Physicians Against Drug Shortages Inc. (PADS)

Before the Federal Trade Commission and
The Department of Health and Human Services

Response to Request for Information
Docket ID FTC-2024-0018

Written Comments from Physicians Against Drug Shortages Inc. (PADS)
Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that are Causing Drug Shortages

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FULL DISCLOSURE: Founded in 2012, PADS is a pro bono patient advocacy group whose sole mission is to end the global generic drug shortage crisis via congressional repeal of the ill-conceived 1987 Medicare anti-kickback “safe harbor” for GPOs. We have no conflicts of interest, no budget, receive no outside contributions, and cover expenses out of our pockets.

Introduction

Thank you for the opportunity to comment on the cause 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 has failed in its duty of care to stop it. For nearly 13 years, 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 perverse underlying economics. Your joint investigation into the real root cause—the exhaustively documented anticompetitive contracting and pricing practices of giant hospital group purchasing organizations (GPOs) and their "Big Three" distributor partners—-is a welcome development. About 15 months earlier, our coalition of nine advocacy groups, including the American Economic Liberties Project, had sent a letter to Federal Trade Commission Chair Lina Khan urging the agency to do just that.

The vast documentation accumulated over the last 25 years on GPO abuses comprises federal and state investigations, including a mid-2000s Justice Department criminal probe; four Senate Antitrust Subcommittee hearings from 2002-2006, multiple Senate and House hearings on drug shortages starting in 2011; major media exposés, notably an award-winning 2002 *New York Times* series entitled "Medicine's Middlemen," and two *60 Minutes* segments; multiple successful antitrust lawsuits against GPOs and/or their dominant supplier partners, independent scholarly reports; incriminating documents and public statements by GPO executives themselves, a 2009 book entitled "Group Purchasing Organizations: An Undisclosed Scandal in the U. S. Healthcare Industry," (Palgrave MacMillan, 2009) by S. Prakash Sethi, distinguished university professor at the Baruch College Zicklin School of Business; and even a barely

fictionalized 2011 Hollywood film, *PUNCTURE*, starring Captain America's Chris Evans. A selection of key documents and articles appear as an attachment to this submission, and the rest are posted on our website, www.physiciansagainstdrugshortages.com.

Taken together, this documentation overwhelmingly affirms the following:

- For nearly a quarter century, these anticompetitive abuses, including sole-source contracting and double-digit "fees" (aka "legalized" kickbacks), tying and bundling, and forced compliance using penalty pricing and other questionable practices have caused the shortages of hundreds of lifesaving generic drugs, resulting in the deaths of countless sick people and harming millions more, worldwide; oncologists estimate that the treatment of up to 500,000 American cancer patients has been interrupted, discontinued, rationed or otherwise jeopardized by the chronic shortages of vital chemotherapeutic agents;

- GPOs have decimated the domestic generic injectable drug industry, causing some manufacturers to halt production of certain drugs, forcing others into bankruptcy, and driving production of other drugs from contaminated plants in the U.S. to even more contaminated plants in China and India;

- During the pandemic, GPOs exacerbated demand-driven shortages of personal protection equipment (PPE), including N95 masks, and surgical gowns, as well as ventilators and other vital supplies; forcing American dependence on often defective Chinese imports, and threatening the national security of the United States;

- By awarding sole-source contracts to favored dominant suppliers and extorting outrageous "fees" from them as the price of admission to their member hospitals, GPOs forced the consolidation of drugmakers and other suppliers and undermined market competition in the entire health care supply chain, inflating prices of these goods by an estimated 30%, or upwards of $100 billion annually. According to at least one former senior GPO contracting officer, hospitals typically increase these already inflated invoice prices by three or four times for billing purposes, driving up the cost of American healthcare by a huge but indeterminate amount. To put

this in perspective: The cost of hospital supplies is a major but little-recognized contributor to the high cost of healthcare, since these expenses are the second largest component of hospital costs after labor expense, and total hospital costs are a major component of all healthcare expense in the U.S.;

- GPOs have created a distribution oligopoly of a few huge drug and supply distributors by permitting only those companies to receive chargebacks or rebates on GPO-contracted products. That has made it extremely difficult for small to medium-sized distributors to compete on price in this marketplace;

- Four Senate Antitrust Subcommittee hearings from 2002 to 2006 documented how GPOs have undermined competition and innovation in the medical device industry; the same venal practices that were the subject of the hearings caused the shortages of generic injectable drugs;

- These shortages and their often deadly consequences were triggered by the passage of the misguided 1987 Medicare anti-kickback safe harbor statute, which exempted GPOs (and later pharmacy benefit managers, or PBMs) from criminal prosecution for taking kickbacks from suppliers;

- Meanwhile, these predatory middlemen and the CEOs of certain of their shareholder hospitals have gotten very rich —-Wall Street-type rich—-by exploiting the ill-conceived safe harbor, flouting the letter and spirit of the statute and the intent of Congress;

- Since at least 2010, the White House, Congress, and federal antitrust enforcement agencies have been aware of the role of GPOs in causing this crisis, but until the FTC/HHS announced their joint investigation they had failed to take effective action to address it. Instead, Congress has held interminable hearings, proposed ineffective legislation, and admonished the FDA for its alleged inaction in countless letters to the agency, when in fact that it lacks the authority to address the underlying economics.

Before elaborating, I'll explain my interest and involvement in this issue. I'm an award-winning financial journalist (formerly *American Banker, Wall Street Journal, Bloomberg, BusinessWeek* etc.) and national best-selling author turned patient advocate. In October 2012, I co-founded pro bono Physicians Against Drug Shortages Inc. (PADS) with several anesthesiologists who were outraged that they couldn't get propofol and other drugs 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 actual root cause of the shortages: the anticompetitive abuses, self-dealing, conflicts of interest,"legalized" kickbacks and "share backs" of GPOs.

Today, three for-profit buying cartels—-Vizient (the largest, formerly Novation), publicly-held Premier Inc. [PINC], and HealthTrustPG —-control purchasing for about 90% of an estimated $250 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 programs.

Over the years, my PADS colleagues and I have written numerous articles and submitted countless comments on this to the FDA, the HHS Office of Inspector General (OIG), the FTC and congressional committees—obviously to little effect until February 14, 2024. For an overview, read our op-eds in *The New York Times* of September 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 [1]*60 Minutes* on a May 22, 2022 segment that examined how these predatory middlemen caused shortages of vital chemotherapeutic agents by extorting huge "fees" (aka "legalized" kickbacks) in return for access to their member hospitals. PADS Chair Mitch Goldstein M.D. M.B.A. was featured in the segment. 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

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[1] 60 Minutes, "In Short Supply" 5/22/22:https://www.youtube.com/watch?v=0VdEFWq1P0I&t=48s

addressing the underlying economics—-which are driven by GPOs. In recent interviews, he's pointed the finger directly at them.

So has Senate Finance Committee Chair Ron Wyden. On December. 5, 2023, he opened a hearing on drug shortages by highlighting GPO consolidation. We strongly recommend breaking up these cartels, but the overriding problem is that they all operate on the safe harbor "pay-to-play business model. Yet in a "bipartisan" January 25 white paper, the committee proposed changes in Medicare reimbursement policy—which has nothing to do with the shortages— offer "bonuses" to hospitals for selecting reliable suppliers and maintaining buffer stock, and even provide "incentives" for GPOs (p.6). In our view, the only "incentive" GPOs need is reinstatement of criminal penalties for taking kickbacks from suppliers. To enable the generic sterile injectable industry to become financially viable again, policymakers must remove *disincentives,* including sole-source contracts, exorbitant fees (aka kickbacks) share backs, and other anticompetitive practices that have caused this unprecedented market failure.

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 *BusinessW*eek, 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 an upstart safety syringe maker, which was Exhibit A in the article, asked me to consider taking a sabbatical from journalism to try to reform this corrupt system. I agreed, and soon began working with [2]*60 Minutes* correspondent Mike Wallace on a segment, which aired February 25, 2001, on how these monopolistic practices denied health care workers access to needles that protect them from potentially deadly accidental needle stick injuries. The producer then accepted a job as an investigative editor at *The New York Times* and launched the paper's "Medicine's Middlemen" series.These reports, along with many other

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[2] 60 Minutes "Needles," 2/25/01:https://www.youtube.com/watch?v=E1fTC2djVmk

exposés and documents, are posted on our website: www.physiciansagainstdrugshortages.com.

These stories focused primarily on anticompetitive GPO practices that undermine market access, competition and innovation in the entrepreneurial medical device sector. But one article in the *Times* of March 26, 2002 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. The *Times* reported that Premier had parlayed a $100 investment in 1996 into shares valued at $46 million, enabling former Premier executives 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 APP stake. But that was just a minor setback in Premier's unceasing quest for profits at the expense of patients. Media coverage of this issue triggered the Senate Antitrust hearings and the other investigations that followed.

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 Bellevue and several other New York City hospitals banded together to form a nonprofit co-op. Member hospitals paid dues to cover salaries, rent, and other administrative expenses. By all accounts, that worked fine for more than 80 years.

The 1987 Medicare Anti-Kickback "Safe Harbor"

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" statute [42 CFR § 1001.952j], 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. Incredibly, they argued that since suppliers were *already* paying illegal kickbacks, why not just "legalize" them? In fact, at a November 8, 2017

FTC conference on drug market competition, Todd Ebert, CEO of the Health Care Supply Chain Assn. (HSCA), the GPO trade group, acknowledged this, saying, [3]"What it merely did was clarify that the existing business practices were lawful."

Equally stunning was the admission by Stephanie Trunk, an attorney with Arent Fox, one of HSCA's law firms, that "I do believe that being paid by the suppliers can create a conflict of interest for the GPOs with those members, as we've seen today."

The idea of enacting a statute that legalized previously illegal practices—-I.e. kickbacks, bribes and payola—-that were criminal violations in virtually every other industry would seem preposterous on its face. Still, the safe harbor rules promulgated by the HHS Office of the Inspector General on July 29, 1991 made clear that Congress was "concerned" about "excessive" fees, meaning fees that exceeded 3%.

This amendment to the Social Security Act upended the entire medical supply chain, creating perverse financial incentives that led to higher, not lower, prices for hospital goods. That's because GPO kickbacks are calculated based on price times volume purchased; higher prices translate into more profits for GPOs—-and more "dividends" for their shareholder hospitals. Congress awarded GPOs a "Get Out of Jail Free Card," becoming the only industry we know of that has received such a questionable gift. GPOs were no longer the servants of hospitals. Instead, virtually overnight, they became the marketing department for dominant suppliers. 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 health care supply chain into a vestige of the disgraced ex-Soviet economic system. They are the oligarchs of American health care.

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[3] FTC Transcript 11/8/17: https://nebula.wsimg.com/c24bfbded6401fc2f5d0153a3d70da32?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

The HHS OIG was designated to write, monitor and enforce compliance with the safe harbor rules, but the GPO industry flouted both the letter and spirit of the law and the rules, clearly ignoring the intent of Congress. 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. However, 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.

It should be clear to any reasonable observer that the rule makers considered “admin” fees to be “all-in” or total fees. And by requiring GPOs to report excess “admin fees” to hospitals, they clearly regarded hospital executives as fiduciaries, not as potential participants in an elaborate pay-to-play scheme. To circumvent that requirement, the GPOs simply cut CEOs of certain major shareholder members in on the action.

Here’s a related section of the July 29, 1991 rules disseminated by the HHS Inspector General:

“Comment: To promote administrative convenience, efficiency, and cost- containment purposes, several commenters requested that the GPO should be permitted to specify the range of fees to be paid by the potential vendors instead of the actual amount. One commenter asserted that because of the varying contracts between GPOs and their vendors, it was impossible to determine and disclose in advance the amount the GPO would receive from its vendors.

Response: We agree that it is not necessary, in all circumstances, to specify the exact fees the GPO will receive from its vendors as a result of a particular member's purchases. The legislative history to this exception, however, shows Congress's concern for excessive GPO fees, particularly those exceeding 3 percent. (See, H.Conf. Rep. 1012, 99th Cong., 2d Sess. 310-11 (1986)) For this reason, we are revising this provision (see paragraph (j)(1)(i)) so that a GPO needs to specify the administrative fee it is paid from vendors only if any fee will be above 3 percent.

In the event that the fee cannot be ascertained at the time of the contract or the fee is not fixed at 3 percent or less, the contract must state the maximum amount that could be paid to the GPO by the vendor. This mechanism will permit some flexibility in payments made to the GPO, yet retain the focus on excessive fees about which Congress was concerned.”

Lawmakers and rule makers probably didn't anticipate that the hospital owners of a large GPO—-Premier Inc., now the second largest—- would take the company public, adding yet another conflict of interest to the mix and enriching top insiders by many millions. For more detail on the controversy surrounding the [4]September 2013 IPO, see my comments of Feb. 16, 2021 to the [5]HHS OIG on safe harbors. Under the terms of the IPO, hospital shareholders were permitted to sell one-seventh of their shares a year.

Two of the biggest, if not the biggest, profiteers are Ken Raske, president of the Greater New York Hospital Association (GNYHA) and Lee Perlman, executive vice president. They received distributions totaling about $32 million each for the seven years from 2014 to 2020. Until 2020, GNYHA was the largest shareholder of Premier Inc. [PINC] and a GPO in its own right. The figures in the [6]table were compiled from GNYHA's IRS 990 filings for that period. These equity distributions were in addition to their regular compensation for the same period of $13,035,261 for Raske and $9,408,904 for Perlman. **Recommendation: Request, or if necessary, subpoena, financial records of the nearly 100 other hospital shareholders in Premier to determine how they allocated the proceeds from the sale of their stock.**

In early 2020, GNYHA agreed to sell its GPO business to Premier for $291.5 million. We urge the FTC to investigate the disposition of that money as well.

For-profit Vizient is privately held, so it disbursed "share backs" to CEOs of certain major shareholder hospitals. Nearly all of these transactions are confidential. However, thanks to a Maryland law that requires hospital

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[4] SEC Form S-1, 9/16/13: https://www.sec.gov/Archives/edgar/data/1577916/000104746913009072/a2216569zs-1a.htm

[5] PADS Comments to HHS OIG on safe harbors, 2/16/21: https://nebula.wsimg.com/5e3d638c13fcb2eac4a4049e065dfbe6?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[6] GNYHA, Equity Distributions & Comp to Raske, Perlman &Heller, 2014-2020: https://nebula.wsimg.com/8a5fc890472c6b75c98983486f596efe?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

trustees to publicly disclose their hospital-related income in excess of $10,000, we found documentation of payments by [7]Vizient to Kevin Sowers RN, CEO of Johns Hopkins Hospital. For the 12 month periods ending on June 30, 2019, 2020, and 2022, he received a total of $1,419,973 in what appear to be share backs. The filings, which are posted on the "GPO Documents" page of our website, do not indicate how GNYHA allocated these funds.

Equity distributions and share backs are the glue that keeps this scam firmly in place and explain why the hospital lobby has opposed repeal of the safe harbor. These transactions may also help explain why at least two federal agencies, the HHS Inspector General in 2005 and the Government Accountability Office (GAO) in 2014, found that hospitals didn't always report to the Centers for Medicare and Medicaid Services (CMS) the revenue they receive from GPOs as the law requires. These payments are treated as reductions on hospital cost reports and are used to determine appropriate levels of Medicare reimbursement.

The unsafe "safe harbor" transformed the GPO business model from nonprofit cooperatives that saved hospitals money to unscrupulous for-profit middlemen that exist only to make money for 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. This pernicious practice was cited in the June 2021 White House 100-day report on supply chain resilience, which President Biden ordered shortly after he took office.

According to Novation [8]"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-

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[7] Vizient payments to Hopkins CEO Kevin Sowers, 6/30/19: https://nebula.wsimg.com/7561fd0bac0a58342ffc20a4c5c9efbc?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1. For 2020 & 2022 see GPO documents page of PADS website.

[8] Novation "Excess Fee Reports," 1998: https://nebula.wsimg.com/c15ea9a527af70ceaaaf434f3cd3ce0e?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1 For 1999 & 2001, see the GPO Documents page of our website.

digits, and sometimes more than half of a company's total revenue for a single drug. Because there's virtually no transparency or disclosure, oversight or regulation on this industry, documentation like this remains a closely guarded secret. GPOs perform no medically, socially or financially useful function. They are nothing more than a "legalized" fraud.

Recommendation: The FTC should request, or if necessary, subpoena GPO, hospital, distributor & supplier contracts.

Although the opacity of the GPO industry makes it exceedingly difficult to systematically connect the dots between contract terms—-including fees, sole-sourcing, and duration—-and shortages, sometimes this information ends up in the public domain. For example, in October 2007, Baxter issued a press release touting its sole-source contract with Novation (now Vizient) for IV solutions; in its reporting on the deadly heparin contamination scandal, the [9]*Wall Street Journal* of 2/9/08 reported that Baxter, again, had a sole-source contract with Novation; and a letter from contrast dye maker Bracco Diagnostics to the Senate Antitrust Subcommittee complaining that Novation blocked its access to the market was published in the [10]transcript of the hearing of 7/16/03.

An October 25, 2023 *New York Times* article, which has nothing—-and everything—-to do with drug shortages, illustrated 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 GPO lobbying and PR operation metastasized like a cancerous tumor to preserve and protect the malignant safe harbor.

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[9] WSJ, 2/9/08: https://nebula.wsimg.com/897f243514df5ef30c47d3e8aa587a06?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[10] Senate Antitrust Subcommittee hearing, 07/16/03 (p.81): https://www.govinfo.gov/content/pkg/CHRG-108shrg91807/pdf/CHRG-108shrg91807.pdf

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.

More examples on the deleterious impact of outrageous GPO "fees" are found in [11]"The Dirty Secret of Drug Shortages" by Sara Sirota of the American Economic Liberties Project.

One document, which plaintiffs obtained in an antitrust lawsuit against Vizient, tells the whole story. Incredibly, [12]Vizient's marketing material boasts that one of the services it offers contracted suppliers is "Protection from Competitive Threats and Rebidding."

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, there is no evidence that it has ever done so. This was underscored in a [13]March 30, 2012 GAO report entitled "Group Purchasing Organizations: Federal Oversight and Self-Regulation."

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[11] "The Dirty Secret of Drug Shortages," 10/19/23:https://www.economicliberties.us/our-work/the-dirty-secret-of-drug-shortages

[12] Vizient marketing material, date unknown: https://nebula.wsimg.com/22ca1d09dd60af766fb14af4d6400e02?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[13] GAO Report,3/30/12: https://www.gao.gov/products/gao-12-399r

In 2005, Senators Herb Kohl (D-WI) and Mike DeWine (R-OH), who presided over the Antitrust hearings, drafted a [14]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 Greater New York Hospital Association, the American Hospital Association and its state affiliates torpedoed it. It is a system in which the rich get richer, and the sick get sicker.

Not a single piece of drug-shortage legislation that has been promoted or introduced since the Kohl/DeWine "Discussion Draft" would accomplish anything at all.

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 Obama administration officials testified before two congressional committees on the central role of GPOs in causing this ongoing public health emergency. In the middle of what was apparently the [15]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."(P. 47 & 60)

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

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[14] "Discussion Draft: Ensuring Competition in Hospital Purchasing Act,"2005: https://nebula.wsimg.com/a862289b485f16554cfb4f8d8567221a?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[15] House E&C hearing, 9/23/11: https://www.govinfo.gov/content/pkg/CHRG-112hhrg77032/pdf/CHRG-112hhrg77032.pdf

hearing, was asked to respond. She said: “You [Dr. Koh] have said what I would say. Thank you.”

Then, on December 15, 2011, in a hearing before the [16]Senate Committee on Health, Education, Labor and Pension (HELP), Sherry Glied Ph.D, HHS Assistant Secretary for Planning and Evaluation, zeroed in on questionable GPO contracting practices. The takeaway: GPOs had undermined the law of supply and demand.

As the GPOs ratcheted up their disinformation campaign to protect 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, 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, and the creation of a massive new federal bureaucracy, as has been proposed in the May 3 Senate Finance “Discussion Draft” is a nonstarter. So are proposals that call for expanding nonprofit manufacturing or a federal takeover of the generic drug business, They would be a total waste of taxpayers’ money.

Safe Harbor Cost Analysis

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. At least three government studies

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[16] Senate HELP hearing, 12/15/11: https://www.help.senate.gov/hearings/prescription-drug-shortages-examining-a-public-health-concern-and-potential-solutions

or investigations have found that there isn't a single shred of independent evidence that they save hospitals a dime. They include:

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

- [18]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. Put another way, people who believe that the Publishers Clearing House saves them money might believe that GPOs save hospitals money.

- [19]2010 Senate Finance Committee Minority Staff Report on GPOs requested by Sen. Chuck Grassley. It found that there was no independent evidence that GPOs save hospitals money. Nothing has changed.

- 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. For details, see my [20]"Safe Harbor Cost Analysis" (updated April 2, 2024). My methodology was admittedly unscientific, because there is no independent publicly available data on these transactions. Some well-informed supply chain practitioners have told me that my estimate is too low. For other views on the extent to which

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[17] GAO Pilot Study, 4/30/02: https://www.gao.gov/products/gao-02-690t

[18] Kohl/DeWine letter to Defense secy Donald Rumsfeld, 5/2/03: https://nebula.wsimg.com/2c05bf026ed6c9ae9cd03339d59efe78?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[19] Senate Finance Comm (minority) report, 2010: https://nebula.wsimg.com/32ce499df16ad66aede1ee5b4ed7d2a0?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[20] "Safe Harbor Cost Analysis," 4/2/24: https://nebula.wsimg.com/6d8b8a93bb8e7651d4300550dfbebffc?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

GPOs inflate prices, see [21]*dBusiness* [Detroit Business) of November 27, 2018, “Medical Monopoly.” One thing GPO critics agree on is that competition reduces prices, whereas 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 distributors**. These are mostly small-to-mid-sized "mom and pop” firms that provide smaller quantities of drugs to providers, 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, Cencora (formerly AmerisourceBergen), and Cardinal—because they’re not permitted to get “chargebacks,” or rebates, from GPO-contracted suppliers. Premier demonized them in a misleading [22]August 2011 report. The FBI investigated and found no wrongdoing, as reported in the inaugural [23]February.10, 2014 GAO report on drug shortages (p.69), 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 “intermediate” causes. [For

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[21] dBusiness, Nov/Dec 2018: https://www.dbusiness.com/business-features/medical-monopoly/#.XAVPPBNKhsY

[22] Premier “Buyer Beware,” 8/11: https://nebula.wsimg.com/d3a344fdd23eb3bb66bb8aa740c5e417?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[23] GAO drug shortage report, 2/10/14: https://www.gao.gov/assets/d14194.pdf

more on pricing, read [24]"Connecting the Dots" of January 4, 2012, a white paper by drug distribution consultant Pat Earl and Zweig.]

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

- **Overzealous FDA inspections**. I began to hear this in late 2011 after Bedford, OH-based Ben Venue Labs shuttered, causing dire shortages of methotrexate, Doxil and other lifesaving chemo meds. 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 cost-saving measure intended to cut the time workers needed to de-gown, do their business, re-gown, scrub back in and return to work. 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 drugs 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. Medicare reimbursement and the ASP formula have nothing at all to do with drug shortages, she explained, because they don't affect money actually received by suppliers. And contrary to popular belief, Medicare reimbursement prices aren't subject to price controls.

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[24] "Connecting the Dots," 1/4/12: https://www.gao.gov/assets/d14194.pdf

She explained that in a December 23, 2014 letter to the editor of the [25]*Journal of Oncology Practice.*

- **FDA backlog in approving generic drug applications.** Yes, there was a backlog in applications. But a 2016 study by the [26]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 [27]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 [28]*MONOPOLIZED*, a 2020 book by the *American Prospect's* David Dayen.

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[25] Journal of Oncology Practice, 12/23/14: https://ascopubs.org/doi/abs/10.1200/JOP.2014.002683?journalCode=jop

[26] Center for American Progress," 2016: https://www.americanprogress.org/article/fda-is-not-the-problem/

[27] Baxter press release, 10/9/07:https://nebula.wsimg.com/aaa5dd2ecdbff775fd9a64971fd3469f?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1

[28] Monopolized: https://prospect.org/culture/books/monopolies-are-why-salt-and-water-in-a-bag-became-scarce-dayen-monopolized-book/

- **Geopolitical Issues.** That was the bogus explanation given for the acute shortages of contrast dye, which began in April 2022 with the COVID-era lockdown of a GE Healthcare plant in Shanghai. Here again, the underlying cause was exclusive, anticompetitive GPO contracting. This issue surfaced as early as 2003, when Bracco Diagnostics, an Italian maker of contrast dye, complained in a letter to the Senate Antitrust Subcommittee about Novation's (now Vizient) exclusionary practices. Perhaps because of the letter, Bracco was able to break into the market, or the shortages would likely have been even worse. For more on this, see page 81 of the transcript of the hearing on GPOs before the [29]subcommittee of July 16, 2003.

- **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 in a remarkably prescient Oct 4, 2008 article in[30] *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."** A **c**atchy but misleading buzz phrase. It contends 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. GPOs have undermined this immutable economic principle. Most so-called "experts" who blame low GPO prices are obviously unaware of the outrageous kickbacks they've extorted from drugmakers have transformed a low margin but generally reliable business into a financial bloodbath. In making decisions about whether to continue making these drugs or exiting the business, what matters is their net revenue and profit margins. Of course, when a drug or any other product is in short supply, prices inevitably skyrocket. A table in my

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[29] op.cit: Senate Antitrust Subcommittee hearing, 7/16/03.

[30] Infection Control Today, 10/4/08: https://www.infectioncontroltoday.com/view/us-pandemic-could-severely-strain-face-mask-other-ppe-supply-pipeline

> "Safe Harbor Cost Analysis" (p. 14) provides a snapshot of prices health care facilities and other providers were forced to pay for essential generic injectable drugs after they became scarce.

I'll address a few other points that were raised by members at the hearing;

- **Low quality foreign made drugs.** Yes, all too many foreign-made drugs are of poor quality, particularly those made in China and India. But thanks to exorbitant GPO "fees," so are many drugs that have been "Made in the USA." The classic case is Ben Venue Labs of Bedford, OH. a longtime manufacturer of generic sterile injectables, including lifesaving chemotherapeutic agents like methotrexate, cisplatin, and carboplatin. See "Overzealous FDA Inspections," above.

- **Burdensome Federal Regulation.** Bad legislation—like the "safe harbor"—gives rise to bad regulation.

- **Big Hospitals (the "Haves") vs. Small, Rural Hospitals (the "Have Nots").** We have no hard data on this, but allocation of drugs in shortage may also be based on whether or not a hospital system is a GPO shareholder. According to news reports, patients and clinicians in rural areas have much more difficulty obtaining scarce drugs than those in large cities.

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 outright support of medical "thought leaders." They include former FDA Commissioner Scott Gottlieb M.D. In 2018, he told the [31]*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 [32]"Buckraking" in *BIG* (a blog) of July 7,

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[31] AP 7/12/18:https://apnews.com/national-national-998a244e3ac849b787bcd3c893eb6806

[32] Buckraking, 7/7/22: https://www.thebignewsletter.com/p/buckraking-did-a-medical-monopolist?utm_source=substack&utm_medium=email&utm_content=share

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). For health care journalists on deadline to produce drug shortage stories, she is the go-to source because she owns the data. But there would be no data, no shortages, and no stories, if it weren’t for the entities that fund her activities.

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, attached below.

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.

Virtually everyone who works in the health care supply chain knows it’s broken, And they know why it’s broken and who broke it: GPO middlemen and their big wholesaler cohorts. So do members of Congress. Some of the same senior members of Senate Finance and the House Energy and Commerce Committee who have presided over hearings in the last year were in attendance in 2011 when those same committees held essentially the same hearings. It’s high time that members exercise their duty of care to their fellow citizens and end the “legalized” kickbacks and “share backs” by repealing the unsafe safe harbor. So here’s our New Year’s message to Congress: You broke it. You fix it.

See also attached “Key Articles and Documents on GPOs and Drug Shortages” (Annotated).”Feel free to contact us if you have questions or would like to discuss this issue further.

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Dinesh S. Thakur Retweeted

Joseph Hill @JosephMHill · 24 Jul 2017

.@foxerinr and her team does a great job of tracking #drugshortages on ashp.org/shortages

DISCLOSURE

- This presentation represents my own opinions
- University of Utah Drug Information Service receives funding from Vizient (a GPO) to provide drug shortage content
- University of Utah Health is Vizient member

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

Consultancies: Snehal Bhatt (Janssen Pharmaceuticals Inc.); Michael B. Bottorff (Esperion); James C. Coons (Medicure); Erin Fox (Civica Rx, Vizient); Kristen Gardner (Board of Pharmacy Specialties, biostrategies); Ian R. McGrane (Mountain Pacific Quality Health, Montana Mental Health Trust); Jo E. Rodgers (Novartis);

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Honoraria: Snehal Bhatt (Portola Pharmaceuticals); Amber Cipriani (Amgen); Erin Fox (Mayo Clinic, European COST Project, ASHP, ACCP, FDA, Drug Information Association, Joint Commission of Pharmacy Practitioners, University of Illinois, National Academy of Sciences, Engineering, and Medicine, American Society of Anesthesiologists, Anesthesia Patient Safety Foundation, Massachusetts Society of Health System Pharmacists, Idaho Society of Health System Pharmacists); Ian R. McGrane (University of Montana Skaggs School of Pharmacy, Montana Pharmacy Association, Northwestern Pharmacy Conference); Amber Cipriani (Amgen)

Other:

Nothing to disclose: Ohoud Almalki; Bassam Atallah; Michael Brenner; Laura Tsu Chen; Estella M. Davis; Katherine E. Di Palo; Shannon Finks; Mona Fiuzat; Gregory Shawn King; James C. Lee; Yee Ming Lee; Joel Marrs; Natasha Nicol; Manish Patel; Carrie S. Oliphant; Kathleen A. Packard; Mary Parker; Kelly C. Rogers; Cynthia A. Sanoski ; Andrew J. Smith; Dustin D. Spencer; Rebecca JC Tran; Benjamin Van Tassell; Ellen B. Yin; Monty Yoder; Eman Younis;

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