PhysiciansAgainstDrugShortages

Agency: Food and Drug Administration, HHS
Docket No. FDA-2013-N-0124

Food and Drug Administration Drug Shortages Task Force and Strategic Plan; Request for Comments

March 12, 2013

PhysiciansAgainstDrugShortages (PADS) greatly appreciates the opportunity to comment on the development of a strategic plan to prevent generic drug shortages, in accordance with the provisions of the Food and Drug Administration Safety and Innovation Act and the Federal Register Notice Request for Comments of February 12, 2013. PADS also recognizes the FDA's dedication and commitment to ensuring the safety, adequacy and effectiveness of America's drug supply and believes the agency has done everything within its statutory authority to mitigate the devastating clinical impact of the generic drug shortages.

However, the root cause of this crisis is economic and therefore beyond the FDA's purview, a point that the agency has made publicly. Consequently, the solution is also outside the FDA's jurisdiction. Still, the FDA must make every effort to understand the origins of this problem and exercise its moral authority and influence with the White House and Congress to end what has become a global public health emergency. That is why PADS is submitting these comments.

PADS is a grassroots coalition of physicians whose goal is to end these chronic, unprecedented shortages by restoring integrity and free market competition to the broken generic prescription drug industry. We organized PADS for one reason and one reason only: doctors simply cannot get the drugs they need to properly treat their patients. As a result, millions of patients are suffering needlessly, and in many cases dying. Most of the drugs in short supply are sterile injectable chemotherapies and anesthetics administered in hospitals, outpatient facilities and clinics.

These massive shortages are simply unacceptable in what is supposed to be a free market economy. To end this crisis, which was entirely

preventable, we believe it is essential to focus on the underlying cause, not the symptoms. Having thoroughly examined this issue, we're now convinced that the anticompetitive contracting practices, kickbacks, market manipulation and other abuses of giant hospital group purchasing organizations (GPOs) are the root cause.

This buyers' monopoly, which controls the purchasing of an estimated $250 *billion* in goods annually for some 5,000 hospitals, has made it unprofitable for many generic drug companies to safely manufacture these inexpensive, low-margin drugs. In a nutshell, their "pay to play" business model has badly damaged a market that for decades could be relied on to supply lifesaving generic drugs to patients worldwide.

It is no coincidence that virtually all of the drugs in short supply are sold to healthcare facilities through GPO contracts, rather than directly to consumers at retail pharmacies or pharmacy benefit managers (PBMs). The GPOs have decimated the injectables market by undermining the laws of supply and demand that govern virtually every other U. S. industry, from autos to zucchini. Indeed, these cartels have stifled competition in the *entire* hospital supplies industry, including medical devices, capital equipment, and other supplies, from catheters to garbage bags and surgical towels.

There is extensive documentation on these questionable practices, focusing largely on the role of GPOs in undermining competition and innovation in the medical device industry in the years leading up to the drug shortage crisis. This material includes four hearings before the Senate Antitrust Subcommittee; investigations by the Government Accountability Office (GAO), the Office of the Inspector General of the Department of Health & Human Services, and the Connecticut Attorney General's office; media reports, including a prize-winning 2002 investigative series in *The New York Times* entitled "Medicine's Middlemen"; numerous successful antitrust lawsuits filed by entrepreneurial medical device firms against GPOs and/or their dominant supplier partners[1]; independent academic research, and even a book entitled "Group Purchasing Organizations: An

[1] See www.puncturemovie.com

Undisclosed Scandal in the U. S. Healthcare Industry."[2] Many of these documents appear on www.puncturemovie.com.

These anticompetitive practices include, but are not limited to:

- Exclusionary, sole source, long-term contracts awarded to vendors in return for huge but undisclosed administrative, marketing, advance and other fees (a/k/a kickbacks) as well as prebates and rebates;
- Tying and bundling of product lines to give the advantage to large incumbent suppliers and discourage competition from smaller, entrepreneurial companies with fewer products;
- Forced compliance programs that impose stiff penalties on hospitals and wholesalers if the volume of their purchases from manufacturers on contract drops below 95%, in many cases, for a particular product or product line;
- A Byzantine system of manufacturers' rebates to large, favored distributors that ensures that only those distributors can sell to GPO-member hospitals.[3]

Much as the GPO industry lobby, the Healthcare Supply Chain Association (HSCA) would have the Obama Administration, Congress, the healthcare community, and the general public believe that the shortages are complex and the result of a "perfect storm" of "multifactorial" causes---including "overzealous FDA plant inspections, government price controls, "gray market" drug distributors, raw materials shortages, "just-in-time" inventory methods and so on----these explanations simply do not hold up to careful scrutiny.[4] They are either irrelevant, red herrings, or consequences, not

---

[2] Sethi, Prakash, Palgrave MacMillan, 2009.

[3] Earl, Patricia & Zweig, Phillip, "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage," A white paper. January 5, 2012 and Moss, Diana PhD, American Antitrust Institute, White Paper: "Healthcare Intermediaries: Competition and Healthcare Policy at Loggerheads?," May 7, 2012.

[4] ibid.

causes. There is in fact just one root cause: market rigging by the GPOs themselves.

In fact, for knowledgeable market observers, the very existence of prolonged shortages affecting an entire industry would itself implicate anticompetitive behavior.

We'll examine briefly each of the most frequently cited "multifactorial" causes:

- **"Overzealous" FDA inspections.** The kinds of violations FDA inspectors have reported at generic drug plants---mold and metal filings in vials, a 10 gallon bucket of urine in the sterile production area, and so on---can hardly be described as trivial.[5] FDA inspection reports indicate that these findings have often resulted from customer complaints. Asked about allegations of FDA overzealousness, one senior quality control manager, who was laid off after his plant was shuttered, told PADS that they were absolutely untrue. "They [the inspectors) were dedicated people. They did their job like they were supposed to." Amid calls for strong FDA oversight of unregulated compounding pharmacies in the wake of the meningitis outbreak, this putative "cause" has, in our opinion, lost all currency.

- **Government Price Controls:** Some so-called healthcare "experts" have opined that the Medicare drug reimbursement formula, established by the Medicare Modernization Act of 2003, is a form of price control that has caused the drug shortages by squeezing drug maker margins. This formula calls for Medicare to pay an average sales price (ASP) plus 6%. This average sales price is calculated based on data provided by manufacturers. So this is a market price, not a rigid price ceiling. It has no bearing whatsoever on the drug shortages.[6]

---

[5] FDA 483 Inspection Report, 11/7/11-12/2/11

[6] *InsideHealthPolicy.com,* "HHS Rejected ASP Hike Afer Weighing GPO, Drug Distribution Issues, Nov. 9, 2011

- **Manufacturing problems.** Yes, manufacturing problems are a proximate cause of the shortages, but they are the consequences of the market disruptions caused by GPOs.

- **Raw materials shortages.** The GPOs have squeezed the entire generic drug supply chain, from raw materials suppliers to manufacturers and providers. This is a red herring, as evidenced by the fact that products in short supply include simple dextrose (sugar) solution and sodium chloride (salt) solution. As one drug manufacturing consultant put it, "if you can sweeten your coffee, you can make dextrose solution."

- **"Just-in-time" inventory methods.**This is preposterous on its face. Production and inventory managers simply do not sacrifice sales and market share on the altar of "just-in-time" inventory methods.

- **"Price gouging" and "hoarding" by "gray market distributors".** In a disingenuous 2011 "study" on the drug shortages and in subsequent public pronouncements, Premier Inc, one of the big three GPOs, used this term to scapegoat small and mid-sized distributors as "gray market" players and "price gougers." [7] Many of these distributors have operated for decades and perform an important---and perfectly legal--- market function. Often they locate small quantities of drugs on an emergency basis for client facilities. To increase their stranglehold on the supply chain, the GPOs have been seeking to drive out these distributors and to consolidate this function in the hands of three large GPO "authorized" distributors: McKesson, Cardinal, and Amerisource Bergen. Because the smaller distributors are not able to avail themselves of the manufacturers' rebates paid to the Big Three, they must purchase goods at a much higher price. A small quantity of a drug frequently has to pass through several hands before it reaches the distributor who initiated the order. By creating the shortages, the GPOs have caused prices to skyrocket. Trouble is, many drugs are unavailable at any price. The GPOs are the real price gougers.

Whatever infractions a few small drug distributors might have committed

---

[7] Cherica, Coleen *et al,* "Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance analysis," Premier Inc. Mar. 2011.

in the midst of the shortages, they pale in comparison to the damage inflicted on this market by the GPOs. The fact remains that for many hospitals these so-called "gray market" distributors remain the *only* source of many essential drugs.

Our view is entirely consistent with the conclusion of a recent study by Janet Woodcock MD and Marta Wosinska PhD of the FDA that the shortages have resulted from economic and market forces, specifically the "...inability of the market to observe and reward quality."[8] While their study does not delve into the murky details of GPO operations and practices, it does drop the problem right on their doorstep. Our analysis takes their conclusion one step further. The anticompetitive, exclusionary contracting practices, kickbacks, and other abuses of GPOs have completely undermined the economics of this business, to the point where many firms have stopped making these inexpensive drugs altogether rather than produce them at a loss. These practices have also crippled the ability of other drug makers to maintain their plants, equipment, and quality control, resulting in tainted drugs, adverse FDA inspections, and plant closings. This system has dramatically reduced the number of suppliers of vital generic drugs and discouraged potential competitors from entering the marketplace. The barriers to entry created by GPO sole source or dual source contracts are virtually impossible for an entrepreneurial drug maker to overcome.

As a result, there are now just one or two suppliers of many vital drugs, or none at all. For example, APP Pharmaceuticals is currently the only U. S. supplier of propofol, the preferred anesthetic for many surgical procedures. Before the GPOs gained a stranglehold on this marketplace, there were three or more. Propofol is now so difficult to find that some providers have reportedly been forced to pay as much as 3000% of the "normal" pre-shortage price. It is no coincidence that APP was co-founded in 1996 as American Pharmaceutical Partners by Premier Inc., one of the three largest GPOs, as a captive supplier for Premier's member hospitals. According to *The New York Times* of March 26, 2002, Premier executives enriched

---

[8] Woodcock, J. & Wosinska, M, "Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages," Journal of Clinical Pharmacology and Therapeutics, Feb. 2013.

themselves personally by exercising stock options after the company went public in 2001.[9]

Mustargen, the preferred chemotherapy for many pediatric Hodgkin's disease patients, is no longer available at all. According to a study reported in the *New England Journal of Medicine* of December 27, 2012, patients have suffered relapses as a result.[10] Although physicians have worked tirelessly to shield patients from the devastating effects of shortages by substituting first line therapies with second, third, and fourth line alternatives, that practice clearly has failed in this case.

The ongoing deadly meningitis outbreak, which was caused by contaminated drugs sold by an unregulated compounding pharmacy, the New England Compounding Center (NECC), is also a direct result of the shortages. Because FDA-regulated generic drug makers stopped making a widely-used steroid pain killer, many providers were forced to buy it from now-shuttered NECC. That drove NECC to produce the drug in volumes far beyond its capacity to do so safely. Ameridose, a sister company that has also been shut down because of quality problems, had contracts with at least three of the largest GPOs. As of March 11, 2013, 50 people had died and 720 had been sickened by this rare disease, according to the Centers for Disease Control.[11]

On Nov. 15, Rep. Ed Markey (D-MA) and five senior House colleagues called on the Government Accountability Office (GAO) to investigate the role of GPOs in the drug shortages and the compounding pharmacy/ meningitis tragedy.[12]

So how could something like this happen in the U. S., which for years was the world leader in producing safe, effective, inexpensive generic drugs?

---

[9] Bogdanich, Walt *et al,"*When a Buyer for Hospitals has a Stake in Drugs it Buys," *The New York Times,* Mar. 26, 2002.

[10] Metzger, M. L. *et al,* "The impact of Drug Shortages on Children with Cancer---the Example of Mechlorethamine," *New England Journal of Medicine*, Dec. 27, 2012.

[11] Centers for Disease Control website, fungal meningitis outbreak data, Mar. 11, 2013.

[12] Letter from Rep. Edward Markey (D-MA) *et al* to Gene Dodaro, Acting Comptroller General of the U. S.,Nov. 15, 2012.

It began with misguided federal government legislation and policy.

Incredibly, an obscure federal statute, the 1987 Medicare antikickback "safe harbor" provision, exempted GPOs from criminal prosecution for taking kickbacks from healthcare suppliers. Under this "pay-to-play" arrangement, suppliers buy market share by paying GPOs exorbitant but undisclosed "administrative" fees and other remuneration, in return for contracts giving their products exclusive access to GPO-member hospitals.

This was an abrupt departure from the old GPO business model, which worked well for more than 80 years, from the early 1900s until the early 1990s, when the safe harbor rules issued by the Office of Inspector General of the Department of Health and Human Services were implemented.[13] Under the old model, GPOs operated as cooperatives (like REI and the Harvard co-op) that saved money for member hospitals through volume discounts, which is the one and only reason for the existence of GPOs. GPOs were the servants of hospitals. Administrative costs were covered by hospital dues. There may have been occasional shortages involving a handful of drugs, but they were few and far between.

That changed for the worse with the advent of the "safe harbor" GPO business model, which created an inherent conflict of interest. Overnight, GPOs become the marketing agents for vendors, not the servants of hospitals. It also gave rise to perverse incentives in which higher prices for supplies meant more money (a/k/a kickbacks) for GPOs. That's because GPO revenue is based on a percentage of sales volume (price X units sold). So GPOs have an built-in incentive to maximize prices, not lower them. And that's exactly what they've done. Vendors compete for GPO contracts based on who can pay the biggest kickbacks, *not* who can supply the best product at the best price. Today's GPOs are like the troll under the bridge. By paying the toll to the troll, dominant vendors gain exclusive access to member hospitals and eliminate or squeeze competitors. GPOs don't perform research and development, manufacture, maintain inventory, or distribute goods.

---

[13] Medicare and State Health Care Programs; Fraud & Abuse, OIG Antikickback Provisions Jul. 29, 1991.

What's more, purchasing agents, *not* clinicians, typically decide which drugs, medical devices and supplies physicians can use for their patients. These decisions are based largely on how much kickback revenue these products can generate for the GPOs, *not* what is best for patients. As a result, patients and healthcare workers are often denied access to lifesaving, cost-effective goods, from drugs to hip implants, pacemakers, pulse oximeters, safety needles, and countless other products.

But generic drug makers and other vendors have lately found that exclusive access is a double-edged sword. One recent indication that they had finally awakened to that fact occurred in February 2011, when Medtronic, the giant medical device maker, announced that it had cancelled $2 billion in Novation and Premier contracts because they increased healthcare costs.[14] The exorbitant administrative and other fees that the GPOs force generic drug makers and other vendors to pay for the privilege of marketing their goods to member hospitals have rendered many of these companies unprofitable. As one generic drug company executive told a PADS member in early March 2013, "We're not a profitable company because of the GPOs." Generic drug manufacturing is a low margin business to begin with. The presence of an superfluous middleman, which subtracts rather than adds value, can easily turn black ink into red, leaving little money left for investment in equipment, quality control and maintenance.

In the case of smaller, entrepreneurial medical device companies and suppliers, the GPOs have blocked market entry for entire companies and their often innovative products. They achieved the same questionable goal---maximization of kickback revenue---with generic drug makers using a somewhat different tactic. With the drug makers, they have awarded exclusive contracts on a drug by drug basis, with disastrous consequences.[15]

So it is no surprise that FDA inspectors have discovered shocking sanitary and quality violations at many of these facilities. Incredibly, in late 2011 FDA inspectors at the Ben Venue Laboratory plant in Bedford, OH found, among other egregious infractions, a 10 gallon bucket of urine in the sterile

---

[14] Kamp, Jon, "Medtronic Makes Pact-Ending Move," *Wall Street Journal,* Feb. 25, 2011

[15] Op. cit. "Connecting the Dots," Earl & Zweig.

production area. The reason: the company apparently determined that it could reduce head count if workers didn't have to spend 20 minutes "de-gowning" and "re-gowning" after leaving the sterile area to go the bathroom. So Ben Venue, which made critical chemotherapy and other drugs, was forced to shut down. As a result, cancer patients have had to settle for less effective drugs, or none at all.

Documents obtained through discovery in a 2003 whistleblower lawsuit against Novation, Ben Venue's primary GPO, provide a clue as to why the contract drug maker would resort to such outrageous cost-saving methods. These documents show that in 1998, 1999, and 2001, Ben Venue was paying Novation as much as 56.25% of its total annual revenue for a single drug, diltiazem.[16] To be sure, these documents are dated. But because the GPOs refuse to disclose these fees and lobby aggressively to make sure they never have to, recent data is unavailable.

Indeed, the huge unknown in the drug shortage scandal is the amount of the kickbacks the GPOs have extracted from the drug makers and other suppliers, for that matter. Under the safe harbor rules, administrative fees were supposedly limited to 3% of total revenue. To prevent abuses, the GPOs were required to report excess vendor fees to member hospitals.[17] Presumably the rule makers figured that hospital executives would exercise a fiduciary duty to prevent abuse. So to circumvent this, the GPOs cut the executives in on the action, granting them "patronage fees"[18] as their reward for maintaining hospital compliance with GPO contracts. Although the HHS Inspector General was authorized to request this data, a March 30, 2012 report by the Government Accountability Office found that since 2004 the HHS OIG "has not routinely exercised its authority" to do so.[19]

---

[16] Excess Fee Report, Novation, 1998, 1999, 2001.

[17] Op.cit. OIG Antikickback Provisions.

[18] Novation Patronage Fee Agreement, 2003 (see www.puncturemovie.com.

[19] Government Accountability Office, "Group Purchasing Organizations: Federal Oversight and Self-regulation," Mar. 30, 2012.

Thanks to the powerful GPO lobby, which includes the American Hospital Association, there is virtually no disclosure, transparency, regulation or oversight of this industry. Few, if any outsiders know where all the billions in kickbacks are going. In a statement describing his GPO investigation to the Senate Antitrust Subcommittee hearing of March 15, 2006, Connecticut Attorney General Richard Blumenthal (now Sen. Blumenthal, Democrat of Connecticut) referred to GPOs and a related slush fund as "an insidious, incestuous, insider system."

This is first and foremost a life and death issue. But it also has significant budgetary implications. While decimating the generic injectables market, these cartels have also inflated healthcare costs by at least $30 billion annually, according to an empirical study published in the fall 2011 issue of the *Journal of Contemporary Health Law and Policy.*[20] In fact, if the 38%-40% savings now being achieved in a Medicare demonstration project through *bona fide* open competitive bidding for home health care supplies---wheelchairs, oxygen tanks, hospital beds, and the like---were applied to the approximately $250 billion in supplies sold annually through GPO contracts, the savings would be staggering. History has shown, time and again, that competition lowers prices. Cartels increase them.

PADS 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. healthcare supplies industry. To accomplish that, it is essential to repeal the 1987 Medicare antikickback safe harbor provision, which created the GPO pay for access scheme in the first place.

This legislation would in effect reinstate the old, tried and tested, pre-safe harbor GPO business model, in which GPOs actually saved hospitals money. We are by no means advocating the elimination of GPOs.

The drug shortage legislation enacted last July 2012 under the Food and Drug Administration Safety and Innovation Act simply will not end the drug shortages, because it's focused on symptoms, not causes. It fails to address the underlying economic and market forces that caused this crisis

---

[20] Litan, Robert, Singer, Hal, & Birkenbach, Anna, "An Empirical Analysis of Aftermarket Transactions by Hospitals," The Journal of Contemporary Health Law and Policy, Fall 2011.

in the first place. Further, it tacitly accepts drug shortages as the “new normal.” PADs does not. This travesty is inexcusable. It was preventable. It should never have been allowed to happen.

A bipartisan “Discussion Draft” bill that would have repealed the safe harbor was drafted in 2005 by staff members for former Senators Herb Kohl (D-WI) and Mike DeWine (R-OH), then chairman and ranking member, respectively of the Senate Antitrust Subcommittee.[21] Unfortunately, the bill never made it out of the Subcommittee.

PADS believes that if that bill had been enacted in 2005, there would never have been a drug shortage crisis. Repealing the "safe harbor" now would represent a huge step forward in repairing this broken marketplace. It would immediately send a signal to established generic drug makers that they would be able to turn a profit even after upgrading plant and equipment to comply with FDA requirements and good manufacturing practice (GMP). Repeal would also encourage new entrants into the marketplace. Accordingly, we urge the Obama Administration and Congress to enact a repeal bill without further delay.

Other proposals cited in the Federal Register Notice, including the “qualified manufacturing partner program” would be rendered totally unnecessary by the repeal of the safe harbor and the restoration of free market competition and open competitive bidding. Other incentives to encourage manufacturers to “establish and maintain high quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and /or create other conditions to prevent or mitigate shortages” would also be rendered unnecessary if free market forces were finally permitted to work their magic in the generic injectable drug marketplace.

The FRN also requests information on other U. S. government agencies that could help prevent or mitigate the drug shortages. In fact, besides the White House and Congress, several other U. S. government agencies ignored repeated requests by stakeholders and several members of

---

[21] U. S. Senate, 109th Congress, 1st Session, Discussion Draft: A bill to amend title XI of the Social Security Act to repeal a safe harbor with respect to vendors in order to ensure full and free competition in the medical device and hospital supply industries.

Congress to correct the inherent flaws in the GPO system and provide oversight over the industry.

- **The U. S. Justice Department and the Federal Trade Commission.** Both of these agencies, which share antitrust enforcement authority, have failed to diligently investigate numerous complaints of anticompetitive GPO practices and stop GPO abuses. Healthcare Statement 7 gives DOJ and FTC clear authority to halt "anticompetitive contracting practices." As recently as November 9, 2011, nine days after President Obama announced his Executive Order to the FDA to stop drug shortages, five U. S. senators signed a letter to FTC chairman Jon Leibowitz asking the FTC to "review" anticompetitive GPO practices.[22] To the best of our knowledge, no action was ever taken. Accordingly, the White House should immediately order DOJ and the FTC to undertake thorough investigations into GPO anticompetitive practices, self-dealing, possible misuse of funds and other abuses and to prosecute violations of criminal law where appropriate.

- **The Office of Inspector General, Department of Health and Human Services.** As the GAO report of March 30, 2012 pointed out, since 2004 the OIG has failed to exercise its authority to request information on fees paid by vendors to GPOs. The FDA should prevail upon the Secretary of HHS to demand that the GPOs supply this data immediately and make it available to the public on the OIG Website.

But while these investigations and audits would be useful in identifying and exposing violations of law by GPOs, vendors, and hospitals, they would still not correct the underlying problem and restore the generic injectable drug industry to health. That can only be achieved through repeal of the Medicare antikickback safe harbor. Accordingly, we strongly urge FDA Commissioner Margaret Hamburg to advise the President and Congress to enact this critical legislation without further delay.

---

[22] Letter from Sen. Herb Kohl (D-WI) *et al* to Federal Trade Commission Chairman Jon Leibowitz, Nov. 9, 2011. (see www.puncturemovie.com.

Full disclosure: PADS members have no conflicts of interest or financial vested interests in this matter. We are working on this project on a pro bono basis and covering all expenses out of our own pockets.

Respectively submitted,

Phillip L. Zweig MBA (NY)
Executive Director
PhysiciansAgainstDrugShortages
(212) 490-0811
(347) 920-8188 (cell)
Email: plzweig@aol.com

Joel Zivot MD (GA)
Chairman
PhysiciansAgainstDrugShortages
(404) 783-4338
Email: joel.zivot@gmail.com

Co-chairs
Sean Adams MD (IL)
Curtis Baysinger MD (TN)
Robert Campbell MD (PA)
Mollyann March MD (MD)
Harry Parr DO, MBA (MI)
Michael Rie MD (KY)