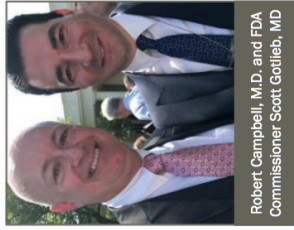
The cost of healthcare is beyond the reach of too many middle-class Americans. Repealing the GPO/PBM Safe Harbor for Kickbacks will fix this problem. A bill is already written and gets it introduced.

Physicians Against Drug Shortages is doing what it can to get it introduced. Mid-term elections are approaching. Politicians will need to make themselves available to their voting constituents. The theme for the mid-term elections should be let doctors and patients join together to save healthcare. Physician-driven and patient-centered Healthcare Town Halls will be coming to many communities. If you wish to host one just let me know. I anticipate 60 in 60 different districts nationwide, but we may have even more. Repealing this Very Unsafe Safe Harbor will be item number one for discussion.

There is no path to affordable, high quality healthcare until free-market competition is restored to the drug/medical supply marketplace. This is possible only if Congress repeals the GPO/PBM Safe Harbor for Kickbacks. Find healthcare kickbacks or opposed. Both Pennsylvania Senators Casey and Toomey are briefed and are in favor of kickbacks. Repeal could be "disruptive" to the market. That is the goal, Senators. Pennsylvanians deserve better. Replace the broken marketplace with a new competitive market that works and lowers costs for patients. What a perfect issue for physicians to assert leadership!



Robert Campbell, M.D. and Senator Bill Cassidy, MD of Louisiana



Robert Campbell, M.D. and FDA Commissioner Scott Gottlieb, MD



President Donald Trump on lowering the cost of prescription drugs at the May Rose Garden Speech said, "We're very much eliminating the middlemen. The middlemen became very, very rich. Whoever those middlemen were—and a lot of people never even figured it out—they're rich. They won't be so rich anymore."

Throughout 2008 America endured an unprecedented year-long financial crisis. The financial infrastructure of the wealthiest nation in the world unraveled week by week, and month by month. It was not until years after the financial marketplace collapsed that experts determined the root cause of the collapse. Collateralized Debt Swaps (CDS), mysterious secret contracts authored by obscure financial middlemen, were identified as the fundamental cause of this financial calamity.