November 22, 2022

Federal Trade Commission 600 Pennsylvania Avenue NW Washington, DC 20580

CC:

Commissioner Robert M. Califf Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Chair Khan, Commissioner Phillips, Commissioner Slaughter, Commissioner Wilson, and Commissioner Bedoya:

We write to urge the Federal Trade Commission (FTC) to investigate the monopolistic middlemen in the healthcare supply chain known as group purchasing organizations (GPOs). Right now, glaring shortages in medical equipment markets, skyrocketing healthcare costs, and overreliance on sole-sourced, overseas production jeopardize patient safety and national security, especially our dependence on Chinese manufacturing of key medical supplies. We believe GPOs play a key and under-appreciated role in fostering and exacerbating shortages and the offshoring of production, while their influence on costs remains chronically under-analyzed. The FTC has not conducted a study into this consolidated sector and its relationship with medical shortages, but the commission has the authority to fill this gap by conducting a study under section 6(b) of the FTC Act (15 U.S.C. § 46(b)).

Group purchasing organizations negotiate procurement contracts for pharmaceuticals and medical supplies on behalf of hospitals and other healthcare providers, serving as industry middlemen who neither manufacture medical equipment and goods nor directly provide health care. By leveraging the collective supply needs of their member hospitals, nursing homes, and other health care providers, GPOs have the power to exert greater bargaining power and obtain better contract terms for buyers. But decades of consolidation and regulatory exemptions have given them monopsony negotiating leverage, allowing them to obstruct the competition of a functioning market. For example, GPOs accept what are effectively kickbacks from suppliers, creating a pay-to-play scheme in the medical equipment market. GPOs also lock their members into sole-sourced purchases and vendors into fixed prices, preventing from making organic adjustments in response to either their own costs or health care needs. What's more, they generate exorbitant profits for owners at the expense of the public interest. And despite representing hundreds of billions of dollars in procurement annually, much of which is paid for by Medicare, Medicaid, and other government programs, GPOs face next to zero oversight or transparency standards.

Over several decades, many government agencies and media watchdogs have expressed concern with GPOs' sway over the industry and the extent to which they actually reduce costs. Most recently, 60 Minutes ran a news segment exposing how they create shortages of essential drugs

such as pediatric chemotherapy medication.¹ In response to President Joe Biden's executive order on U.S. supply chain risks last year, the White House reported that GPO contracting methods, especially sole-sourced agreements, may lead to reduced competition among medical suppliers.² The U.S. Food and Drug Administration also reported in 2020 that GPO schemes leave suppliers with such low profit margins that they do not have sufficient resources to invest in production or excess capacity.³ Meanwhile, a 2010 Senate Finance Committee report ordered by then-Ranking Member Sen. Charles Grassley (R-Iowa) found that limited data exists to verify whether GPOs achieve savings for buyers.⁴

This letter will first explain the main features of the group purchasing organization industry, its level of consolidation, and the conflicts of interest inherent in the current business model. Second, it will detail how GPOs contribute to medical shortages and the offshoring of the manufacturing for critical medical equipment and products. Third, it will detail the history of the GPO industry, showing the policy changes and process of consolidation that created the perverse incentives and harms that we see today. We close by identifying the core features of the GPO industry and business model that should be investigated through a 6(b) study.

Section I: The Group Purchasing Organization Industry

What are Group Purchasing Organizations?

GPOs pool the collective buying power of hospitals, nursing homes, and other healthcare providers to negotiate procurement contracts with manufacturers for everything from surgical masks and gloves to prescription drugs. When a GPO signs a contract with a supplier, the members it represents can then use that contract to buy a designated product at the negotiated price over a specified timeframe. GPOs may bundle several products from one or multiple vendors in a single contract, supposedly negotiating a discounted price for the group. But the extent of these discounts in reality is unclear. As then-Senators Mike DeWine, R-Ohio, and Herb Kohl, D-Wis., warned Defense Secretary Donald Rumsfeld in 2003, the benchmarks that GPOs use to demonstrate savings are based on a manufacturer's list price, which hospitals rarely use.⁵

GPOs are typically for-profit entities that are either owned by their hospital members or have contracting arrangements with them, which may include participation fees charged to the members

¹ Bill Whitaker, "Medical Middlemen: Broken system making it harder for hospitals and patients to get some life-saving drugs," 60 Minutes, May 22, 2022, https://www.cbsnews.com/news/generic-drugs-pharmaceutical-companies-60-minutes-2022-05-22/.

² "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," The White House, June 2021, https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.

³ "Drug Shortages: Root Causes and Potential Solutions," U.S. Food and Drug Administration, February 21, 2020, https://www.fda.gov/media/131130/download.

⁴ "Empirical Data Lacking to Support Claims of Savings With Group Purchasing Organizations," Senate Finance Committee Minority Staff Report, September 24, 2010, https://www.grassley.senate.gov/imo/media/doc/2010-09-24-GPO-Report.pdf

⁵ Mike DeWine and Herb Kohl, Letter from Sens. Mike DeWine and Herb Kohl to Defense Secretary Donald Rumsfeld, May 2, 2003,

https://nebula.wsimg.com/2c05bf026ed6c9ae9cd03339d59efe78? Access KeyId=62BC662C928C06F7384C& disposition=0& alloworigin=1.

for using the GPO's services. However, GPOs earn most of their money by charging contract administrative fees to suppliers, rather than revenue from members. These fees are typically calculated as a percentage of a given product's price – which is claimed to be on average less than 3%, though at times have effectively risen above 50% through a chain of ancillary fees – and the GPOs are legally obligated to disclose them annually to members. The manufacturer pays the administrative fees when a purchase is made off the contract. Generally speaking, the fees greatly exceed operating costs, and the GPOs often, though not always, distribute part of the excess sum back to the buyer.⁶

Beyond administrative fees, manufacturers may pay advertising and licensing fees to GPOs in order to, for example, market their products under the GPO's brand name. GPOs also sponsor events for hospital members and offer educational grants. In addition to suppliers, GPOs raise revenue from distributors, which typically pay no more than 3% of the total invoice price. A portion of these gains may also be distributed back to members. However, as detailed below, GPOs have a history of adding a range of other hidden fees charged to the manufacturer that inflate these costs, and hospitals do not always account for these fees when reporting their supply costs to Medicare, leading the government to pay more than it's supposed to.⁷

Furthermore, much of the revenue that GPOs make doesn't necessarily go towards offsetting hospitals' purchasing costs. Instead, hospital executives are accustomed to seeing funds that are trickled back instead go towards their salaries. This kind of slanted interest is what led a pension fund in March 2022 to sue the board and current and former CEOs of the publicly traded GPO, Premier, the largest in the country. The fund alleged that the board and CEOs overpaid Premier's pre-initial public offering investors – its member-owners – by more than \$200 million as part of what's called a tax receivable agreement.

Consolidation among GPOs

The GPO sector is dominated by just a few corporations. Three GPOs – Vizient, Premier, and HealthTrust – manage procurement for 90% of medical equipment today, leaving health care providers and small producers with little bargaining power. ¹⁰ "If you refuse to sell through a group

⁶ Phillip L. Zweig, "White Paper: A Cost Analysis of the 1987 Medicare Anti-kickback Safe Harbor for Group Purchasing Organizations and Pharmacy Benefit Managers," Physicians Against Drug Shortages, February 15, 2021.

 $[\]underline{https://nebula.wsimg.com/cd1702b03dd5bdcbf25da39704c4045c?AccessKeyId=62BC662C928C06F7384C\&disposition=0\&alloworigin=1.}$

⁷ "Empirical Data Lacking to Support Claims of Savings With Group Purchasing Organizations," Senate Finance Committee, September 24, 2010,

 $[\]underline{https://nebula.wsimg.com/32ce499df16ad66aede1ee5b4ed7d2a0?AccessKeyId=62BC662C928C06F7384C\&disposition=0\&alloworigin=1.}$

⁸ Phillip Zweig and Frederick Blum, "Where Does the Law Against Kickbacks Not Apply? Your Hospital," *Wall Street Journal*, May 7, 2018, https://www.wsj.com/articles/where-does-the-law-against-kickbacks-not-apply-your-hospital-1525731707.

⁹ Mike Leonard, "Premier Inc. Board Sued Over \$474 Million Payout to Insiders," *Bloomberg Law,* March 16, 2022, https://nebula.wsimg.com/2c067980ccf8c874b6dc77596ddb8e7b?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

¹⁰ "Medical Middlemen: Broken system making it harder for hospitals and patients to get some life-saving drugs."

purchasing organization, or through drug wholesalers, you will not exist," Bill Simmons, a former generic drug executive, told *60 Minutes* in May 2022. "You are out." ¹¹

As such, GPOs are gatekeepers to the largest medical buyers in the United States; a manufacturer looking to sell its products in the health care market has little other choice but to partner with them. Indeed, the Government Accountability Office reported in 2010 that hospitals across the country make about 73% of their nonlabor purchases through a GPO contract. Although there are hundreds of GPOs in the United States, hospitals on average have membership in two to four companies.¹²

Since then, the industry has only consolidated further. Vizient formed in 2015 when VHA Inc., University HelathSystem Consortium, and Novation combined; it then acquired a MedAssets subsidiary in 2016 and Intalere (formerly Amerinet) in 2021. It is now the largest GPO in the country with more than \$100 billion in purchasing volume, putting its procurement budget on a similar scale with the Pentagon. Premier acquired Greater New York Hospital Association's GPO subsidiary in 2020. It is today the second-largest GPO in the country with at least \$69 billion in purchasing volume. HealthTrust is the third largest, boasting more than \$20 billion in purchasing volume. These major GPOs have also acquired a number of other smaller companies over the years to achieve their current purchasing power. The FTC has not challenged any of these mergers.

Conflicts of Interest

The vendor-based revenue setup creates perverse incentives for GPOs to guarantee greater returns by locking members into long-term contracts with incumbent suppliers. GPOs purport to use competitive bidding strategies, but there have nevertheless been examples of sole-sourced, long-term deals, such as when GPOs Premier and Novation, now known as Vizient, awarded such contracts to an incumbent oximeter company, undermining a superior, life-saving alternative's access to buyers, as a *New York Times* investigative series exposed in 2002.¹⁶

One result of inflexible contracting and consolidation in GPO buying power is shortages. In a healthy market, a manufacturer, faced with low or negative margins on a product sought by end consumers, could simply raise prices. But GPOs have destroyed the ability of sellers to adjust prices in response to supply shocks or increases in production costs. Many products are now bought

¹² "Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices," U.S. Government Accountability Office, August 2010, https://www.gao.gov/assets/gao-10-738.pdf.

https://www.nationaldefensemagazine.org/articles/2020/2/10/budget-2021-trump-proposes-flat-pentagon-budget; "Frequently asked questions," Vizient, https://www.vizientinc.com/frequently-asked-questions.

¹¹ Ibid.

¹³ The Pentagon's procurement budget was \$136.9 billion in 2021. See Jon Harper, "BUDGET 2021: Trump Proposes Flat Pentagon Budget," National Defense, February 10, 2020,

¹⁴ Premier, Inc., Form 10-K For The Fiscal Year Ended June 30, 2021, U.S. Securities and Exchange Commission, https://www.annualreports.com/HostedData/AnnualReports/PDF/NASDAQ_PINC_2021.pdf.

¹⁵ "HealthTrust Purchasing Group Participates in White House Discussion in White House Discussion on 'Greening America's Hospitals,'" Fierce Healthcare, July 27, 2012, https://www.fiercehealthcare.com/healthcare/healthtrust-purchasing-group-participates-white-house-discussion-greening-america-s.

¹⁶ "New York Times Series On GPO's," Masimo, https://www.masimo.com/company/news/media-room/nyt-series/.

under fixed-price contracting, with high fees owed to middlemen. And since there are effectively only three national GPOs, a manufacturer can't turn to an alternative buyer if they need to increase prices. As a result, manufacturers are often unable to invest in greater production even when there are constraints on supply and clear demand by hospitals. They simply stop making the good. That is why suppliers in a host of areas have abandoned the production of critical, low-margin products, and cut costs by moving production overseas where regulatory standards are lower. These outcomes foster shortages, drive new producers of superior or more affordable goods out of the market, and increase dependence for essential items on an unreliable global supply chain. Indeed, as the early months of the Covid-19 pandemic revealed, the United States is dependent on China for the manufacturing of such low-margin, routine medical supplies, which pose a national security risk in the event of a natural disaster, another pandemic, or geopolitical tensions in the Asia-Pacific region.

The rationale for group buying is that it ostensibly saves hospitals money. Indeed, the GPO industry insists that it saves members between 10% and 18% in procurement costs, ¹⁷ the many convoluted transaction fees likely obscure real costs. GPOs are required to disclose any administrative fees to members that exceed 3% of a good's price, but they have found ways to avoid disclosure through various junk fees for ancillary schemes such as "marketing," "advance," "conversion," and "licensing" payments, as well as rebates and prebates that together can add up to well above 3%. ¹⁸

The GPO revenue model, charging fees to suppliers for access to the buyer markets, is currently organized under an exemption from the Medicare Anti-Kickback Statute that the federal government granted in 1987 to permit administrative fees. However, a series of scandals more than 20 years ago revealed improper, conflicted, and potentially illegal relationships. There were cases, for example, of GPO executives having investments in manufacturers or seats on their boards. Under pressure from Congress, the industry adopted new voluntary ethical codes that, for instance, banned GPO executives involved in contracting decisions from having equity ownership in supply companies Little substantive policy action by regulators or enforcers was taken, except for a mandate that the Food and Drug Administration maintain publicly available lists of drug shortages that the problematic market structure in the GPO market induced. Meanwhile, antitrust authorities continued to allow mergers to proceed apace.

Section II: Critical Medical Supply Shortages and Overseas Production

Shortages for medical supplies in the United States are frequent and widespread. These key features of the GPO industry distort medical supply markets such that they are characterized by frequent medical supply and drug shortages and dependence on unreliable, overseas production, putting patients at risk of losing access to their needed treatments.

¹⁸ Phillip L. Zweig, "White Paper: A Cost Analysis of the 1987 Medicare Anti-kickback Safe Harbor for Group Purchasing Organizations and Pharmacy Benefit Managers," Physicians Against Drug Shortages, February 15, 2021.

 $[\]underline{https://nebula.wsimg.com/cd1702b03dd5bdcbf25da39704c4045c?AccessKeyId=62BC662C928C06F7384C\&disposition=0\&alloworigin=1.}$

The FDA shortage list has demonstrated that the U.S. is currently lacking sufficient amounts of items like cancer, parenteral nutrition, and blood pressure drugs, as well as saline, automated external defibrillators, and iodinated contrast. ¹⁹ Other medications and equipment may not meet the FDA's shortage threshold, but are at significant risk due to exclusive contracting schemes and few available production sources.

In an interview with 60 Minutes earlier this year, Dr. Mitch Goldstein, a neonatologist at Loma Linda University Children's Hospital in California, described the severity of shortages for drugs used to treat premature and sick babies.

"It can be certain minerals. It could be certain salts. Things that you would ordinarily find in a college chemistry lab, we can't get."

"These are basic things: glucose, sugar. It's not hard to make. But the point is we can't get it." ²⁰

60 Minutes reported that there are shortages of about 300 essential drugs on most days, sometimes leaving hospitals with no other choice b ut to put patients on medications that aren't as safe or as effective as their usual treatments.

At the same time as the U.S. is a leading global producer of advanced medical equipment, it is highly dependent on China and other countries to produce basic medications and supplies like personal protective equipment. This reliance leaves the U.S. vulnerable in the event of an unforeseen disruption to global supply chains, such as during the Covid-19 pandemic, when hospitals could not access sufficient amounts of N95 masks, which are almost entirely produced abroad.

In September 2020, American Economic Liberties Project's Rethink Trade Director Lori Wallach, then of Public Citizen, testified before the U.S. International Trade Commission on this issue. Her research found that the U.S. had a global trade deficit of about \$6 billion for critical medical goods during the one year preceding the March 2020 domestic outbreak of Covid-19, a figure which temporarily worsened during the early months of the pandemic.²¹

What's more, the production of many of the drugs imported to the U.S. is highly concentrated in just two countries. In 2019, 84% of U.S. diuretic imports arrived from India, 76% of U.S. anti-inflammatory and painkiller medication imports came from India and China, and 62% of U.S. cardiovascular drug imports derived from India.²²

¹⁹ "Report to Congress: Drug Shortages for Calendar Year 2021," U.S. Food and Drug Administration, https://www.fda.gov/media/159302/download; "FDA Drug Shortages," U.S. Food & Drug Administration, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

 ^{20 &}quot;Medical Middlemen: Broken system making it harder for hospitals and patients to get some life-saving drugs."
 21 Lori Wallach, Written Testimony, U.S. International Trade Commission Hearing on Covid-19 Related Goods:
 The U.S. Industry, Market, Trade, and Supply Chain Challenges," September 21, 2020, https://www.citizen.org/wp-content/uploads/Public-Citizen-Written-Testimony-Covid-and-trade-with-Add-Submission.pdf.
 22 Ibid.

These shortages do not happen by chance, and are not merely the result of expensive domestic production costs or mismanagement in the American health care system. GPOs play a significant role in contributing to this problem. As examples of medical equipment that have faced harmful shortages in recent years as a result of GPOs' middleman position and our resultant dependence on other countries for production, we highlight personal protective equipment (PPE) and pediatric chemotherapy drugs.

Personal Protective Equipment (PPE)

Early on during the COVID-19 pandemic, the U.S. experienced a severe shortage of PPE, including medical masks, gowns, and gloves. Much of this is attributable to China's decision to cut off its exports of various medical supplies to cater to its domestic needs. While the U.S. does make some of its own PPE, a significant amount is imported – mostly from China. In 2019, Chinese companies manufactured 75% of imported PPE to the U.S., a significant increase from 13% thirty years prior.²³

The greater production affordability in China compared to the U.S. is an attractive factor for any supplier deciding where to locate their manufacturing. By demanding administrative fees to sell products to their hospital members, GPOs tilt the scale even more towards the cheaper source. Indeed, Vizient was among the corporate interests lobbying the U.S. Trade Representative to grant exceptions to tariffs on China for medical supplies like PPE.²⁴

Furthermore, an October 2020 national survey of healthcare supply chain executives by FTI Consulting found that GPO contractors offered minimal help during the spring 2020 surge in demand for PPE. The consulting firm found:

"Suddenly, a program contractually designed to help most American hospitals control their expenses had little to no effect or influence in doing so. In fact, many hospitals that pledged and were honoring their GPO's high-commitment purchasing thresholds, created through single-supplier contract strategies, found themselves aggressively competing with peers in their purchasing aggregation cohort for the same supply pallet of PPE, sparking bidding war frenzies among local hospitals within the same community."²⁵

Pediatric Chemotherapy Drugs

In May 2022, 60 Minutes aired a segment documenting how GPOs have made it challenging for medical facilities to obtain pediatric drugs like vincristine, an essential and inexpensive

management.pdf?rev=60da887c96ce46148227c4f02beef21e&hash=67C8C18F497032BE5AA8F6D5D35434F9.

²³ Ibid.

²⁴ Shoshana Krilow, Letter from Vizient Vice President of Public Policy & Government Relations Shoshana Krilow to U.S. Trade Representative Robert Lighthizer, December 22, 2020, https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20201222_letter_urging_tariff_exclusions_extension.pdf

²⁵ "Rethinking Healthcare Expense Management Post-COVID," FTI Consulting, 2021, https://www.fticonsulting.com/emea/-/media/files/us-files/insights/articles/2021/jan/covid-19-rethinking-healthcare-expense-

chemotherapy medication used to treat leukemia, among other diseases. ²⁶ As a generic medication that's been around for decades, a vincristine dose has a price-tag of about \$5, significantly lower than new, brand drugs that can cost buyers well into the tens, if not hundreds, of thousands, of dollars. This price factor makes more expensive medications far more attractive for pharmaceutical companies to manufacture, regardless of how crucial a generic drug may be.

By charging excessive fees to suppliers, GPOs make the preference for highly profitable drugs worse. As of 2019, just two companies produced vincristine, Teva Pharmaceuticals and Pfizer, but the former decided in July of that year to stop making it. The result was not just Pfizer's subsequent monopoly, but also that when Pfizer ran into a quality control issue forcing it to pause production for six weeks, health care providers had no alternative to turn to. The supply shortage left pediatric cancer patients without an essential chemotherapy drug they had been using for years. Teva eventually agreed to restart production following an outcry, though in a troubling sign for the company, it closed a key facility in Irvine, California in August. ²⁷

Section III: The History of Group Purchasing Organizations

Group purchasing organizations were not always so concentrated, nor did they always have this sort of payment structure. Indeed, shortages themselves are relatively new in the American medical system. According to the Healthcare Supply Chain Association, the first GPO, called the Hospital Bureau of New York, was created in 1910.²⁸ The number of GPOs rose slowly to just 10 by 1962, at which time the organizations focused mostly on disposable goods and other commodities for purchase by hospitals in a given city or state.²⁹ With the establishment of Medicare and Medicaid in 1965, hospital executives sought to reduce operational expenses by driving down supply costs, resulting in significant demand for and growth of GPOs during the 1970s.³⁰

It was during this time that the GPO business model started to change. Initially, hospitals and other healthcare providers had pooled their resources together to fund GPOs as nonprofits. In the mid 1970s, however, large hospital chains began to establish for-profit companies to which other hospitals could pay dues in order to become a member. By 1980, there were more than 120 GPOs, and nearly all hospitals in the country belonged to one.³¹ But consolidation also began among many of the GPOs as private, investor-owned hospitals and nursing homes entered the market

²⁶ "Medical Middlemen: Broken system making it harder for hospitals and patients to get some life-saving drugs."

²⁷ Eric Palmer, "Teva to produce children's chemo drug again as shortage leads to backlash," *Fierce Pharma*, November 14, 2019, https://www.fiercepharma.com/manufacturing/teva-to-produce-children-s-chemo-drug-again-as-shortage-leads-to-backlash; Fraiser Kansteiner, "Updated: Teva won't reopen troubled California site, where 300-plus are losing their jobs," *Fierce Pharma*, August 23, 2022, https://www.fiercepharma.com/manufacturing/teva-puts-more-300-staffers-permanent-shore-leave-drydocked-california-injectables.

²⁸ A Primer on Group Purchasing Organizations Questions and Answers," Healthcare Supply Chain Association, https://www.hiscionline.org/sites/supplychainassociation.org/resource/resmgr/research/gpo_primer.pdf.

²⁹ Bernard L. Weinstein, "The Role of Group Purchasing Organizations (GPOs) in the U.S. Medical Industry Supply Chain," Estudios de Economia Aplicada, December 2006, https://www.redalyc.org/pdf/301/30113807006.pdf.

³⁰ "Hospital Group Purchasing: Lowering Costs at the Expense of Patient Health and Medical Innovations?,"

Hearing before the Subcommittee on Antitrust, Business Rights, and Competition of the Senate Judiciary Committee, April 30, 2002, https://www.govinfo.gov/content/pkg/CHRG-107shrg85986/html/CHRG-107shrg85986.htm.

³¹ Mariah Blake, "Dirty Medicine," *Washington Monthly*, July 1, 2010, https://washingtonmonthly.com/2010/07/01/dirty-medicine-2/.

during this decade. The variety of products procured by GPOs also widened, as drugs started to make up a larger proportion of procurement deals. This trend continued in the 1980s. 32

For most of their history, GPOs were also locally or regionally based. However, in 1977, Voluntary Hospitals of America launched the nationwide model that exists today, followed by American Healthcare Systems, the Consortium of Jewish Hospitals (today known as Premier), and MAGNET. In 1984, 27 nonprofit medical centers merged to create University HealthSystem Consortium (today known as Vizient). In 1986, four regional GPOs – Rhode Island's Haricomp, Missouri's Health Services Corporation of America, Hospital Shared Services of Western Pennsylvania, and Utah's Intermountain Healthcare – combined to form AmeriNet (today known as Intalere).³³

Late 1980s: Anti-Kickback Safe Harbor

Rising health care costs led Congress to transition the Medicare program from a fee-for-service to a fixed-rate payment model in the Social Security Amendments of 1983. Looking to make up for the ensuing revenue losses, hospitals adopted new cost-saving business strategies, such as physician incentive plans, hospital-physician joint ventures, and physician recruitment programs. But these arrangements risked violating the federal Anti-Kickback statute, which outlaws renumeration in return for patient referrals or medical supply purchases. 34

President Ronald Reagan signed into law the Medicare and Medicaid Patient and Program Protection Act of 1987. Section 14 of the measure directed the Health and Human Services (HHS) Department to issue exemptions, known as safe harbors, to the anti-kickback laws for GPOs and other business ventures. In return, the law sought to broaden the federal government's enforcement power by giving the HHS Office of Inspector General (OIG) the civil authority to exclude a violating medical center from the Medicare and Medicaid programs. Previously, criminal prosecution by the Justice Department was the sole enforcement mechanism.³⁵

The HHS OIG issued its final rules in July 1991, dictating that GPO-negotiated contracts do not have to put administrative fee percentages that suppliers would pay in writing to members unless they are above 3%. Nevertheless, GPOs would have to report to their hospital members the fees they received from contractors annually. ³⁶

35 Ibid.

³² Bernard L. Weinstein, "The Role of Group Purchasing Organizations (GPOs) in the U.S. Medical Industry Supply Chain," Estudios De Economia Aplicada," 2006, https://www.redalyc.org/pdf/301/30113807006.pdf.

³³ Rick Dana Barlow, "GPO Evolution and Progress, 1977-1987," Healthcare Purchasing News, February 20, 2017, https://www.hpnonline.com/sourcing-logistics/article/13000520/gpo-evolution-and-progress-19771987; James Spitler, "Group purchasing: Case reports: AmeriNet," American Journal of Hospital Pharmacy, November 1, 1987, https://academic.oup.com/ajhp/article-abstract/44/11/2496/5205184?redirectedFrom=PDF; "About us," Vizient, Inc., https://www.vizientinc.com/about-us.

³⁴ Francis J. Hearn, Jr., "Curing the Health Care Industry: Government Response to Medicare Fraud and Abuse," Journal of Contemporary health Law & Policy, 1989, https://scholarship.law.edu/cgi/viewcontent.cgi?article=1648&context=ichlp.

³⁶ "Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback," Department of Health and Human Services Office of Inspector General, July 29, 1991, https://oig.hhs.gov/documents/compliance/857/072991.htm.

Despite effectively charging suppliers more than 3% of a good's price, GPOs found ways to avoid having to disclose that in contracts under the HHS OIG's rule.³⁷ GPOs invented junk fees such as "marketing," "advance," "conversion," and "licensing" payments, as well as rebates and prebates that together can add up to well above 3%, and they have risen in some cases to more than 50%. For instance, the GPO Novation, now known as Vizient, in 1998 charged a 56.25% fee from Ben Venue Laboratories to market Diltiazem, a medication used to treat high blood pressure, to its member hospitals. This excessive fee only came to light because of a federal whistleblower lawsuit against Novation.³⁸

In a 2012 study called "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-Dealing by Hospital Group Purchasing Organizations Caused the U.S. Drug Shortage," Phillip Zweig, an investigative journalist and executive director of Physicians Against Drug Shortages, and Patricia Earl, then CEO of Secure Pharma Distributor Network LLC, described the fallout of the 1987 GPO safe harbor decision as follows:

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 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.³⁹

1990s: More Deregulation and Industry Consolidation

Supposedly looking to make healthcare more affordable, the administration of President Bill Clinton took further steps to limit enforcement of antitrust laws. In 1993, the Justice Department and FTC announced new "antitrust safety zones," or ventures that the agencies would not challenge. These included joint purchasing arrangements among health care providers or GPOs, essentially supporting the development of buyer cartels in healthcare. Unless there were "extraordinary circumstances," the Justice Department and FTC pledged not to challenge such arrangements "if the group's purchases account for less than 35 percent of the total purchases of the relevant product or service, and the cost of the product or service being jointly purchased

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³⁷ "The FACTS about GPOs," Physicians Against Drug Shortages, https://www.physiciansagainstdrugshortages.com/gpo-facts--pay-to-play-.html.

³⁸ "White Paper: A Cost Analysis of the 1987 Medicare Anti-kickback Safe Harbor for Group Purchasing Organizations and Pharmacy Benefit Managers."

³⁹ Patricia Earle and Phillip Zweig, "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital Group Purchasing Organizations (GPOs) Caused the U.S. Drug Shortage," February 14, 2012, https://careandcost.com/2012/02/14/connecting-the-dots-how-anticompetitive-contracting-practices-kickbacks-and-self-dealing-by-hospital-group-purchasing-organizations-gpos-caused-the-u-s-drug-shortage/">https://careandcost.com/2012/02/14/connecting-the-dots-how-anticompetitive-contracting-practices-kickbacks-and-self-dealing-by-hospital-group-purchasing-organizations-gpos-caused-the-u-s-drug-shortage/">https://careandcost.com/2012/02/14/connecting-the-dots-how-anticompetitive-contracting-practices-kickbacks-and-self-dealing-by-hospital-group-purchasing-organizations-gpos-caused-the-u-s-drug-shortage/.

accounts for less than 20 percent of the total revenues from all products or services sold by each participant in the joint purchasing arrangement."⁴⁰

The Justice Department and FTC followed these pledges with clarifying statements in 1994, though the guidance on GPOs specifically remained largely the same. ⁴¹ The agencies made further revisions in August 1996, describing safeguards that GPOs falling outside the antitrust safety zone can use to mitigate the likelihood that they otherwise raise anticompetitive concerns. The agencies' statements appear to have served as a guide for GPOs to skirt antitrust laws while violating them in spirit. For example, GPOs can forego requiring members to use the arrangement for all their purchases of a particular product, employ an agent to negotiate with suppliers who is not employed by a member, and keep communications with individual members confidential. ⁴²

The revised guidelines also give GPOs great leeway in deciding whether to block market access to certain health care providers, based on structural conditions at the time:

The existence of a large number and variety of purchasing groups in the health care field suggests that entry barriers to forming new groups currently are not great. Thus, in most circumstances at present, it is not necessary to open a joint purchasing arrangement to all competitors in the market. However, if some competitors excluded from the arrangement are unable to compete effectively without access to the arrangement, and competition is thereby harmed, antitrust concerns will exist.⁴³

Such statements, condoning or allowing GPOs to refuse to do business with certain hospitals or providers, gives them another tool to expand their market power by serving as gatekeepers for health care providers' access to medical supply markets.

However, the diversity of firms in the GPO industry would not last. In 1990, Greater New York Hospital Association, Rochester Regional Hospital Association, and Nassau-Suffolk Hospital Shared Services joined to form Healthcare Purchasing Alliance. In January 1996, American Healthcare Systems, SunHealth Alliance, and Premier Healthcare Alliance merged to form Premier Inc. Premier oversaw purchasing for approximately 33% of hospitals in the U.S. In January 1998, VHA and University HealthSystem Consortium merged to form Novation. By 1998,

⁴⁰ "Antitrust Enforcement Policy Statements Issued For Health Care Industry," Department of Justice, September 15, 1993, https://www.justice.gov/archive/atr/public/press_releases/1993/211661.htm.

⁴¹ "The United States Department of Justice and the Federal Trade Commission Issue New Statements of Antitrust Enforcement Policy for Health Care," Wiggin and Dana LLP, January 1, 1999, https://www.wiggin.com/publication/the-united-states-department-of-justice-and-the-federal-trade-commission-issue-new-statements-of-antitrust-enforcement-policy-for-health-care/.

⁴² "Statements of Antitrust Enforcement Policy in Health Care," U.S. Department of Justice and the Federal Trade Commission, August 1996, https://www.justice.gov/atr/page/file/1197731/download.

⁴³ "Statements of Antitrust Enforcement Policy in Health Care," U.S. Department of Justice and the Federal Trade Commission, August 1996, https://www.justice.gov/atr/page/file/1197731/download.

⁴⁴ Bernard L. Weinstein, "The Role of Group Purchasing Organizations (GPOs) in the U.S. Medical Industry Supply Chain," Estudios de Economia Aplicada, Vol. 24-3, 2006, https://www.redalyc.org/pdf/301/30113807006.pdf.
https://www.redalyc.org/pdf/301/30113807006.pdf.
https://www.redalyc.org/pdf/301/30113807006.pdf.
https://www.redalyc.org/pdf/301/30113807006.pdf.

Group Organizations (GPOs) Caused the U.S. Drug Shortage."

⁴⁶ Phillip Zweig and Wendy Zellner, "Locked Out of the Hospital," Bloomberg, March 16, 1998, https://www.bloomberg.com/news/articles/1998-03-15/locked-out-of-the-hospital#xj4y7vzkg.

the six largest GPOs controlled procurement contracts for at least 80% of the roughly 5,400 acute-care hospitals in the U.S.⁴⁷

Late 1990s-Early 2000s: Allegations Trigger Media & Government Investigations

Over the course of the late 1990s and early 2000s, a number of media and government investigations brought attention to GPOs' potentially negative effects on the quality and abundance of medical supplies. Journalists and lawsuits exposed how GPO contracting arrangements propped up the legacy providers of dangerous needle sticks and less effective oxygen monitors and prevented superior alternatives from entering the market.⁴⁸ These revelations led the Senate Judiciary Subcommittee on Antitrust, Business Rights, and Competition to hold four hearings on GPOs between 2002 and 2006 where lawmakers raised concerns about improper financial ties between GPOs and providers, a lack of supplier diversity, and high prices of goods.⁴⁹

During this timeframe, the GAO released studies on the industry, one of which found that GPOs did not guarantee that hospital members saved money.⁵⁰ In July 2004, the Justice Department and FTC released a study on health care competition, stating that the "[a]gencies would examine on a case-by-case basis the facts of any alleged anticompetitive contracting practice to determine whether it violates the antitrust laws. The HHS OIG also released an audit of three of the largest GPOs, finding their revenue from suppliers "significantly exceeded operating costs." The audit then evaluated how 21 GPO members accounted for the distributed funds they received, determining they did not fully account for them on their Medicare cost reports.⁵¹

Later, in September 2010, Grassley released a Senate Finance Committee minority report that studied the conduct of seven major GPOs. The assessment found, among other conclusions, that these organizations offer services outside traditional GPO activities, funded with administrative fees that exceed the original intent of the 1987 safe harbor, and a portion may be distributed to members, only to then be given back to the GPOs in the form of payments for other services. The report ultimately concluded that Congress and the American public did not have data to determine the success of the safe harbor provision, and given the industry's evolution over the years, lawmakers should consider legislation that would give HHS OIG more oversight.⁵²

In November 2011, Sens. Barbara Boxer, Grassley, Kohl, Richard Durbin, and Tom Harkin wrote Federal Trade Commission Chairman Jonathan Leibowitz, requesting that the agency review the

⁴⁸ "Congressional Hearings;" "Needles," CBS News, February 22, 2001, https://www.cbsnews.com/news/needles-22-02-2001/; "Connecting the Dots."

⁴⁷ Ibid.

⁴⁹ "Hospital Group Purchasing: Lowering Costs At The Expense of Patient Health and Medical Innovations?" Hearing Before The Subcommittee on Antitrust, Business Rights, and Competition of the Committee on the Judiciary United States Senate, April 30, 2002, https://www.govinfo.gov/content/pkg/CHRG-107shrg85986.htm.

⁵⁰ Marjorie Kanof, "Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products," Government Accounting Office, July 16, 2003, https://www.gao.gov/assets/gao-03-998t.pdf.

⁵¹ "Review of Revenue From Vendors at Three Group Purchasing Organizations and Their Members," Department of Health and Human Services Office of Inspector General, January 19, 2005, https://oig.hhs.gov/oas/reports/region5/50300074.pdf.

^{52 &}quot;Empirical Data Lacking to Support Claims of Savings With Group Purchasing Organizations."

anticompetitive practices of GPOs in the health care marketplace.⁵³ While the FTC did not act, the GAO continued to release investigations, revealing in March 2012, for example, that the HHS OIG does not routinely exercise its authority to review disclosures of GPO contract administrative fees.

Conclusion

A comprehensive 6(b) study of the GPO industry is essential to prevent medical supply shortages and disincentivize overreliance on offshore production. Specifically, we request that the FTC investigate the following:

- 1. The effects of concentration in the GPO industry;
- 2. GPOs' effects on competition in medical supply markets;
- 3. The effects of GPOs on medical supply prices and reliability of medical supplies;
- 4. The effects of GPO purchasing and contracting practices on medical supply shortages;
- 5. The frequency and effects of GPOs' use of sole-sourced or exclusive contracts;
- 6. The connection between GPO concentration and the offshoring of medical supply production;
- 7. Whether elimination of the anti-kickback statute safe harbor would alleviate any of these problems, and
- 8. Whether the "antitrust safety zones" for joint purchasing arrangements should be eliminated.

Federal agencies, congressional committees, and watchdog organizations have gathered clear evidence of exploitation by GPOs over three decades. GPOs diminish medical supply market resilience, weaken patient care, and threaten national security. We urge the FTC to launch an investigation immediately.

Sincerely,

American Economic Liberties Project
Center for Economic and Policy Research
Demand Progress Education Fund
Free to Care
Our Revolution
Physicians Against Drug Shortages
Practicing Physicians of America
Public Citizen
Revolving Door Project

⁵³ Barbara Boxer and Charles Grassley, et al, Letter from Sens. Barbara Boxer and Charles Grassley, et al, to Federal Trade Commission Chairman Jonathan Leibowitz, November 9, 2011, https://nebula.wsimg.com/cd13f861f90d691c0388d44c1f82607e?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.