Physicians Against Drug Shortages Inc. (PADS)

Statement for the Record

Senate Finance Committee Hearing:

"Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective"

Date of Hearing: Tuesday, December 5, 2023

Submitted by:

Phillip L. Zweig M.B.A.
Executive Director/Co-founder
Physicians Against Drug Shortages Inc. (PADS)
New York, NY 10016

Mitch Goldstein M.D. M.B.A.
Chair, PADS
Professor of Pediatrics & Neonatology
Loma Linda University School of Medicine
Loma Linda, CA

Thank you for the opportunity to comment on the cause, impact, and solution to the decades-long artificial shortages and inflated prices of essential generic drugs. These mainstay medications, which are mostly sterile injectables, include lifesaving cancer drugs, antibiotics, anesthetics, painkillers, nutritional IV fluids, even sterile saline and dextrose solution. Countless patients have died because they couldn't get their drugs. My comments also apply to the deadly shortages of N95 masks, gowns, gloves and other personal protection equipment (PPE) and medical supplies during the pandemic.

To put it bluntly, Congress created this travesty and failed in its duty of care to stop it. For more than a decade, it has kicked this can down the road with interminable hearings, ineffective legislation, and stern letters to the FDA, which lacks the authority to address the underlying economics. So it's up to Congress to fix it. Chairman Ron Wyden has taken an important step in that direction by focusing at the hearing on the fundamental role of giant hospital group purchasing organizations (GPOs) in causing this crisis, but that recognition must now be followed by remedial legislation.

Before elaborating, I'll explain my involvement in this issue. I'm a financial journalist (formerly with the *American Banker, Wall Street Journal, Bloomberg, BusinessWeek* etc.) and national best-selling author turned patient advocate. In October 2012, I co-founded Physicians Against Drug Shortages Inc. (PADS), a pro bono patient advocacy group, with a clutch of anesthesiologists who were outraged that they couldn't get propofol and other drugs that they needed to put their patients to sleep, but they didn't understand why. I did. Since then, I've served as unpaid executive director. Our mission is to expose and prevail on policymakers to address the real root cause of the shortages: the exhaustively documented anticompetitive contracting and pricing practices, self-dealing, conflicts of interest,"legalized" kickbacks and "share backs" of GPOs.

Today, three for-profit buying cartels—-Vizient (the largest, formerly known as Novation), publicly-held Premier Inc. [PINC], and HealthTrustPG —-control purchasing for about 90% of an estimated $250 billion to $300 billion in annual GPO contract volume. Nearly half of this amount is for drugs and supplies for patients covered by Medicare, Medicaid, and other government health care programs.

My PADS colleagues and I have written numerous articles and submitted many comments on this in response to requests for comment by the FDA, the Dept. of Health & Human Services Office of Inspector General (OIG), the Federal Trade Commission (FTC) and congressional committees—obviously to little effect. For an overview, read our op-eds in *The New York Times* of Sept. 3, 2013 ("How a Cabal Keeps Generics Scarce") and *The Wall Street Journal* of May 8, 2018 ("Where Does the Law Against Kickbacks Not Apply? Your Hospital"). More recently, we worked with *60 Minutes* on a May 22, 2022 segment that examined how these predatory middlemen caused shortages of vital chemo agents by demanding that suppliers pay them huge "fees" (aka kickbacks) in return for access to their member hospitals. PADS Chair Mitch Goldstein

M.D. M.B.A. was featured in the segment, entitled “In Short Supply." Three days later, in testimony on the baby formula shortages before the House Energy and Commerce Committee, FDA Commissioner Robert Califf M.D. repeatedly urged members to watch it. He has testified that ending this crisis requires addressing the underlying economics —-which are driven by GPOs. In recent interviews and speeches, he’s pointed the finger directly at them.

On November 22, 2022, a coalition of nine advocacy groups, including the American Economic Liberties Project, a respected anti-monopoly think tank, PADS and Public Citizen, sent a letter to FTC Chair Lina Khan urging the agency to investigate the GPOs’ role in causing the shortages and inflated prices.

Eleven years earlier, on October 31, 2011, when President Obama announced an executive order to the FDA to address the drug shortage crisis, I was unaware that there was one, but I immediately knew what had caused it. As a finance editor at *BusinessWe*ek, I had initiated and co-written the first article, entitled “Locked Out of the Hospital” (3/16/98) on how GPOs block entrepreneurial medical device companies that make innovative and more cost-effective devices from marketing them to thousands of hospitals. About 18 months later, the CEO of safety syringe maker Retractable Technologies, which was Exhibit A in the article, asked me if I would consider taking a sabbatical from journalism to try to reform this corrupt system. I agreed, and soon began working with *60 Minutes* on a segment with correspondent Mike Wallace on how these harmful practices denied health care workers needles that virtually eliminate the risk of potentially deadly accidental needle stick injuries. It aired on February 25, 2001. Producer Walt Bogdanich then accepted a job as an investigative editor at *The New York Times* and launched a year-long series on GPO abuses. The *60 Minutes* segment and the prize-winning *Times* series are posted, along with many other media reports and documents on GPOs, on our website: www.physiciansagainstdrugshortages.com.

These stories focused primarily on anticompetitive GPO practices that undermine competition and innovation in the entrepreneurial medical device sector. But one article in the *Times* of March 26, 2002, entitled “When a Buyer for Hospitals Has a Stake in the Drugs it Buys,” foretold the havoc GPOs would wreak on the generic drug industry, patients, clinicians, and our health care system generally. It revealed how Premier Inc., now the second largest GPO, had begun to take control of the generic drug market by co-founding American Pharmaceutical Partners (APP) and taking it public in late 2001. According to the *Times*, Premier parlayed a $100 investment in 1996 into shares valued at $46 million, enabling at least two former Premier executives with stock options to hit the jackpot. Sen. Herb Kohl (D-WI), then chairman of the Senate Antitrust Subcommittee, called this arrangement “scandalous” and forced Premier to divest its stake in APP. But that was just a minor setback in Premier’s unceasing quest for profits at the expense of patients.

The media coverage triggered four Senate Antitrust Subcommittee hearings, from 2002 to 2006, on GPO abuses; federal and state investigations, including a Justice Department criminal investigation of Novation (since renamed Vizient), which ended

inconclusively; multiple successful antitrust lawsuits filed by medical device entrepreneurs against GPOs and/or their dominant supplier partners; independent research; a 2009 book ["Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry"] by Distinguished Professor S. Prakash Sethi of Baruch College's Zicklin School of Business, and even a barely fictionalized 2011 Hollywood film, *PUNCTURE*, starring Captain America's Chris Evans.

The original and sole purpose of GPOs was to save hospitals money by purchasing supplies in bulk. The first one was founded in 1910 when several New York City hospitals, including Bellevue, banded together to form a nonprofit co-op. Member hospitals paid dues to cover salaries, rent, and other administrative expenses. By all accounts, this worked fine for more than 80 years.

But Congress couldn't leave well enough alone. In 1987, at the behest of hospital lobbyists, it enacted what became known as the Medicare anti-kickback "safe harbor" [Section 1128B(b) of the Social Security Act], which exempted GPOs (and later, pharmacy benefit managers, or PBMs) from criminal prosecution for taking kickbacks from suppliers. Lobbyists claimed that GPOs would somehow save more money if suppliers paid the fees. What's more, they argued that since suppliers were *already* paying illegal kickbacks, why not just "legalize" them? This amendment to the Social Security Act upended the entire medical supply chain, creating perverse incentives that led to higher, not lower, prices for hospital goods. That's because GPO kickbacks are calculated based on price times volume purchased. Congress awarded GPOs a "Get Out of Jail Free Card," becoming the only industry we know of that has received such a dubious gift. It is no coincidence that generic drug manufacturing is also the only industry we're aware of that has experienced debilitating chronic shortages in the post-WWII era. Any freshman economics student knows that we're simply not supposed to have prolonged shortages *of anything* in a market economy. But the GPOs have turned our drug and health supply industries into a vestige of the disgraced ex-Soviet economic system. They are the oligarchs of American health care.

The HHS OIG was designated to write and monitor compliance with the safe harbor rules, which it issued on July 29, 1991. The rules called for a "soft cap" of 3% for "admin fees" and authorized the OIG to request data on fees that exceeded this amount. But the GPOs deviously circumvented this restriction by inventing other fees: advance, conversion, licensing, private label and marketing fees, even fees, said one longtime critic, to sit next to a GPO contracting officer at dinner. The unsafe "safe harbor" transformed the GPO business model from nonprofit cooperatives that saved hospitals money to unscrupulous middlemen that exist only to make money for top GPO insiders and executives of major GPO shareholder hospitals. They do this by literally selling market share, in the form of sole-source contracts, for outrageous fees to the highest bidder, a pernicious practice cited in the June 2021 White House 100-day report on supply chain resilience, which was ordered by President Biden shortly after he took office. According to Novation "Excess Fee Reports," which were initially "requested" by

the Antitrust panel in 2002 and later obtained in discovery in a 2003 federal whistleblower case, these fees often amounted to double-digits, and sometimes more than half of a company's total revenue for a single drug. GPOs perform no medically, socially or financially useful function. They are nothing more than a sophisticated "pay-to-play" scheme---a "legalized" fraud.

An October 25, 2023 *New York Times* article, which has nothing—-and everything—-to do with drug shortages, explained what usually happens when people pay or take bribes for government contracts. In this instance, a Hawaii wastewater (aka cesspool) equipment dealer paid millions in bribes to several state and Maui County officials for sole-source, no-bid contracts. They were convicted and sentenced to prison.

Over the years, an elaborate, well-financed lobbying and PR operation metastasized like a cancerous tumor to preserve and protect the malignant safe harbor.

The analysis is actually quite simple. GPO middlemen, who do little but award exclusionary contracts, are making all the money, while the companies that actually produce the drugs are left with crumbs. Compare, for example, the 2019 financial statements (SEC 10K) and seven-figure executive compensation packages at publicly-held Premier Inc.[PINC] with those of Akorn Pharmaceuticals [AKRX], which filed for bankruptcy under Chapter 7 in February 2023 after more than 50 years manufacturing ophthalmic drugs and other essential medications. Akorn's collapse exacerbated existing shortages of these drugs as well as albuterol, an important asthma medication.

One document that was obtained by plaintiffs in an ongoing antitrust lawsuit against Vizient tells the whole story. Incredibly, Vizient's marketing material boasts that one of the services it offers contracted suppliers is "Protection from Competitive Threats and Rebidding!" [exclamation point added].

Moreover, there is virtually no disclosure, transparency, oversight or regulation of this powerful industry. The OIG is ostensibly responsible for overseeing compliance with the safe harbor. But it has proven to be a paper tiger. For example, it is authorized to request data on excess GPO "fees" from GPOs and their rebates to shareholder hospitals, but to the best of our knowledge, it has rarely, if ever, done so. This was underscored in a March 30, 2012 GAO report entitled "Group Purchasing Organizations: Federal Oversight and Self-Regulation."

In 2005, Senators Herb Kohl D-WI) and Mike DeWine (R-OH), who presided over the Antitrust hearings, drafted a bipartisan bill, called the "Ensuring Competition in Hospital Purchasing Act" that would have restored free, fair and open competition to the supply chain by repealing the ill-conceived safe harbor. But it died in the subcommittee because of fierce opposition by the powerful GPO and hospital industries. We later learned why the American Hospital Association and its state affiliates opposed it: CEOs of certain major GPO shareholder facilities get a piece of the action, sometimes in the form of six to seven figure "share backs" or "equity distributions." One veteran GPO

critic used to describe this shell game as a “partial refund of a deliberate overcharge.” It is a system in which the rich get richer, and the sick get sicker. I would be pleased to provide the committee with documentation, including names of individuals, institutions and amounts, on request.

If the safe harbor had been repealed in 2005, the public health emergency that prompted President Obama’s 2011 executive order would not have happened. In fact, in late 2011, three administration officials testified before two congressional committees on the central role of GPOs in causing this disaster. In the middle of what was apparently the first congressional hearing on drug shortages, on September 23, 2011 before the House Energy and Commerce Committee, HHS Assistant Secretary for Health Howard Koh M.D. was asked by Rep. John Shimkus (R-IL), “What has distorted the fundamental principle of supply and demand…I think that is the heart of this issue.” Indeed it is.

Dr. Koh replied: “First of all, these agreements are made often through these long-term contracts and so also this whole process involves multiple stakeholders, especially and including the pharmacy benefit managers and the group purchasing organizations. So it complicates this environment and sort of does not make relevant the sort of standard supply and demand economic principles that we see in other businesses.” FDA Deputy Director Sandra Kweder M.D., who accompanied Dr. Koh to the hearing, was asked to respond. She said: “You [Dr. Koh] have said what I would say. Thank you.”

Then on December 15, in a hearing for the Senate Committee on Health, Education, Labor and Pension (HELP),, Sherry Glied Ph.D, HHS Assistant Secretary for Planning and Evaluation (ASPE) zeroed in on questionable GPO contracting practices. The takeaway: GPOs had undermined the law of supply and demand. But no one listened.

As the GPOs ratcheted up their disinformation campaign to protect and preserve the safe harbor, Congress, the FDA and other federal agencies, medical societies and other stakeholders continued to act as if the cause of the shortages was among the great unsolved mysteries of the universe.

Contrary to the false protestations of GPO industry executives, repeal would not have eliminated GPOs. It would only have ended the corrupt GPO “pay-to-play” system. With generic drug makers foundering or exiting the business at a rapid clip, repeal would make domestic production of generic drugs financially viable again. Tax breaks, government subsidies, low interest rate loans, various convoluted and unworkable quality rating systems, “buffering” and stockpiling, expansion of nonprofit manufacturing, or a federal takeover of the generic drug business, as one senator has proposed, are not the answer. They would be a total waste of taxpayers’ money.

Besides creating chronic shortages, GPOs have grossly inflated prices of drugs and other hospital goods, which are the second largest component of hospital expense after labor. While they and their cohorts claim that they save hospitals billions, the only documentation they can provide are questionable “sponsored research studies”

produced by ethically-challenged academics and consultants. Over the years, at least three government studies have found that there isn't a single shred of independent evidence that they save hospitals a dime. They include:

- GAO pilot study of April 30, 2002, which found that prices of pacemakers purchased through GPO contracts were often up to 39% higher than when they were bought off-contract.

- May 2, 2003 letter from Senators Kohl and DeWine to Secretary of Defense Donald Rumsfeld advising him against hiring a GPO to purchase medical supplies for the military. They explained that the "savings" GPOs claim are nothing more that discounts from list prices, which no one pays.

- 2010 Senate Finance Committee Minority Staff Report on GPOs requested by Sen. Chuck Grassley.

- In 2021, I reviewed all of the available empirical and anecdotal evidence on GPO pricing over more than 20 years and concluded that they actually inflate prices of hospital supplies by at least 30%, or roughly $100 *billion* annually. Some well-informed supply chain practitioners have told me that my estimate is too low. Competition reduces prices. Cartels inflate them.

Since 2011, when drug shortages became page one news, the GPO industry and their proxies have disseminated various bogus explanations for the shortages, all of which have been thoroughly discredited by government or other independent researchers. Their basic mantra is that the causes are "complex and multifactorial," or a "perfect storm." This is absolute nonsense. There is a cause and a solution: repeal of the safe harbor. Other spurious GPO explanations include:

- **Alleged "price-gouging, "gray market" drug distribution companies**. These are mostly small to mid-sized "mom and pop" firms that provide smaller quantities of drugs to physicians, hospitals and other medical facilities, often in emergencies and on weekends. They perform a perfectly legitimate market function. But they can't compete on price with the "Big Three" GPO-authorized distributors—- McKesson, Amerisource Bergen, and Cardinal—-because they're not permitted to get "chargebacks," or rebates, from GPO-contracted suppliers. Premier Inc. demonized them in a misleading August 2011 report. The FBI investigated and found no wrongdoing, as reported in the inaugural February 10, 2014 GAO report on drug shortages, which was mandated by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). That same report identified GPOs as a potential "underlying cause." It concluded correctly that manufacturing and quality problems and other issues were secondary or intermediate causes. [For more on GPO pricing, read "Connecting the Dots" of January 4, 2012, a white paper by drug distribution consultant Pat Earl and me.]

- **340B Program and Medicaid Rebates.** Another red herring. In a normal market, suppliers would be able to incorporate these costs into their prices. But the pharmaceutical and medical goods supply chain is a rigged market.

- **Overzealous FDA inspections**. I began to hear this in late 2011 around the time Bedford, OH-based Ben Venue Laboratories shuttered, causing acute shortages of methotrexate, Doxil and other chemo drugs. The FDA inspection report indicates otherwise. Inspectors even found a 10-gallon bucket of urine near the production area. According to an expert in sterile drug production, this was a bizarre cost-saving measure that was intended to reduce the time workers needed to de-gown, do their business, re-gown, scrub back in and return to the production area. In a Linkedin search, I located someone familiar with Ben Venue's collapse and the FDA inspection. Fearing retribution, this person initially declined to speak with me. I asked this individual to answer just one question: Were these allegations against the FDA true? This person, who requested anonymity, replied: "Absolutely not. They were professionals. They did their job." Some of the same cancer meds that had been manufactured for years by Ben Venue were later made by what *Bloomberg News* of July 21, 2016 described as a contaminated plant in China that was "banned" by the FDA.

- **Change in the Medicare reimbursement formula from wholesale acquisition cost (WAC) to average sales price (ASP) plus 6%** under the Medicare Modernization Act of 2003. Former HHS Assistant Secretary Sherry Glied Ph.D, who had conducted a formal study on this issue, walked me through it in person after she left office. The Medicare reimbursement formula has nothing to do with drug shortages, she explained, because it doesn't affect monies received by suppliers. And contrary to popular belief, Medicare reimbursement prices weren't subject to price controls. She explained that in a December 23, 2014 letter to the editor of the *Journal of Oncology Practice.*

- **FDA backlog in approving generic drug applications.** Yes, there was a backlog in applications. But a 2016 study by the Center for American Progress found that very few of those applications were for drugs in short supply. They were scarce for one reason: drug makers couldn't earn a reasonable profit and stopped making them.

- **Just-in-time inventory practices.** Totally false and illogical. Just-in-time inventory works when supply is adequate and reliable, but no competent supplier would continue to use just-in-time for drugs in short supply.

- **Hurricane Maria**. When the hurricane devastated Puerto Rico in September 2017, Baxter's plants, which produced sterile saline and other critical IV drugs, were heavily damaged. So the GPOs blamed the shortages on Maria. However, for several years before the storm, the U. S. had been importing saline from Spain, Germany and Norway. Afterwards, the U. S. had to import it from

additional countries. The real reason: sole-source contracts. In fact, in 2007 Baxter boasted in a presser about its sole-source Novation (now Vizient) contract for IV fluids, including sterile saline. For more on this, see the GPO chapter in *MONOPOLIZED*, a 2020 book by the *American Prospect's* David Dayen.

- **COVID-19.** The pandemic provided GPOs with a convenient but misleading alibi for shortages of many drugs and supplies, including N95 masks. To be sure, COVID exacerbated drug shortages, and demand for PPE surged. But the GPOs contributed mightily to the shortages of N95 masks and other PPE. In a remarkably prescient October 4, 2008 article in *Infection Control Today,* Mike Bowen, EVP of Prestige Ameritech, a small Texas mask maker, was quoted as saying that the U. S. wouldn't be prepared for a future pandemic because of the GPO "chokehold" on the medical supplies industry.

- **"Race to the Bottom."**This is a catchy but misleading buzz phrase. It suggests that the "low prices" paid to drug makers are real prices when in fact they're rigged prices. Real prices adjust according to the law of supply and demand. Rigged prices don't. The GPOs have undermined this immutable economic principle. The outrageous kickbacks GPOs have extorted from generic drug makers have transformed a low margin but generally reliable business into a troubled, money-losing proposition.

I should add here that while the number of big GPOs has consolidated from eight or so in the late 1990s to the "Big Three," the primary problem is their corrupt "pay-to-play" business model. I'm all in favor of breaking up the "Big Three," but that would have to be accompanied by repeal of the safe harbor to make domestic generic drug manufacturing attractive again.

The GPO industry exists only because of its highly aggressive PR and lobbying activities, including mountains of campaign cash. They have literally bought the silence or active support of medical "thought leaders," former top federal officials, academics, even medical societies and prominent media personalities. They include former FDA Commissioner Scott Gottlieb M.D. In 2018, he told the *Associated Press* of July 12, 2018 that GPOs had caused the shortages by squeezing manufacturers' profit margins. Then after he left office, he went silent on the GPO issue. He also became a speaker-for-hire for Vizient. For the details, see "Buckraking: "Did a Medical Monopolist Buy Off CNN?" In *BIG* (a blog) of July 7, 2022, by Matt Stoller, research director of the American Economic Liberties Project.

By far the most visible GPO hired gun is so-called "drug shortage expert" Erin Fox D.Pharm, who collects data on shortages as director of the University of Utah Drug Information Service (UUDIS). I was well-aware of her conflicts of interest with the GPO industry, notably Vizient. In October 2017, we had a conference call with FTC staff who were organizing a conference on drug market competition. They denied our request to participate as panelists, saying that the speakers had already been selected. They

declined to name names, but they did tell us the occupations that would be represented, including a pharmacist. “Erin Fox?,” I asked. There was stone silence at the other end of the line. I then enumerated her conflicts of interest. She’s a lobbyist, PR spokesperson, and consultant to Vizient, and an employee of the University of Utah Medical Center, a major Vizient shareholder facility. She has invariably denied, at least in interviews and public forums, that GPOs have anything at all to do with drug shortages, when in fact they have *everything* to do with drug shortages. FTC staff apparently prevailed on her to disclose these conflicts at the conference. Here’s my recent Linkedin post on her conflicts: **https://www.linkedin.com/in/phillip-l-zweig-491ba83/recent-activity/all/**

So we were appalled when she appeared as the lead witness in the March 22, 2023 Senate Homeland Security and Government Affairs hearing on the national security implications of drug shortages.

Those the GPOs can’t buy—-including PADS—-they’ve harassed and even threatened. In 2018, someone presumably affiliated with the GPO industry hired a would-be online “investigative” outfit called “Checks and Balances” to try to intimidate me and certain physician members. His targets were mostly PADS doctors who practiced at academic medical centers and had written negative articles about GPOs. Its principal, Scott Peterson, a former Wall Street PR rep, sent letters to the heads of their schools or hospitals falsely alleging that they had egregious conflicts of interest. Nothing came of the resulting “investigations,” but our members wasted precious clinical and research time responding to Peterson’s unfounded charges.

In late 2018, after the November 27, 2018 FDA conference on drug shortages, Peterson posted this item about my actions at the all-day meeting:**https://checksandbalancesproject.org/philip-zweig-disrupts-health-policy-forum/** He accused me of disrupting the meeting with my persistent commentary on GPOs from the floor during the question and answer session. To that I plead guilty.

Everyone who works in the health care supply chain knows that it is broken, And they know why it’s broken and who broke it: GPO middlemen. So do members of Congress, including members of the Senate Finance Committee. Some of the same members who attended the December 5, 2023 hearing were present at the first one on December 7, 2011, almost *exactly twelve years earlier.* It’s high time that members exercise their duty of care to their fellow citizens and end the kickbacks (aka bribes, payola etc) and “share backs” (dividends, patronage fees, rebates etc.) by repealing the unsafe safe harbor. So here’s our New Year’s message to Congress: You broke it. You fix it.

FULL DISCLOSURE: PADS and I have no financial conflicts of interest. We have no budget and cover expenses out of our own pockets.

###