FOR RELEASE: Wednesday, January 4, 2012

"Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U. S. Drug Shortage"

By Patricia Earl, Principal/CEO, Secure Pharma Distributor Network

and Phillip L. Zweig, Financial Journalist, Author, & Independent Consultant

Authors Note: Because of widespread misinformation on the causes of this public health emergency and the extreme urgency of resolving it, we have written this paper in a timeline format. Kindly cite the authors and report if you use this material. We thank Bill Bandy, retired CEO and founder of United Medical Supply, a Dallas-based medical supplies distribution firm, for his invaluable research assistance.

COPYRIGHT © 2012 by Patricia Earl and Phillip L. Zweig

Abstract:

Recent reports by the Department of Health and Human Services (HHS) Office of Planning and Evaluation (ASPE)¹, the Food and Drug Administration (FDA)² and other sources on the acute shortage of generic drugs have attributed the shortages to everything from raw materials shortages and manufacturing problems to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and FDA drug approval delays. Based on these analyses, President Obama on October 31 issued an Executive Order instructing the FDA to require manufacturers to notify the agency of impending shortages, to expedite regulatory reviews, and to increase staff in its drug shortages program.

In this white paper, the authors argue that these explanations, and President Obama's Executive Order, miss the point entirely. These reasons are ancillary to the root causes of this crisis. In fact, it is the direct result of the anticompetitive, exclusionary contracting practices, self-dealing, collusion, kickbacks and conflicts of interests of giant hospital group purchasing organizations (GPOs), which have undermined free market competition in drugs, medical devices, and supplies in the U. S. These purchasing cartels, which contract for \$200 billion+ in hospital goods each year for about 5,000 non-profit, acute care hospitals, have rigged this market in favor of a handful of dominant suppliers and distributors, thereby making it unprofitable for other companies to make or sell these inexpensive, hard-to-manufacture drugs.

These practices have eroded manufacturing capacity for these products to the point where the U. S. is the only developed country with such critical shortages. Incredibly, the HHS and FDA reports neglect to mention GPOs as a contributing factor, much less the primary cause, of this crisis. Further, contrary to GPO claims that they obtain the lowest prices for drugs and other hospital supplies, the opposite is in fact the case. The evidence shows that they inflate healthcare costs by tens of billions a year.

Accordingly, President Obama's order will do nothing to alleviate the shortages in the long-term. The only viable solution is to restore integrity and free market competition to this corrupt marketplace. And that, the authors argue, can only be accomplished by repealing an obscure 1987 statute called the Medicare anti-kickback "safe harbor" provision, which gave rise to this debacle in the first place. Enacted ostensibly to give small hospitals more bargaining leverage with suppliers, the safe harbor exempted GPOs from criminal

¹ Glied, Sherry *et al*, "Economic Analysis of the Causes of Drug Shortages," Department of Health and Human Services Office of Planning and Evaluation, Oct. 2011.

² Food and Drug Administration, "A Review of FDA's Approach to Medical Product Shortages," Nov. 3, 2011

prosecution for receiving kickbacks from vendors. The result is a massive pay-to-play scheme that benefits only healthcare executives and other insiders.

Highlighting the questionable ties between Premier Inc., the second largest GPO, and APP Pharmaceuticals, the authors describe in detail the origin and evolution of the current crisis. They conclude by urging Congress to repeal the anti-kickback safe harbor with deliberate haste and call on the appropriate federal and state law enforcement agencies to use their subpoena power to thoroughly investigate the business and financial dealings of GPOs and executives of GPOs, manufacturers and member hospitals. Finally, these agencies should prosecute those suspected of violating the law in connection with this unpardonable national scandal.

Background: GPOs and the Drug Shortage:

America is facing a severe and growing drug shortage that is jeopardizing the health of millions of patients, including an estimated 500,000 cancer victims. At least 15 patients have reportedly died because they were unable to get their medications. With stock shelves becoming bare in hospital pharmacies and at drug distributors throughout the nation, physicians are unable to effectively treat their patients, especially those with the most critical illnesses. As of November 23, 2011, 88 critical care and oncology medications, mostly sterile injectable drugs, were on the Food and Drug Administration's (FDA) shortage list. While the shortage has been building for several years, it came to a head on October 31, when President Obama issued an Executive Order to the FDA to take emergency action to address it. Overnight, drug shortages became page one news.

Reports by HHS, the FDA, the Government Accountability Office, and witnesses in congressional hearings have offered a number of explanations for the crisis, ranging from raw materials and labor shortages to manufacturing problems, burdensome regulation and FDA drug approval delays. All of these reasons are totally off the mark. The real reason is that there is no free market in drugs, medical devices and healthcare supplies in the U. S.

Shortages of this magnitude and duration are unprecedented in modern times. Other than disruptions triggered by events such as wars, strikes, external political shocks, and natural catastrophes---World War II, the 1973 Arab Oil Embargo, Hurricane Katrina and the Japanese tsunami come to mind---they simply do not occur in a free market economy. To cite one shocking example on the FDA list, how is it possible that hospitals could run short of simple intravenous saline solution, which is nothing more than water and sodium chloride, a/k/a table salt?

The reason: Giant hospital group purchasing organizations (GPOs), which control the purchasing of an estimated \$200+ billion in drugs, devices and supplies for about 5,000 private acute care member hospitals, have rigged the entire healthcare supply chain, not just for generic drugs but also medical devices and supplies. The list includes everything from chemotherapy medications to cotton balls and syringes. In a throwback to the disgraced Soviet economic system, these purchasing cartels have undermined market competition and the laws of supply and demand using a myriad of anticompetitive abuses. Make no mistake: this is an artificial shortage that was entirely preventable. It was created by bad government policy and lack of regulatory oversight, healthcare industry collusion and self-dealing, and massive lobbying and campaign contributions by GPOs and other healthcare special interests to key members of Congress. It will take smart, honest government policy to remedy it.

This industry is a monopsony (a buyer's monopoly) dominated by six GPOs, which control about 90% of the goods bought by hospitals through GPOs. Two of them---Irving, TX-based Novation and Charlotte, NC-based Premier Inc.--- account for approximately two thirds of the goods under contract. Virtually every such hospital, other than government-run facilities, belongs to at least one GPO. GPO executives and contracting officers---not clinicians---dictate which drugs, devices, and supplies are used in these hospitals, and which companies are allowed to sell them.

³ Food and Drug Administration, "Current Drug Shortages," Nov. 23, 2011.

⁴ Press Release, White House, Oct. 31, 2011.

The GPOs use a variety of anticompetitive, exclusionary practices that favor dominant manufacturers that can pay them the largest kickbacks, which were permitted as a result of the passage of the 1987 Medicare anti-kickback "safe harbor" exemption. These practices include, but are not limited to:

- Exclusionary, sole source, long-term contracts;
- 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.

These practices have created a concentrated market that excludes other existing and would-be suppliers and distributors. So increases in demand for generic drugs have resulted in shortages and surging prices, with no other suppliers able or available to fill the gap. It is no coincidence that the problem is generally limited to generics sold to healthcare facilities through GPO contracts rather than directly to consumers through retail pharmacies. Or that shortages on this scale have not been reported in Europe, although it now appears that skyrocketing U. S. prices may be siphoning off supplies of certain drugs there.

The pernicious role that anticompetitive GPO contracting practices, not to mention collusion, kickbacks, self-dealing, conflicts of interest and other abuses, play in the healthcare supply chain has been well-documented for the medical devices and supply sectors of this marketplace. Overwhelming evidence accumulated over more than a decade shows that these corrupt practices harm, and even kill, patients and healthcare workers by denying them access to innovative, cost-effective devices and supplies, such as safety syringes, pulse oximeters, and surgical towels. What's more, they undermine competition, medical innovation and job creation and inflate healthcare costs by up to \$37.5 billion a year, including \$17.3 billion in government outlays for Medicare and Medicaid, according to one recent study. These figures, of course, do not begin to take into account the incalculable costs of medical errors, malpractice lawsuits, and pain and suffering.

This evidence includes testimony in four Senate Antitrust Subcommittee hearings, investigations by federal and state agencies, media exposés, numerous civil antitrust lawsuits, reports by academics and industry consultants, and even a book, entitled "Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry." Much of this material can be found at www.puncturemovie.com. These same anticompetitive GPO practices have now produced an unprecedented national medical emergency.

Over the last decade, it has become abundantly clear to objective participants in the healthcare supply industry that the kickback-based GPO business model benefits no one except top GPO and hospital executives, "K" Street lobbyists, academics-for-hire, and powerful politicians seeking campaign contributions. Indeed, some portion of the vendor kickbacks winds up in the campaign coffers of members of Congress, who in turn make sure the GPOs get to keep their kickbacks. So it is no wonder that politicians of both parties feed at the GPO trough and preserve this venal enterprise. This scandal is Wall Street redux.

However, until the drug shortage reached crisis proportions, it was not apparent that the GPOs had undermined free market competition for generic drugs as well. Because generic drugs are commodity products---one manufacturer's propofol or sodium chloride solution is virtually identical to another's---the same anticompetitive practices in this market segment have created a shortage. This is just the latest, most visible example of how, under this scheme, the rich get richer and the sick get sicker.

⁵ Litan, Robert E. & Singer, Hal J., "Do Group Purchasing Organizations Achieve the Best Prices for Member Hospitals? An Empirical Analysis of Aftermarket Transactions," Navigant Economics, Oct. 2010.

⁶ Sethi, Prakash, Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry," New York: Palgrave/Macmillan, 2009.

This dire predicament is a direct result of the perverse incentives and market distortions created by the antikickback "safe harbor" provision, which exempts GPOs from criminal prosecution for taking kickbacks from healthcare vendors. In virtually every other industry in America, paying or taking kickbacks is illegal. Not surprisingly, the safe harbor soon became a pirate cove.

What follows is a timeline that documents in detail the origin and evolution of the drug crisis, beginning with the passage of the anti-kickback safe harbor. Highlighting the questionable ties between Premier Inc., its senior executives, and APP Pharmaceuticals, a giant U. S. generic drug supplier with 18 drugs on the November 23 FDA shortage list, it will show how exclusionary contracts, self-dealing, and conflicts of interest gave rise to this debacle. It will also show how this crisis was created in Washington by moneyed special interests:

- GPOs have plundered the healthcare supply system with the full knowledge and consent of the United States government, notably the Congress, the Department of Health and Human Services, the Justice Department and the Federal Trade Commission. The Justice Department and the FTC, which are empowered to halt anticompetitive contracting practices and other abuses, have to date failed in their duty of care to the American people.
- Senator Herb Kohl (D-WI), chairman of the Senate Antitrust Subcommittee, former Senator Mike DeWine (R-OH), former Connecticut Attorney General Richard Blumenthal (now Sen. Blumenthal), Sen. Patrick Leahy (D-VT), Sen. Charles Grassley (R-IA), and Bill Nelson (D-FL) are among the handful of members of Congress or former members who have courageously attempted to halt these practices or have spoken out publicly against them. On the other hand, Sen. Charles Schumer (D-NY) has steadfastly opposed legislation that would have ended GPO kickbacks and avoided the current crisis. Elikewise, Sen. Max Baucus (D-MT) appears to have been co-opted by the powerful GPO lobby. In May, he launched a misguided "investigation" into why a major medical device maker cancelled more than \$2 billion in GPO contracts, when he should have joined with Senate colleagues who have been investigating the GPOs.
- The only way the drug shortage will be resolved in the long term is by restoring integrity and free market competition to the GPO industry. That can only be achieved by repealing the anti-kickback safe harbor, which would reinstate criminal penalties for paying or accepting vendor kickbacks.

Timeline:

1910-1987

From the early 1900s to 1987, group purchasing organizations had been an entirely legitimate way for hospitals to save money on supplies, devices and drugs by buying in bulk. They were a kind of buyer's cooperative, created by groups of hospitals to boost their negotiating leverage in dealing with manufacturers. They covered their costs from a percentage of the savings they achieved for their hospital members.

Then in 1987, GPO industry lobbyists persuaded Congress that hospitals, particularly small ones, could save more money if "administrative fees" were paid by vendors rather than from cost savings. The Medicare anti-kickback safe harbor was passed as an amendment to the Social Security Act. Overnight, Congress turned a bona fide, cost-saving business model into one that was replete with conflicts of interest. Before long, GPOs morphed into a corrupt "pay to play" scheme whose goal was to maximize vendor kickbacks. In return for billions in kickbacks, the vendors got sole source and dual source contracts that gave them exclusive access for their often inferior, unsafe and obsolete products at GPO member hospitals. And because GPO revenue (kickbacks) is based on a percentage of vendor sales volume, higher product prices mean more money for the GPOs. Hospitals really don't care because the higher prices are reimbursed by Medicare---and

⁷ Hearings before the Senate Antitrust Subcommittee, April 30, 2002 and Mar. 15, 2006.

⁸ Press Release, "Baucus Investigates Medtronic to Ensure that Patients, Hospitals Don't Bear Increased Costs," Senate Finance Committee Web site, May 2, 2011.

ultimately taxpayers. GPOs became the marketing agents for dominant vendors that could pay the biggest kickbacks, turning their backs on their original role as servants of patients and hospitals.

By overriding the laws of supply and demand that operate in the rest of the economy, GPO kickbacks have created market distortions and concentrations that have resulted in the drug shortage and price spikes. Whether patently illegal or blessed by Congress, kickbacks are kickbacks. They destroy competition and inflate prices for everyone, whether they are consumers of medical services, condominium buyers, or even restaurant-goers.

Under the "safe harbor," administrative fees are capped at 3% of sales. If they exceed that level, the GPOs are supposed to report them to the hospitals and, if requested, to the Department of Health and Human Services. Trouble is, the GPOs have played a semantics game with the 3% limit, inventing new fees---marketing fees, prebates, rebates and the like--- that together have amounted to up to 20% or more of the total sales price. And by lining the pockets of senior hospital executives with kickbacks, the GPOs ensure that this reporting requirement is meaningless. According to *Washington Monthly* of July/August 2010, total fees paid by one manufacturer to Novation on one product line amounted to 94% of the total sales volume. All of these fees are built into the manufacturers' Wholesale Acquisition Cost (WAC), which is based on their true costs of production and the marketing fees they expect to incur when selling products to GPO members.

1996:

In a move that would quickly lead to a major consolidation of GPOs, the Justice Department and Federal Trade Commission revise antitrust rules, giving GPOs additional protection against antitrust actions except under "extraordinary circumstances." As in the case of the anti-kickback safe harbor, the U. S. government expands antitrust protection in the name of giving GPOs more ability to negotiate better deals for hospitals. In fact, these changes would have the opposite effect. In their wake, two GPOs, Novation and Premier Inc. emerge as the dominant players.

Jan. 1: American Healthcare Systems, SunHealth Alliance, and Premier Healthcare Alliance combine to form Premier Inc.

Dec. 1996:

Aided by grants totaling \$650,000 from the National Institutes of Health, Texas engineer Thomas J. Shaw begins to market a revolutionary, FDA-approved safety syringe that would virtually eliminate the risk of potentially deadly accidental needle stick injuries among healthcare workers. Each year, an estimated 800,000 workers get stuck with contaminated needles, and more than 1,000 of them contract HIV/AIDS, hepatitis and other blood-borne diseases. But just as his company, Retractable Technologies, Inc. (RTI), launches a marketing campaign, Becton Dickinson (BD), the dominant syringe maker, signs a \$1.8 billion, 7 ½ year sole source contract with Premier Inc., one of the two largest GPOs, to supply syringes, blood collection holders, and related devices. That effectively prevents Retractable from marketing VanishPoint products to about 1,500 Premier Inc. member hospitals.

Not coincidentally, that same year, Premier co-founds American Pharmaceutical Partners, a generic drug maker, with a \$100 investment. Before long, Premier starts directing its members to buy generics from American Pharmaceutical rather than competitors.¹⁰

⁹ Blake, Mariah, "Dirty Medicine," Washington Monthly, July/Aug. 2010.

¹⁰ Bogdanich, Walt, Meier, Barry, & Walsh, Mary Williams, "When a Buyer for Hospitals Has a Stake in Drugs It Buys," *The New York Times*, Mar. 26, 2002.

1997:

Retractable Technologies, Inc. hires William "Bill" Price, a former United States attorney for the Western District of Oklahoma, to press the Justice Department Antitrust Division to examine alleged anticompetitive activities of GPOs. The Antitrust Division initiates an investigation, but concludes "that GPO contracting practices were not a 'substantial barrier' to hospitals' purchasing safer products if they so chose." ¹¹

Dec: 12: American Pharmaceutical Partners signs a six-year contract with Premier.

1998:

Mar. 16: *Business Week* publishes "Locked out of the Hospital," the first article on how GPOs block entrepreneurial device makers from marketing safer devices and other supplies to member hospitals. RTI is Exhibit A in the article. 12

Jun. 29: Premier and McKesson, a major wholesaler, strike a deal in which McKesson pays \$155 million for a company in which Premier owns a minority stake and Premier, in turn, awards McKesson a 20-year exclusive contract to supply pharmaceutical, medical and surgical products under its so-called "Provider Select Program." ¹³

Aug. 6: Sen. Paul Sarbanes (D-MD) writes to Antitrust chief Joel Klein on behalf of a constituent, Greiner Meditech, a medical supply firm, expressing concern about the anticompetitive contracting practices of GPOs.

August 17: Sen. John McCain (R-AZ) writes to Andrew Fois, assistant Attorney General for legislative affairs, expressing similar concerns. On August 28, Klein replies to Sen. Sarbanes that the Antitrust Division is "currently engaged in an evaluation of the competitive impact of GPO contracting practices under the federal antitrust laws."

Sept. 1998: Apparently in response to public and media pressure, Novation contacts Shaw offering to market RTI's safety blood collection tube holder with a Novation private label, according to an article by Shaw in the *Dallas Business Journal*. ¹⁴ Under that arrangement, Novation proposes that RTI change its own label to Novation's. And instead of charging just 27 cents per unit, as Shaw had proposed, Novation would charge its own hospital members \$1 each. Novation and RTI would share in the 270% markup, providing RTI stops "talking to the press." Shaw declines the offer.

Sept. 1998: RTI files a civil antitrust lawsuit against VHA Inc. (parent of Novation), Becton Dickinson, Tyco International and other defendants in state court in Brazoria County. Texas.

2000:

Jan. 2000: Former President George H. W. Bush and Donald Berwick, M. D., president and CEO of the Institute for Healthcare Improvement (IHI) address Premier's Governance Education Conference at the

¹¹ Letter from Sen. Patrick Leahy (D-VT) to U. S. Attorney General John Ashcroft, Mar. 5, 2001.

¹² Zweig, Phillip & Zellner, Wendy, "Locked Out of the Hospital," *Business Week*, Mar. 16, 1998.

¹³ Hensley, Scott, "A First for Premier," *Modern Healthcare*, June 29, 1998.

¹⁴ Shaw, Thomas, "Examine the 'Questionable' Side of GPOs," Dallas Business Journal, Mar. 14, 1999.

Phoenician hotel in Scottsdale, Arizona. Speaking fees are not disclosed. ¹⁵ Berwick would later serve briefly as administrator of the Centers for Medicare and Medicaid Services (CMS) in the Obama Administration.

July 17: In response to a letter requesting clarification on the legality of up-front payments, rebates, signing bonuses and prebates by vendors to GPOs, the Office of the Inspector General, HHS, states that payments intended to "induce the purchase of items or services, some of which are Federally reimbursable...appear to pose a significant risk of fraud and abuses." He adds that these and "similar payments are suspect under the anti-kickback statute, placing persons offering or receiving them potentially at risk." ¹⁶

Sept. 28: Sen. Patrick Leahy writes to Justice Department expressing concern about antitrust barriers to hospitals purchasing safer products. On December 8, the Justice Department replies that following an investigation in 1998 and 1999, the Antitrust Division had "concluded that GPO contracting practices were not a 'substantial barrier' to hospitals' purchasing safer products if they so chose." ¹⁷

Nov. 6: President Bill Clinton signs the Needle Stick Safety and Prevention Act of 2000, requiring that "safety-engineered" needles and other safety devices be used, whenever available, at healthcare facilities. But despite the superior safety technology of RTI and other entrepreneurial safety device makers, they would continue to be blocked from marketing their products to GPO-member hospitals. One company, Bio-Plexus Inc., maker of a highly-rated safety blood collection device, is forced to file for bankruptcy and eventually goes out of business.

2001

Jan. 29: Retractable Technologies, Inc. re-files antitrust case against Becton Dickinson, Tyco International, and VHA Inc. in federal district court in Texarkana, TX, adding defendants Novation, Premier Inc. and Premier Purchasing Partners.

Feb. 25: 60 Minutes airs segment with correspondent Mike Wallace on how anticompetitive, exclusionary contracts keep safer retractable needles out of hospitals in favor of poorly-rated "safety" needles made by Becton Dickinson, the dominant manufacturer. Among other findings, 60 Minutes reveals that 1) The New Jersey Hospital Association, receives a kickback from Becton Dickinson, its "preferred" supplier, for every syringe sold to its member hospitals; and 2) Janine Jagger, the BD Professor of Healthcare Safety at the University of Virginia, acknowledges that her needle safety data base doesn't collect information on the make and model of syringes involved in accidental needle stick injuries.

Mar. 5: Citing the *Business Week* article and *60 Minutes* segment, Sen. Patrick Leahy writes to Attorney General John Ashcroft asking DOJ to "once again to conduct a thorough an immediate examination of this aspect of the health care marketplace in order to determine if there have been violations of our antitrust laws." Noting that his wife is a nurse, Sen. Leahy writes, "I know that I would be devastated if my wife were ever stuck with a contaminated needle. Keeping safe needles off the market can be a deadly risk."

Sept. 21: Sen. Leahy writes Health and Human Services Inspector General Janet Rehnquist requesting a status report on an HHS study on the anti-kickback "safe harbor" for GPOs.

2002:

Mar. 4: *The New York Times* launches "Medicine's Middlemen," a year-long investigative series on GPOs that documents numerous examples of GPO anticompetitive abuses, self-dealing, exclusionary contracts and

¹⁵ Press Release, Premier Inc. "Governance Conference speakers include Bush, Berwick," 1999.

¹⁶ Letter from D. McCarty Thornton, chief counsel to Inspector General, HHS, to unnamed recipient, July 17, 2000.

¹⁷ Letter from Sen. Patrick Leahy (D-VT) to Attorney General John Ashcroft, Mar. 5, 2001.

conflicts of interest and describes how these practices have harmed patients, healthcare workers and inflated healthcare costs. In this first article in the series, the *Times* reveals how the GPOs and Tyco block the maker of an innovative oxygen meter, called a pulse oximeter, from marketing the device to hospitals, despite the fact that it had been shown to prevent blindness in infants, among other advantages. The series exposes a pay-to-play system in which companies must pay exorbitant fees to have their devices considered for contracts, and thousands of dollars just to sit next to GPO executives at dinner.

Other articles in the series discuss how GPOs use the vendor kickbacks to establish ill-conceived money losing ventures, such as e-commerce firms, that enable executives to profit from stock and options when the firms go public.¹⁸

In this article and in a March 26 follow-up piece, *The New York Times* exposes collusion and self-dealing between Premier Inc. and generic drug supplier American Pharmaceutical Partners, which in fact had been set up as a drug broker, not a manufacturer. By pushing its 1,500 member hospitals to buy their generic drugs from American Pharmaceutical, Premier was able to parlay its original \$100 investment in American Pharmaceutical into a stake worth \$46 million when the company went public on Dec 14, 2001. At least two top Premier Inc. executives, including former executive vice president William J. Nydam, enriched themselves personally, according to the *Times*. For his part, Nydam received stock options worth \$1.2 million, based on the initial offering price.

Thanks to Premier, American Pharmaceutical had become one of the largest makers of sterile injectable drugs in the U. S., despite serious quality control problems that led to the withdrawal or recall of 20 drugs by the time the article was published. Sen. Herb Kohl, then chairman of the Senate Antitrust Subcommittee, calls the Premier/American Pharmaceutical connection "scandalous." About four months later, Premier Inc. sells its stake in American Pharmaceutical.

The New York Times of August 15 reports that the Inspector General of the Department of Health and Human Services had issued subpoenas to Premier Inc., American Pharmaceutical Partners, Express Scripts, and Horizon Medical Products seeking documents on Premier's ownership of securities in companies to which it had awarded contracts. The *Times* also discloses that Express Scripts, a pharmacy benefit manager, which had been awarded a ten-year contract by Premier in 1995, had in turn awarded stock options to Premier Inc. CEO Richard Norling. ²⁰

While not discussed in the *Times* articles, one example of how Premier enabled American Pharmaceutical to dominate the generic market is seen in the case of propofol, a widely used sedative. When AstraZeneca's Diprivan went off patent in mid-2000, this set up a scramble among five generic drug makers to market their versions of the drug. But instead of competing among themselves to supply propofol to hospitals at the lowest price, they were forced to compete for "winner take all" contracts with the three largest GPOs for the right to sell their products to hospitals. Ultimately, the big winner in this battle was American Pharmaceutical. Because the losing bidders were blocked from marketing propofol to GPO hospitals for the duration of the American Pharmaceutical contract, they stopped making it altogether. That happened for one simple reason: they could no longer make a profit.²¹

¹⁸ Bogdanich, Walt, Meier, Barry, & Walsh, Mary Williams, "Questions Raised of Conflicts at 2 Hospital Buying Groups," *The New York Times*, Mar. 4, 2002.

¹⁹ Bogdanich, Walt, Meier, Barry, & Walsh, Mary Williams, "When a Buyer for Hospitals Has a Stake in Drugs It Buys," *The New York Times,*" Mar. 26, 2002.

²⁰ Walsh, Mary Williams, "3 Medical Supply Companies Receive U. S. Agency Subpoenas," *The New York Times*, Aug. 15, 2002.

²¹ Earl, Patricia, "Going on the Record: Premier's Analysis of the Current Drug Shortage—Myth vs. Reality," Oct. 2011

Although the Senate hearings focused mainly on how anticompetitive GPO practices locked medical device makers out of the hospital marketplace, the GPOs were quietly using many of the same practices in curtailing competition in the generic drug market as well, with a few twists. Once the generic drug market coalesced into a handful of large suppliers, including American Pharmaceutical Partners, Hospira, Baxter and Teva, the GPOs did not exclude any one of them from the entire market, as they did with the entrepreneurial device makers. Instead, they awarded exclusive contracts for a particular drug to each member of the favored few. The result was the same. Drug makers that do not have contracts for say, propofol, cannot compete with those that have contracts to sell it to GPO member hospitals. To win a contract, a manufacturer would often use a drug as a loss leader, bundling it with other generics in its product line.

For the generic drug market, the result was a form of price controls, the elimination of competition, higher prices, and the erosion of manufacturing capacity---all of which by 2011 would produce a drug shortage emergency.

Apr. 30: Senate Antitrust Subcommittee holds first hearing, "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovation," on anticompetitive abuses of GPOs. From 2002 to 2006, Sen. Herb Kohl and former Sen. Mike DeWine would preside over four Subcommittee hearings on these practices. Testimony and documents in this first hearing present evidence of self-dealing, conflicts of interest, exclusionary contracting practices, and other GPO abuses and call into question GPO claims that they save hospitals money. Senators Kohl and DeWine order the GPO industry to create a code of ethical conduct or face corrective legislation and announce that they intend ask the Justice Department and the Federal Trade Commission to "reexamine their guidelines that protect GPOs from Federal antitrust scrutiny in most cases."

Apr. 30: General Accounting Office pilot study on GPOs finds that "buying groups do not always offer hospitals lower prices."

May 23: Masimo Corp, an Irvine, CA maker of highly-regarded pulse oximeters, which was blocked from the marketplace by the GPOs and Tyco, the dominant maker, files an antitrust lawsuit against Tyco.

June 25: Harvard Law School Professor Einer Elhauge releases a legal analysis of anticompetitive GPO practices. In his report, he writes that while media attention has focused on how exclusionary agreements preclude "existing products that are cheaper and better...by far the bigger costs of such exclusionary agreements is that they are likely to prevent all sorts of innovative products from ever being created. These costs are harder to see and estimate because the alternative products are not tangible. But they should be the greatest source of social concern. And it should be no surprise that incumbent firms that currently have dominant market shares for particular devices would be greatly interested in entering into arrangements that discourage innovation that might displace their position."

July 19: *The New York Times* reveals \$1 million payment by Becton Dickinson, described as a "special marketing fee," to Novation in connection with the award of an exclusive, three-year syringe contract to BD. It also discloses an additional \$100,000 payment related to a four-year contract for intravenous catheters. ²³ These payments were at the core of a *qui tam* lawsuit filed on July 15, 2003 by former Novation contracting officer Cynthia Fitzgerald against Novation, BD, and other defendants, as well as a Justice Department criminal investigation of Novation. ²⁴ In a sworn deposition she gave in connection with RTI's antitrust lawsuit, she stated that she was fired by Novation after objecting to the GPO's business practices. According to an

²² Elhauge, Prof. Einer, "The Exclusion of Competition for Hospital Sales through Group Purchasing Organizations," June 25, 2002.

²³ Meier, Barry, & Walsh, Mary Williams, "Questioning \$1 million Fee in a Needle Deal," *The New York Times*, July 19, 2002.

²⁴ USA et al vs. Novation LLC et al, 3:03-cv-01589. Northern District of Texas- Dallas.

article in *The New York Times*, which had obtained a copy of the deposition, Ms. Fitzgerald said she told her supervisor that "I don't look good in orange or in stripes." ²⁵

Sept. 7: New York State Attorney General Eliot Spitzer opens an investigation into whether GPOs had violated federal Medicaid laws and undermined competition in purchasing hospital supplies, according to *The New York Times*. 26

Oct. 8: *The New York Times* publishes "A Region's Hospital Supplies: Costly Ties," disclosing conflicts of interest between Premier Inc. and its New York agent, the Greater New York Hospital Assn. (GNYHA), that result in higher prices for hospital supplies. According to the report, Premier in 2001 supplied \$11.9 million in commissions, or a third of its total, for helping to market goods to GNYHA hospitals. The article quotes local hospital officials as saying that they had gotten better deals for their institutions by buying directly from manufacturers. Premier provides significant financial support to the GNYHA, which is a *de facto* GPO. The article also reveals that a 1997 report on Premier commissioned by the GNYHA itself had questioned Premier's performance in saving money for hospitals.

2003:

May 2: Sen. Kohl and Sen. Mike DeWine write joint letter to Secretary of Defense Donald Rumsfeld cautioning him on DOD's plan to hire GPOs to run the military's healthcare supplies procurement, pointing out that "...the savings figures that GPOs frequently cite as benchmarks to demonstrate savings are based on a manufacturer's list price that hospitals rarely, if ever, pay."

May 7: Retractable Technologies, Inc. announces that it has settled its civil antitrust lawsuit against Premier Inc., Novation and Tyco International for \$50 million in cash and other compensation.

July 16: Senate Antitrust Subcommittee holds second hearing on GPOs, entitled "Hospital Group Purchasing: Has the Market Become More Open to Competition?" The Subcommittee concludes that progress in opening up the medical device marketplace to competition has been slow and inadequate.

2004:

Mar. 2004: Despite the media exposés, the Senate Antitrust investigation, and civil antitrust lawsuits, Secretary of Health and Human Services Tommy G. Thompson appoints a little-known lobbyist named Herb B. Kuhn, a former senior vice president for public affairs at Premier Inc. with no medical credentials, as director of the Center for Medicare Management (CMM). [Mr. Kuhn holds B. S. in business from the Emporia State University of Kansas.] With this questionable appointment, former GPO executives and their allies begin to insinuate themselves into key policy-making positions in the federal healthcare bureaucracy.

July 2: Retractable Technologies announces settlement of antitrust case against BD for \$100 million in cash.

July 2004: Department of Justice and Federal Trade Commission release joint report on competition in health care, which was based on 2003 hearings. While it presents conflicting views of GPOs critics and defenders on anticompetitive practices, tying and bundling, and cost savings, the report is short on conclusions. It does however, reaffirm that Health Care Statement 7, a key tenet of healthcare antitrust law, "does not preclude

²⁵ Walsh, Mary Williams, "Accusation of Conflicts at a Supplier to Hospitals," *The New York Times,* July 19, 2002.

²⁶ Meier, Barry, "Spitzer Opens Inquiry into the Business Practices of Hospital Buying Groups," *The New York Times*, Sept. 7, 2002.

²⁷ Meier, Barry, "A Region's Hospital Supplies: Costly Ties," *The New York Times*, Oct. 8, 2002.

Agency action challenging anticompetitive conduct---such as anticompetitive contracting practices---that happens to occur in connection with GPOs."²⁸

Aug. 21, 2004: *The New York Times* reports that the Justice Department has launched a wide-ranging criminal investigation of Novation, the largest GPO.²⁹ The investigation is reportedly delayed by the untimely deaths, within two months of each other, of two assistant U. S. attorneys involved in the case. They were Thelma Quince- Colbert, head of affirmative civil enforcement in the Ft. Worth U. S. Attorney's office, and criminal chief Shannon Ross in the Dallas office. No action was ever taken by the Justice Department against BD or Novation.

Sept. 14: Senate Antitrust Subcommittee holds third hearing on anticompetitive practices of GPOs, entitled "Hospital Group Purchasing: How to Maintain Innovation and Cost Savings?" While noting that progress had been made in addressing GPO conflicts of interest and anticompetitive practices, Sen. Kohl and former Sen. DeWine, in order to make these reforms permanent, attempt to introduce reform legislation but are rebuffed by the GPO and hospital lobbies and Sen. Charles Schumer.

In a statement submitted to the Subcommittee for the hearing, the Service Employees International Union (SEIU) applauds the Subcommittee's investigation into anticompetitive GPO practices and supports reform. It singles out Novation for special criticism.

2005:

Jan. 2005: Inspector General, Health and Human Services releases study on GPOs disclosing that 21 hospitals in the survey failed to properly account for distributions from three GPOs on Medicare reports.

Feb. 17 & 21: *The Los Angeles Times* reports that UCLA's Bowyer Oncology Center saved \$800,000 on its annual budget of \$13 million for chemotherapy drugs by purchasing them outside a Novation/Cardinal Health contract ---in the face of strong opposition from UCLA officials. The follow-up article discusses the secrecy surrounding GPO contracts, and the refusal of Novation and Cardinal to disclose pricing information and fees paid to Novation by its suppliers.³⁰

Mar. 23: A Los Angeles jury awards Masimo Corp. \$140 million in damages in its antitrust case against Tyco. That amount is automatically tripled to \$420 million.

2005: 109th Congress, First Session. Sen. Herb Kohl and Sen. Mike DeWine circulate "discussion draft" of bill, entitled "Ensuring Competition in Hospital Purchasing Act," which would repeal the Medicare anti-kickback "safe harbor" exemption. The bill never makes it out of the Subcommittee because of opposition from GPOs, hospital executives and Sen. Charles Schumer.

2006:

Mar. 15: Senate Antitrust Subcommittee holds fourth hearing on GPO abuses, entitled "Hospital Group Purchasing: Are the Industry's Reforms Sufficient to Ensure Competition?" In this fourth hearing, the lead witness, Distinguished Professor Prakash Sethi of Baruch College, City University of New York, concludes that

²⁸ Report by the Federal Trade Commission & the Department of Justice, "Improving Health Care: A Dose of Competition," July 2004.

²⁹ Walsh, Mary Williams, "Wide U. S. Inquiry into Purchasing for Health Care," *The New York Times*, Aug. 21, 2004.

³⁰ Hiltzik, Michael, "A Valuable Drug Discovery at UC," *Los Angeles Times*, Feb. 17, 2005 & "Secrets Aid Drug Suppliers, Not UC," Feb. 21, 2005.

the answer is no. "We cannot talk seriously about a meaningful GPO initiative until Congress realigns the financial incentives so that the hospitals and not the vendors are once again the GPOs' only clients," Prof. Sethi says. "As long as vendors continue to pay fees to the GPOs, any attempt to create, implement, and enforce a voluntary code is doomed to failure," he says. Sen. Schumer, meanwhile, defends the hospitals and GPOs and lambasts his Senate colleagues for holding the hearing. "This is getting to the point of absurdity here, to the point of absurdity," he declares.

In a statement submitted to the hearing, Connecticut Attorney General Richard Blumenthal (now Sen. Blumenthal), reports on the findings of his investigation into GPOs and a related private fund called the Healthcare Research & Development Institute (HRDI). Calling GPOs and HRDI an "...incestuous, insidious, insider system...," he states that "My GPO investigation has uncovered suspect interrelationships and questionable business practices involving hospital, GPO and major medical supplier executives whose practices often benefit themselves, rather than patients, insurers and government programs that pay hospital bills." He urges the Subcommittee to introduce corrective legislation and advises "more aggressive federal action to investigate and prosecute antitrust violations by GPOs..."

Although this was to be the final Subcommittee hearing on GPOs, Sen. Kohl would later tell *Antitrust*, a professional journal, that "oversight of hospital group purchasing organizations (GPOs)" would continue to be high on the Subcommittee's agenda. "We're concerned about patients getting access to medical devices and removing anticompetitive obstacles that in the past have blocked patient access to lifesaving devices as a result of some GPO practices. We've done a lot of work in that area. We don't want to let go." And he added: "The GPO industry would prefer that we leave them alone, terminate our oversight, and go away. And we say we're not going away because we've found that once we remove our scrutiny the industry seems to go right back to where they were. So that oversight is important and we're going to continue that."³¹

Apr. 24: Harvard Business School Prof. Michael E. Porter and Prof. Elizabeth Olmsted Teisberg of the UVA's Darden Graduate School of Business publish "Redefining Health Care," a seminal treatise on competition in healthcare. The book includes a scathing indictment of GPOs. "Most troubling is that some GPOs are funded by suppliers rather than solely by hospitals," they write, adding that "To enable value-based competition, every buying group practice should be consistent with open and fair competition. There is no valid reason for buying groups to accept financing or any payments from suppliers; if a buying group adds value, the customers (hospitals) should voluntarily pay for it." 32

May 5: Mitra Behroozi, executive director of the New York Local 1199 SEIU Benefit and Pension Funds, is appointed to a three-year term as a commissioner of the Medicare Payment Advisory Commission, or MedPac, an obscure but influential government agency responsible for advising Congress on Medicare payments policy. At about this time, the SEIU enters into a secret pact with the Greater New York Hospital Association (GNYHA) calling for the SEIU to abandon its support for GPO reform in return for continued generous increases in salary and benefits for members, according to union insiders who requested anonymity.

July 17: New York Times article describes workings of HRDI, a private company owned by hospital and GPO executives that arranged for large vendors to buy access to them with annual payments of about \$40,000 or more, until it was shut down and fined in the wake of an investigation by the Connecticut and Florida attorneys general. HRDI member-owners also received all-expense paid trips to upscale golf resorts and other vacation destinations where the meetings were held. The executive owners included Richard Norling, chairman and CEO of Premier; Joseph Zaccagnino, chairman of VHA Inc., the parent of Novation, and president and CEO of Yale-New Haven Hospital; Barry Friedman, president & CEO of Albert Einstein Healthcare Network and former chairman, Premier Hospitals Alliance and the Greater New York Hospital Association; Gary Mecklenburg, then

³¹ Interview with Sen. Herb Kohl, *Antitrust*, Spring 2007.

³² Porter, Michael E. & Teisberg, Elizabeth Olmsted, "Redefining Health Care," Boston: Harvard Business School Press, 2006.

head of Northwestern Memorial Hospital, president of the American Hospital Association, and a director of Becton Dickinson, was chairman of the group. He received \$50,000 a year, according to the *Times*. ³³

July 31: British press raises questions concerning the selection of Novation to take over the National Health Service's (NHS) £4 billion (\$8 billion US) supply operation, replacing NHS Logistics. *The Mail on Sunday* of July 30 writes that the Labour Party "was last night savaged over its 'creeping privatization' of the NHS after it emerged a firm handed a £4 billion deal is at the centre of a massive fraud probe in America." At the Labour Party convention in Manchester in September, workers from NHS Logistics go on strike in protest. ³⁵ At a "fringe meeting" connected with the convention, Health Minister Patricia Hewitt declines to answer questions on why the British government would hire a firm that was under criminal investigation in the U. S. to run its health care supply operation. ³⁶ According to an official of UNISON, the Britain's largest public sector trade union, who asked not to be named, the U. S. Justice Department had assured the British government that the case "would go nowhere."

Oct. 1: Herb Kuhn, the former Premier lobbyist, is appointed acting deputy administrator of the Centers for Medicare and Medicaid Services (CMS).

Nov. 20: Confronted about his position on GPO kickbacks at a post-election public forum sponsored by *The New York Times*, Sen. Charles Schumer acknowledges, "the kickbacks should go." Five years later, the kickbacks remain.

Nov. 20: Rochester Medical, a maker of a Foley catheter that prevents infection, settles antitrust case against Premier Inc., one of four defendants in the case, for \$8.8 million in cash. Less than a month later, the company settles with C. R. Bard for \$49 million. In 2007, it settles with Novation in return for a contract and in 2009 with Tyco for \$3.5 million, out of which it would pay \$2.5 million in legal expenses.

Nov. 21: U. S. Department of Commerce announces that Premier Inc. and two other companies have been named winners of the 2006 Malcolm Baldrige national quality award. The award, billed as the highest honor the U. S. government can bestow on a business organization, is reported in *USA Today, Charlotte Observer,* the *San Diego Union-Tribune*, and other media. [Premier has offices in Charlotte and San Diego.]

After being notified of the investigations into Premier's business practices and the numerous conflicts of interest between Premier and the Baldrige program, all three newspapers run stories questioning the government's decision to give the award to Premier. Premier CEO Norling, it turned out, was chairman of the Foundation for the Malcolm Baldrige National Quality Awards, the money-raising arm of the award. Premier reportedly had donated at least \$150,000 to the Foundation, and Norling had raised more than \$1 million. Further, the executive director had worked for Norling at Premier, and Premier employees had served as examiners in the program.

In response to misstatements by Norling to the media suggesting that Premier had been exonerated by the Senate Antitrust Subcommittee for anticompetitive abuses, ³⁸ Subcommittee Chief Counsel Jeff Miller takes the

³³ Bogdanich, Walt, "Hospital Chiefs Get Pay and Perks for Advice on Selling to Hospitals," *The New York Times*, July 17, 2006.

³⁴ Churcher, Sharon & Owen, Glen, "US Firm given £4 billion NHS deal by Labour faces 'bribes' probe," *The Mail on Sunday*, July 30, 2006.

³⁵ Percival, Jenny, "Blair 'Buying Time" but leadership loses angry NHS Vote," *The Times*, Sept. 27, 2006.

³⁶ Nunns, Alex "The £4 billion ripoff," *Red Pepper*, Nov. 2006.

³⁷ Weiland, Morgan, "GPO Reform in Offing? Congress Monitors, While Schumer Shifts Stance," *The Gray Sheet*, Mar. 26, 2007.

³⁸ Jones, Del, "Company Exonerated in Antitrust Probe Wins Award," USA Today, Nov. 22, 2006.

highly unusual step of issuing a statement making it clear that was not the case. The Subcommittee's ongoing investigation of GPOs, he says, "uncovered many serious obstacles to competition operating to the detriment of patients and hospitals." While noting that the GPO industry had implemented "substantial voluntary reforms" and promised to halt market-rigging practices, he adds that "We will continue to monitor this industry to ensure that competition prevails and that these voluntary reforms are permanent." 39

In the San Diego Union Tribune of December 8, Curtis Rooney, president of the Health Industry Group Purchasing Association (HIGPA), the GPOs' trade association, tacitly acknowledges that the industry had hoped the award would aid its efforts to preserve the safe harbor. "I hope (Senate subcommittee members) read about the Baldrige and nod approvingly," he said, adding that "This sort of award is like having your friends say great things about you." 40

Despite calls to Premier from previous Baldrige recipients to return the award, it refuses.

2007

May 18: Medical Device Manufacturers Association (MDMA), a trade group of entrepreneurial medical device makers, sponsors a \$1000 per person breakfast fund-raiser at the Grand Hyatt Hotel for Sen. Max Baucus. At the meeting, executives ask Baucus to help in eliminating anticompetitive GPO contracting practices and repealing the anti-kickback safe harbor. One representative cites anecdotal evidence indicating that GPO kickbacks inflate healthcare supplies prices by 30% to 40%, or more than \$30 billion a year. This evidence includes estimates of former GPO contracting officers, as well as examples of how market prices of certain products, such as pulse oximeters, declined after new entrants were finally able to compete against the dominant manufacturers.

2008:

Sept. 10: APP Pharmaceuticals (formerly American Pharmaceutical Partners), is sold to German drug maker Fresenius SE for \$3.7 billion.

2009:

Mar. 27: From Mar. 27 until Sept. 17, 2010, three top executives of the Greater New York Hospital Association (GNYHA), the New York agent of Premier Inc., contribute a total of \$9,800 to Sen. Schumer's campaign war chest, according to the Center for Responsive Politics. Contributors include GNYHA president and CEO Kenneth Raske, GNYHA Ventures president Lee Perlman, and David Rich, head of advocacy.

May 18: Former Premier lobbyist Herb Kuhn is appointed to the Medicare Payment Advisory Commission (MedPac).

June 16: CUNY Distinguished Professor Prakash Sethi publishes "Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry."

Aug. 14: *The New York Times* reports that the Senate committees on finance, aging, and judiciary have launched a joint investigation into GPO business practices, seeking to determine, among other things, whether GPOs were inflating healthcare costs. Senators Herb Kohl, Charles Grassley and Bill Nelson sign a letter to seven GPOs demanding information on their business practices.⁴¹

³⁹ Drummond, Mike, "Award Raises Questions," *Charlotte Observer*, Dec. 1, 2006.

⁴⁰ Darce, Keith, "Local firm wins prize, and some controversy," San Diego Union Tribune, Dec. 8, 2006.

⁴¹ Walsh, Mary Williams, "Senators Investigate Hospital Purchasing," *The New York Times*, Aug. 14, 2009.

Nov. 11: In a *Forbes* commentary, former GPO executive Daniel DeLay writes that the GPO system "raises costs for everyone. It creates an inherent conflict of interest for the GPOs," adding that "the administrative fee system has strayed far from its original purpose of financing contracting operations, morphing into a source of backdoor revenue for hospitals. Even after paying high salaries and operating expenses, large pools of excess fees abound." ⁴²

2010:

Mar. 30: Lawyers for Cynthia Fitzgerald, the relator in a *qui tam* lawsuit against Becton Dickinson and Novation, settle the case for \$3 million. Under the agreement, Fitzgerald was to get 28% of the recovery and the defendants were to donate \$50,000 to a Dallas healthcare facility designated by Fitzgerald.⁴³

July/Aug. 2010: Washington Monthly publishes "Dirty Medicine," an exposé on GPOs that refutes GPO claims of cost savings with actual transaction data. In the article, Diane Smith, a former contracting officer at Dallasbased Broadlane, a major GPO, relates the case of a Tulsa entrepreneur who was struggling to market an innovative surgical towel with a strip that shows up on x-rays, thereby preventing it from being left accidentally in a patient after an operation. "It should have been a no-brainer," she says. "But GPOs make their money by charging vendors fees. And if you get a percentage of sales, going with a lower bid from a little company just loses you money and pisses off the big vendors with multiple contracts." She adds that in order to get hospitals to approve higher-priced contracts, Broadlane employees fed them misleading data. "Our job was to bamboozle hospital CFOs and purchasing managers," she says. "My boss used to call it getting them to drink the Broadlane Kool-Aid."

Aug. 16: APP Pharmaceuticals becomes the sole supplier of propofol to U. S. hospitals after Teva Pharmaceuticals loses its bid for a GPO contract and bows out of the business. ⁴⁵ Quoted in the August 16 issue of *Fierce Pharma Manufacturing*, an online industry newsletter, Teva says that "neither recall, warning, nor lawsuit is behind its exiting the business. Rather, the drug is hard to make and barely profitable."

However, this development does not preclude Teva from selling other generics, since each one of the dominant generic makers has an exclusive or near exclusive contract on one drug. But the overall result is the elimination of competition in the marketing and sale of virtually all generic drugs sold through GPO contracts to hospitals.

Sept. 24: Sen. Charles Grassley, ranking member of the Senate Finance Committee, releases minority report on GPOs rebuking GPO claims that they save hospitals money. The report concludes that "in light of the lack of empirical data on GPO savings, Congress should consider legislation to provide HHS OIG (Office of the Inspector General) with greater oversight. In this way, the OIG could conduct an independent and objective analysis and assess the true value provided by GPOs to hospitals, and in turn, to the Medicare and Medicaid programs."

Oct. 2010: Navigant Economics releases empirical study by researchers Hal Singer and Robert Litan on the cost of the GPO kickback model. Using actual transaction data, they conclude that GPO kickbacks inflate

⁴² DeLay, Daniel, "Watch Out for GPOs," Forbes, Nov. 12, 2009.

⁴³ Hagens Berman Web site, www.hbsslaw.com.

⁴⁴ Blake, Mariah, op. cit.

⁴⁵ Earl, Patricia, op. cit.

⁴⁶ "Empirical Data Lacking to Support Claims of Savings with Group Purchasing Organizations." Senate Finance Committee minority report, Sen. Charles Grassley, ranking member, Sept. 24, 2010.

annual healthcare costs by up to \$37.5 billion, including \$17.3 billion in government outlays for Medicare and Medicaid. 47

2011

Feb. 25: *The Wall Street Journal* reports that Medtronic, the world's largest medical technology company, had cancelled five Novation contracts worth \$2 billion, citing the need to remove costs from the healthcare system. On March 1, Medtronic confirms that it had also cancelled a national spinal-products contract with Premier Inc. earlier in the year. 49

In the article, Tenet Healthcare Corp. CEO Trevor Fetter is quoted as having told analysts that "manufacturers paying for GPOs has always appeared strange, and that customers paying the fees is an appropriate model." Not mentioned in the article is the fact that before becoming CEO of Tenet in Nov. 2002, Fetter had served for nearly three years as CEO of Broadlane, a large GPO founded by Tenet. ⁵⁰ At the behest of the GPO lobby, Senate Finance Committee chairman Max Baucus announces in a May 2 press release that he had opened an investigation into Medtronic's decision to cancel the contracts, asserting that "GPOs allow hospitals and other health care entities to save money by aggregating purchasing volume and using that leverage to negotiate discounts with medical device manufacturers." ⁵¹

Mar. 11: Premier Healthcare Alliance publishes a report attributing the drug shortages and price increases to raw materials "quality situations," manufacturers' financial decisions, enforcement of FDA standards, and "price gouging" by "gray market" distributors. Nowhere is there any mention of its anticompetitive, exclusionary contracting practices. It alleges that these secondary market distributors buy scarce drugs from small regional wholesalers, pharmacies or other sources, hoard them until shortages develop, and then market them to hospitals, often at many times the normal price. In fact, by using their monopsony power to eliminate competition and extract a myriad of fees from both manufacturers and distributors, Premier and other purchasing cartels inflate the prices of healthcare supplies to the end users (the hospitals), creating a "red market" in these goods. Thanks in large part to the GPOs, many American hospitals, and the healthcare system generally, are drowning in red ink, while hospital and GPO executives, as the Connecticut attorney general had found, continue to enrich themselves at the expense of patients, healthcare workers, and taxpayers. Under this corrupt system, every one---manufacturers, distributors, hospitals, clinicians and patients--- is at the mercy of the GPOs.

June 21: Pharmacy benefit manager (PBM) Express Scripts holds a funding-raising luncheon for Sen. Baucus at its downtown Washington offices. Contributions are \$5,000 for a host, \$2,500 for a co-host; and \$1,000 for a PAC or individual, according to the Center for Responsive Politics. Taken together, people associated with Express Scripts are Sen. Baucus's second largest contributors, according to the Center. Express Scripts had a close relationship with GPOs, particularly Premier, for years. In 1995, Premier awarded Express Scripts a 10-year contract, and former Premier CEO Richard Norling had been a board member. In

⁴⁷ Litan, Robert, & Singer, Hal, op. cit.

⁴⁸ Kamp, Jon, "Medtronic Makes Pact-Ending Move," *The Wall Street Journal*, Mar. 25, 2011.

⁴⁹ Kamp, Jon, "Medtronic Also Cancelled Spinal Contract with Premier," *Dow Jones Newswires*, Mar. 1, 2011.

⁵⁰ Trevor Fetter bio on Tenet Healthcare Web site.

⁵¹ Press release, "Baucus investigates Medtronic to Ensure Patients, Hospitals Don't Bear Increased Costs," Senate Finance Committee Web site, May 2, 2011.

⁵² Cherica, Coleen *et al*, "Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance analysis," Premier Inc. Mar. 2011.

2002, the Inspector General of the Department of Health and Human Services subpoenaed Express Scripts in connection with stock options awarded to Norling.

On July 21, 2011, exactly one month after the fund-raiser, Express Scripts would announce plans to acquire rival Medco for \$29.1 billion. The controversial move would generate intense opposition by consumer groups concerned about diminished competition and higher costs. On August 12, GNYHA's Lee Perlman weighed in with a \$1000 contribution to Baucus's campaign war chest, according to the Center for Responsive Politics.

Aug. 2011: In an equally specious, follow-up "study," entitled "Buyer beware: Drug shortages and the gray market," Premier Inc. continues its campaign to discredit small distributors and deflect blame for the drug crisis from where it really belongs: its own monopolistic contracting practices. These practices had made it economically unattractive to manufacture, distribute and sell hard-to-make, cheap-to-sell, critical generic drugs. A drug manufacturer that is willing to push the price of its medicine low enough to secure long-term contracts with the nation's three largest GPOs can lock out other manufacturers from the market, making it economically infeasible for competitors to produce the medicine. In an article in *Health Day* of Sept. 30, 2011, Dr. Jay Brooks, Chairman of Hematology/Oncology at Ochsner Health System in Baton Rouge, Louisiana., sums it up when he says, "Few people make them and the margins are not very high." **

Comparing apples with oranges, Premier Inc. deliberately overstates the markups charged by small distributors, alleging that they averaged 650% and ran as high as 4,533%. However, an analysis by *Pharmaceutical Commerce*, a respected trade publication, would later show that the markups ranged from 29% to 729%. The publication noted that the original and even the revised numbers were not necessarily representative of anything at all, because the sample consisted of solicitations that Premier member hospitals chose to submit, rather than a true scientific sample of invoices.

Premier intentionally omits the fact that these secondary distributors must pay manufacturers significantly higher wholesale acquisition cost (WAC) prices than GPO-designated wholesalers for the same products, rendering their overall profit margins and market share relatively insignificant. Further, because small independent distributors are essentially blocked by the GPOs from selling to about 5,000 private acute care hospitals, they are unable to achieve the scale needed to match the artificially lower negotiated selling prices offered by the large wholesalers.

Take, for example, the case of propofol, which is sold in 20 milliliter (ml) vials. By now, APP Pharmaceuticals had become the sole U. S. supplier of this anesthetic, which had been in short supply since 2009. While Diprivan was a proprietary drug, it was in steady supply and the manufacturer was not forced to drop its prices in competitive bidding situations with GPOs. As noted earlier, that changed after it went off patent in mid-2000.

As indicated in the Sept. 30 *Health Day News* article, the hospital in Baton Rouge, La., has a GPO contract to buy the product for \$0.48 per vial. However, the national drug data base shows that the drug's wholesale acquisition price is \$5.60 for that vial, which is the lowest price a wholesaler or distributor pays to buy propofol directly from the manufacturer. GPOs contract with dominant distributors – usually one of the big three national wholesalers – to be the exclusive, primary Authorized Distributors of Record (ADR) for hospitals. Under the GPO contract, the ADR receives an invoice from the manufacturer for the higher WAC cost of \$5.60. When the ADR pays the invoice, it deducts 2%, or \$0.11, [the ADR's gross profit] from the manufacturer's WAC price, for a net cost of \$5.49. The ADR sells the drug to the hospital for the GPO contract price of \$0.48, then files a claim with the manufacturer, called a "chargeback," to recover the \$5.12 difference between \$5.60 and \$0.48. So that \$0.11 cash discount yields the ADR a 23% gross profit on the transaction (\$0.11/\$0.48x100) plus any service fees the ADR may have negotiated with the GPO for this particular member. This chargeback transaction between the manufacturer and GPO wholesaler is exclusionary and not offered to the secondary distributors when they serve as the back-up supplier to the hospital. [See Table 1]. ⁵⁵ Indeed, this Byzantine

-

⁵³ Cherici, Coleen *et al*, "Buyer beware: Drug Shortages and the gray market," Premier Inc. Aug. 2011..

⁵⁴ Gardner, Amanda, "Drug Shortages Even Worse This Year," *Health Day News*, Sept. 30, 2011.

⁵⁵ Earl, Patricia, op. cit.

system of chargebacks and rebates is a subterfuge devised by the GPOs for one reason and one reason only: to prevent secondary distributors from competing.

Table 1: Examples of Pharmaceutical Contract Pricing When On GPO Contract and Off Contract.

Generic Drug Pricing WAC: On vs. Off Contract	Propofol	Sensorcaine
	<u> </u>	
Price When No-Adverse Market Supply Issue:		
Manufacturer WAC Price - Invoice Price only	\$5.60	\$150.00
Wholesaler Cash Discount of 2% - Deducted off Invoice	\$0.11	\$3.00
Net Cost of Drug to Wholesaler	\$5.49	\$147.00
GPO Contract Price*	\$0.48	\$23.00
Percent Profit Retained by Wholesaler Price (\$0.11/\$0.48)	23.33%	13.04%
Discount off WAC (\$5.60 less 0.48cent)*	\$5.12	\$127.00
Percent Discount Savings	91.43%	84.67%
Price Between Two Distributor Trading Partners:		
Manufacturer WAC Price to Authorized Distributor (ADR)	\$5.60	\$150.00
ADR Invoice Price to Small Distributor**	\$6.60	\$175.00
Cost Plus Invoice Price to Distributor	\$1.00	\$25.00
Percent Markup on ADR to Distributor	17.86%	16.67%
Direction of Occasion Observation	T	I
Price If Market Supply Channel is Disrupted:	# 0.00	0.475.00
Small Distributor Price from ADR**	\$6.60	\$175.00
Sell Price to Hospital-Non GPO Eligible**	\$7.60	\$200.00
Cost Plus Mark-up on Sale to Hospital (\$1.00 per vial)	\$1.00	\$25.00
Percent Markup on Small Distributor Price	15.15%	14.29%
Cost Impact on Hospital Reported to GPO:	<u> </u>	<u> </u>
GPO negotiated contract price on Manufacturer Product	\$0.48	\$23.00
Non-GPO authorized distributor sale at WAC+***	\$7.60	\$200.00
Additional Cost to Purchase Off-Contract Alternative	\$7.12	\$177.00
Cost Impact on hospital reported to GPO	1483.33%	769.57%
Profit Margin on ADR purchase based on GPO Contract	23.33%	13.04%
Profit Margin of ADR on sale to Small Distributor	17.86%	16.67%
Profit Margin on Sale based on Non-GPO Distributor Sale****	15.15%	14.29%

^{*} Manufacturer limited contract price and chargeback's to GPO-designated Wholesaler ONLY

Secondary distributors do not have access to these GPO discounts and are restricted by the GPOs and manufacturers from selling products at these low GPO prices, even if the secondary distributor's customer is a participating GPO member. Instead, if they are forced to purchase a drug from an ADR to supply a customer, secondary distributors must pay the WAC price of \$5.60 plus a negotiated ADR service fee for a total invoice price of \$6.60. The secondary distributor then sells it to the hospital for \$7.60, making \$1.00, or a 16% mark-

^{**} Manufacturer and ADR set price to small distributor

^{***} Manufacturer and GPO restrict contract pricing to ADRs only

^{****} Non-GPO sale is WAC plus reasonable mark-up by small distributor

^{****} May include higher mark-up% for actual UPS/FedEx Overnight shipping charges

up, on this transaction. The \$1.00 markup must cover the cost of processing the order, SG&A, financing inventory, carrying cost, handling, packaging and shipping.

Unlike the ADRs authorized by the GPO, secondary distributors are not entitled to file for the chargeback from the manufacturer, and therefore do not receive a rebate to avoid suffering a loss on a GPO sale. So by comparing the GPO-negotiated rate (\$0.48) to the price (\$7.60) that secondary distributors have to charge for each vial, Premier conveniently neglects to mention that secondary distributors can't sell at GPO prices. The Premier "study" unscrupulously implies that all small distributors are making a 1,483% profit (\$7.60/\$0.48 x 100). The reality is that smaller pharmaceutical distributors in the U.S. are legitimate, licensed, and highly regulated secondary suppliers to hospitals that need expedited orders. In fact, these secondary suppliers have provided a "safety-net" for hospitals when the designated, exclusive primary wholesaler has run short of critical drugs. In other words, when a product is in short supply, secondary distributors fill orders at reasonable markups that are negotiated with their long-standing customers, but without the advantage of the lower, negotiated GPO prices.

Sensorcaine, another APP Pharmaceutical injectable anesthetic in short supply, provides yet another example of how this GPO-rigged system discriminates against non-GPO distributors. As shown in Table 1, the GPO contract price of \$23.00 is 84.67% below WAC (\$150.00) which the non-GPO distributor must pay to the manufacturer. To the lay observer, it may appear that the secondary distributor's markup is 769.57% over the GPO contract price of \$23.00 (\$177/\$23x100). In reality, the secondary distributor's markup is just 14.29% over the actual WAC price (\$25/\$175 x100).

While it might appear that GPOs, by awarding contracts to the lowest bidder, are driving down prices to the end user (hospitals), nothing could be further from the truth. The big question mark here is the total amount of the exorbitant fees paid by the manufacturers and distributors to the GPOs. Despite the fact that 46% of healthcare costs are paid by the government, the GPOs have managed to avoid having to disclose the amount of these fees or the terms of their contracts. So by eliminating competition and extracting fees of indeterminate amounts from other supply chain participants, the GPOs inflate the cost of drugs and other products to hospitals beyond what they would be if free market competition were permitted to work its magic. Based on the findings of the Navigant Economics report, it's highly likely that in a marketplace without GPO kickbacks, that this same vial of propofol would cost the hospital about 36 cents with direct manufacturer discounts instead of 48 cents with GPO fees, and still provide sufficient incentive for manufacturers to produce the drug.

Besides these dubious practices, other perverse incentives of the GPO contracting system have compounded the shortages. Since manufacturers agree not to raise prices for a fixed contract term, they may simply cease production altogether if they can no longer earn a profit. In fact, that is the only way a manufacturer can get out of an exclusive GPO agreement without penalty. On the other hand, if a manufacturer continues to produce a drug but can't supply it in adequate quantities, he can be forced to pay a significant penalty if the price of alternative medications exceeds the original contract price. [See Table 1].

Incredibly, the FDA, HHS, congressional hearing witnesses and even the White House have used the Premier reports as the basis for formulating policy to address the shortages, apparently without performing any due diligence on Premier's well-documented history of anticompetitive practices, self-dealing, conflicts of interest, federal and state investigations, unethical conduct, and multimillion dollar payments to settle civil antitrust lawsuits. Further, Premier, Inc. has failed, as of this writing, to document its claims of "price gouging" by secondary distributors.

Sept. 13: Producers of *PUNCTURE*, starring Captain America's Chris Evans, hold special screening in Washington for congressional staff, media and other stakeholders. Based on a true story, the legal thriller tells how GPO industry corruption denies nurses and other health care workers access to safe needles that can prevent accidental needle stick injuries with contaminated needles. Film opens Sept. 23 in limited release.

Sept. 20: The Health Industry Group Purchasing Association, the GPO lobby, announces that it had "hired" three more former members of Congress for their lobbying effort, Senator Bob Bennett (R-ID), Senator Byron Dorgan (D-ND), and Rep. Phil English (R-PA) to "Further promote transparency, access and ethical business practices." In fact, they were hired to do precisely the opposite: to make sure Congress never takes away their kickbacks or requires disclosure of their financial dealings.

Oct. 9: At a Sunday press conference at the NYU Cancer Institute, Sen. Charles Schumer, joined by codirector William Carroll, M.D., cite Premier "study" in calling on the FTC to investigate "price gouging" by "gray market" drug distributors.

Oct. 12; At its annual international EXPO in Washington, HIGPA announces that it had changed its name to the Healthcare Supply Chain Association (HCSA), dropping the reference to group purchasing organizations. The industry group launches website www.puncturefilmtruth.com in an attempt to debunk the underlying message of PUNCTURE, which is GPO corruption.

Oct. 2011: The Department of Health and Human Services Office of Planning and Evaluation releases its "Economic Analysis of the Causes of the Drug Shortages," which relies heavily on Premier's so-called "studies" on the shortages and input from the Greater New York Hospital Association, Premier's New York agent. For one thing, the premise that GPOs seek to obtain the lowest prices for drugs (and other goods) is simply not the case. Indeed, the opposite is true. While confirming that the GPOs are major middlemen in the generic drug market, the HHS and FDA reports make no mention of GPO contracting as a contributing factor, much less the primary cause, of the drug shortages.

Oct. 31: President Obama issues an Executive Order to the FDA instructing the agency to take emergency action to address the drug shortages. Meanwhile, APP Pharmaceuticals announces that supplies of propofol are now "readily available" and claims credit for playing "a significant role in resolving this critical shortage." In fact, APP Pharmaceuticals and its GPO partners Premier Inc. and Novation, played the key role in creating the shortage in the first place.

Nov. 9: 2011: Senators Herb Kohl (D-WI), Charles Grassley (R-IA), Barbara Boxer (D-CA), Tom Harkin (D-IA) and Dick Durbin (D-IL) send letter to FTC chairman Jonathan Leibowitz requesting a review of anticompetitive GPO practices.

Nov. 23, 2011: FDA issues updated drug shortage list. Of the 88 drugs on the list, 18, or about 20%, are supplied by APP Pharmaceuticals. While the list cites various reasons for the shortages, such as increased demand, manufacturing delays, and discontinuances, the bottom line is that through anticompetitive GPO practices, the generic drug industry has consolidated into a handful of big players, each with exclusive contracts for specific drugs. That has resulted in severely diminished manufacturing capacity for all of the 88 drugs in short supply. This is no coincidence. They are:

Oncology drugs: Paclitaxel, Cisplatin; Doxorubicin, Leucovorin, Mesna and,

Hospital critical care drugs: Calcium Gluconate, Bleomycin, Sensorcaine, Cyancobalamin, Dexamethasone, Etoposid, Fluorouracil, Fosphenytoin, Fursemide, Haloperidol, Magnesium Sulfate, Sodium Chloride, and Vasopressin

November 30: House Oversight and Government Reform Committee, Health subcommittee, holds hearing on drug shortages. Despite the Senate Antitrust hearings and multiple investigations of GPOs, there is virtually no mention of the role played by the GPOs in the drug shortage.

Dec. 6: Sen. Schumer announces that he would introduce a bill to make "price gouging" by secondary drug distributors a federal crime.

Dec. 7: Sen. Max Baucus holds Senate Finance Committee hearing on drug shortages.

Conclusion:

GPOs have undermined competition in the entire U. S. healthcare supply system. The same pernicious, anticompetitive contracting practices that have locked safer, innovative, life-saving medical devices out of 5,000 hospitals for years have now created an unprecedented shortage of lifesaving generic pharmaceuticals that threatens the health of millions of Americans.

This egregious situation has been in the making for years, beginning with the 1987 passage of the Medicare anti-kickback safe harbor, the mid-1990s relaxation of antitrust guidelines for GPOs, and the failure of the Justice Department Antitrust Division, the Federal Trade Commission, and Congress to halt anticompetitive, exclusionary contracting practices in the face of massive evidence of their human and financial toll. As in the Wall Street crisis, the underlying problem is the vast financial and political clout the GPOs and hospital chiefs have been able to bring to bear on Congress and regulatory agencies to maintain the corrupt status quo and avoid any significant disclosure, oversight or regulation of their questionable business and financial dealings.

Meanwhile, the GPOs have created a system of contracts and pricing arrangements, including rebates, prebates, chargebacks, discounts, marketing fees, private labeling fees, administrative and compliance requirements and the like, that is so incomprehensible that only a handful of insiders can understand it. Indeed, that was the whole idea. This is a smokescreen intended to prevent simple comparisons by hospitals, government agencies, and other interested observers of GPO vs. non-GPO prices.

They have used other methods to perpetuate this venal system, including:

- Hiring academics to perform specious research to perpetuate the myth that GPO kickbacks save
 hospitals money. As any student of economics knows, competition reduces prices, while cartels inflate
 them. Anyone who believes that GPOs save hospitals money would have to believe that the
 Publishers Clearing House saves people money;
- Contributions to professional and trade associations, unions, and other stakeholders aimed at dissuading them from supporting repeal of the safe harbor;
- Bullying, intimidation, and retribution against clinicians, Senate witnesses, consultants, former GPO executives and others who speak out against anticompetitive GPO practices.

This is a secret, opaque, closed system. No one, except GPO executives, knows where all the billions in kickbacks are going. And despite four Senate hearings, federal and state investigations, lawsuits, and independent research findings, and media exposés over nearly fourteen years, nothing has changed. No one has been willing or able to stop these cartels.

While Congress and would-be reformers of this system were focused on the impact of GPO practices on the medical device and supply segment of the hospital supply chain, the GPOs were taking control of the generic drug market as well. Unfortunately, until the shortage reached crisis proportions and small drug distributors found themselves unfairly accused by GPOs and members of Congress of "hoarding" and "price gouging," they didn't make their grievances against this system known in the media or on Capitol Hill.

So now we are confronted with the human consequences of these anticompetitive practices. Millions of patients are suffering because they can't get their medications. This situation will not be resolved, in the short or long term, by executive orders.

Repealing the Medicare anti-kickback "safe harbor" provision is the only way the laws of supply and demand and free market competition will be able to function again in the healthcare supply industry, and the only way a steady and safe supply of generic drug manufacturing capacity will be restored. It should now be clear that this safe harbor statute is absurd on its face and should not have been permitted to remain on the books for 25 years.

With the health of millions of patients hanging in the balance, it is high time that Congress reinstate criminal penalties for accepting kickbacks by repealing the anti-kickback safe harbor. Only then will integrity and free market competition be restored, not just to the generic drug industry but to the rest of the healthcare supply chain as well.

Even this will not fix the problem overnight, any more than the collapse of the Berlin Wall instantly transformed the Soviet Union and Eastern Bloc countries into free and functioning economies. It will take time to undo the damage that the kickback-based GPO system has inflicted on the healthcare marketplace. But repeal will send a clear signal to makers of generic drugs and medical devices that the sharks have been purged from the supply chain, and that it will eventually be safe for them to go back into the water. In all likelihood, they will quickly begin rebuilding manufacturing capacity to return to this marketplace.

In addition to calling on Congress to repeal the safe harbor with deliberate haste, the authors urge the appropriate federal and state law enforcement agencies to use their subpoena power to investigate the business and financial dealings of GPOs and their executives and to prosecute those believed to have violated the law in creating this public health emergency.

This travesty must never be repeated.

About the Authors:

Patricia Earl is Principal and CEO of Secure Pharma Distributor Network. An industry veteran, she has worked as a senior executive in pharmaceutical wholesale distribution for over 26 years. Over the last five years, she has worked closely with small, independent distributors in establishing guiding principles for keeping the supply chain safe and secure from adulterated, contaminated, and counterfeit pharmaceuticals. As a result, Pat, along with five premier independent distributors, founded the Secure Pharma Distributor Network LLC. SPDN's goal is to obtain access to pharmaceuticals in the normal supply chain yielding volume discounts and market share recognition based on differentiation, regulatory compliance, and cooperative efforts. She holds a Bachelor of Business Administration, *summa cum laude* in management and marketing from the Tiffin University.

Bowling Green, OH 419-801-4040 pearl@woh.rr.com

Phillip L. Zweig is a prize-winning financial journalist, author, and independent consultant. He has worked as a reporter for the *American Banker, Wall Street Journal* and *Bloomberg Business News* and as a finance editor at *Business Week*, where he co-wrote the first article on anticompetitive GPO practices (Mar. 16, 1998). Later, he worked as an advocate for GPO reform on behalf of entrepreneurial medical device makers, who have been unable to market their innovative products to hospitals because of these practices. Working with *60 Minutes* and *The New York Times*, he helped put this issue on the Senate Antitrust Subcommittee's agenda in 2002. More recently, he worked as a consultant to the producers of *PUNCTURE*, a Hollywood legal thriller that addresses GPO corruption. He holds a B. A. in behavioral psychology from Hamilton College and an M. B. A. in management from the Baruch Graduate School of Business.

New York, NY (212) 490-0811 plzweig@aol.com www.philliplzweig.com

###