AMERICAN ECONOMIC LIBERTIES PROJECT

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 the American Economic Liberties Project Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages

April 26, 2024

We submit this comment in response to the Federal Trade Commission ("FTC") and the Department of Health and Human Services' ("HHS") joint request for information ("RFI") regarding the role of group purchasing organizations and drug wholesalers in America's ongoing drug shortage crisis. The American Economic Liberties Project ("Economic Liberties") is a nonprofit research and advocacy organization dedicated to understanding and addressing the problem of concentrated economic power in the United States. We write to highlight the role of dysfunctional market and contracting relationships in the market for generic drugs, as well as the misguided policy arrangements that have facilitated them. We urge both the FTC and HHS to act with their existing authorities, respectively antitrust enforcement action and rulemaking authority over Anti-Kickback Statute safe harbors and the Medicare Conditions of Participation.

Today, a record number of treatments, for everything from lead poisoning to cancer, are unavailable. At the end of 2022, there was a record five-year high of 295 active drug shortages, with sterile injectables commonly used in hospitals at increased risk.[1] While the pandemic did abnormally strain supply chains, drug shortages have been common since long before Covid-19, and they have continued since. The Food and Drug Administration ("FDA") maintains a list of drugs currently in active shortage, reliably showing frequent shortages of everything from cancer, parenteral nutrition, and blood pressure drugs, to saline, automated external defibrillators, and iodinated contrast.[2] As of today, April 26, 2024, 113 drugs are currently in active shortage, and another 129 drugs have recently been discontinued entirely.[3]

The core driver of generic pharmaceutical shortages is that the prices manufacturers receive for producing these medicines are extraordinarily low, such that manufacturers find it uneconomical to produce the drug at all, lacking resources to invest in production or excess capacity. This problem, however, is greatly exacerbated by various middlemen in medical supply chains, most especially group purchasing organizations and drug wholesalers. Group purchasing organizations

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[1] "Short Supply: The Health and National Security Risks of Drug Shortages," Majority Staff, U.S. Senate Committee on Homeland Security & Governmental Affairs, March 2023, https://www.hsgac.senate.gov/wp-content/uploads/Drug-Shortages-HSGAC-Majority-Staff-Report-2023-03-22.pdf.

[2] "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.

[3] U.S. Food and Drug Administration, "Current and Resolved Drug Shortages and Discontinuations Reported to FDA," accessed April 10, 2024, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

("GPOs") are consolidated buyers of medical supplies and pharmaceuticals, and they push prices for these generic medications lower, as well as using layers of contracts with tying and bundled rebates, exclusivity provisions, and purchasing quotas. These contractual terms trap medical providers within a GPO's procurement ecosystem and make it nearly impossible for new manufacturers to enter the market. Drug wholesalers, who physically deliver the goods to hospitals and pharmacies, are intimately tied up with these GPO contracting arrangements.

This comment is structured as follows. First, we outline the supply chain for generic drugs and the various businesses involved. Second, we explain the general problem in the market for generic drugs—excessively *low* prices, in particular—and how GPOs have contributed to this problem. Third, we highlight a range of contracting provisions frequently used by GPOs and wholesalers that exacerbate these problems, before turning to illustrate how all these contracting terms interact in the context of the contracting systems of the largest GPO, Vizient. Lastly, we outline how HHS and FTC can take action to address these problems under their existing enforcement and rulemaking authorities.

I. The Market for Generic Drugs

Between the drug manufacturer and the final patient or healthcare provider, there are several layers of middlemen in the supply chains for the generic drugs that we frequently find in shortage. Drug wholesalers are responsible for delivering drugs from a manufacturer to medical providers like hospitals, outpatient facilities, and pharmacies. Group purchasing organizations (GPOs), the primary focus of this comment, are responsible for negotiating with manufacturers the prices for drugs and

other medical supplies on behalf of hospitals and medical providers: the prices at which wholesalers will purchase and deliver drugs. Pharmacy benefit managers (PBMs) manage the benefits, patient out-of-pocket pricing, copayments, and reimbursements of drugs for insured patients, particularly in retail drug sales. As a result of their immense influence over consumer drug pricing and access, PBMs have been the focus of increased policy attention in recent years, but they are less directly responsible for the drug shortages we see today than GPOs and wholesalers.

To elaborate, group purchasing organizations (GPOs) operate by pooling the collective buying power of healthcare providers like hospitals, nursing homes, and inpatient clinics to negotiate procurement contracts with manufacturers for everything from surgical masks and gloves to prescription drugs. 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 for using the GPO's services. By making contracts and commitments to order in bulk, GPOs are able to negotiate better prices for supplies and drugs than a single hospital might be able to. GPOs do not buy or move products themselves, but the vast majority of hospitals in the United States belong to at least one GPO and use GPO contracts to purchase medical supplies. The three main GPOs—Vizient, Premier, and HealthTrust Purchasing Group—manage procurement for 90% of medical equipment today.[4]

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[4] American Economic Liberties Project, Letter to Federal Trade Commission, November 22, 2022, https://www.economicliberties.us/wp-content/uploads/2022/11/2022-11-22-AELP-FTC-6B-GPO-Letter-Final.pdf.

Wholesalers distribute medical supplies and drugs to hospitals, fulfilling the terms of GPO contracts. Like GPOs, by purchasing supplies from a manufacturer in bulk at a discount, they put downward pressure on the prices that drug manufacturers can expect. Wholesalers then distribute the supplies for a fee to a variety of local customers in smaller quantities. The three main drug wholesalers are AmerisourceBergen, Cardinal Health, and McKesson, and they collectively account for 95% of the pharmaceutical distribution industry.

II. Drug Shortages, GPOs, and Wholesalers

The combination of no patent protections, very high capital costs, and additional price pressure from GPOs creates a perfect recipe for shortages. Again, drug shortages are most common among cheap, generic drugs, not among the sorts of expensive, overpriced brand drugs that frequently spark outrage. Brand drugs are protected by patents and other regulatory restrictions such that they can and are sold profitably, and pharmaceutical manufacturers invest to ensure that there is a steady supply of the drug to sell to patients. Generic drugs, however, whose patent protections have lapsed, often sell for very low prices, all while manufacturing them still requires very high fixed costs of maintaining the factories to produce them.

This is particularly true among sterile injectables, the class of drugs most susceptible to shortages in recent years. With respect to sterile injectables, the GAO has found that drug shortages are associated with a decreased number of suppliers, the entry of a generic version of the drug, price decline, and the failure of a facility

making the drug.[5] In contrast to some arguments that the problem is primarily driven by corporate negligence or poor FDA oversight,[6] this suggests that the problem is more likely the result of a low-price market segment seeing insufficient returns, despite its societal importance. Likewise, as the GAO found, "In this industry, there is limited inventory in the supply chain, manufacturing capacity is constrained because production is scheduled months in advance, new manufacturers must receive regulatory approval before entering the market, and the production process is complex. After a supply disruption for any reason, if other manufacturers are not able to increase supply in a timely manner, a shortage may ensue."[7] Larger and more established providers are compelled to discontinue certain product lines, while smaller ones and startups can hardly afford to stay in business.

However, these problems on the manufacturing and cost side of the market are dramatically exacerbated by the contracting and business practices of the middlemen who connect them to the final patient or medical provider. Concentrated by just a few companies, the GPO industry has enormous bargaining power to negotiate for lower prices. Vizient alone manages procurement for more than 450,000 staffed beds,

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[5] United States Government Accountability Office Report to Congressional Committees, "Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge," July 2016, https://www.gao.gov/products/gao-16-595.

[6] See, for example, the Opening Statements of Chairman Gary Peters and Ranking Member Rand Paul in the Homeland Security and Governmental Affairs Full Committee Hearing, "Drug Shortage Health and National Security Risks: Underlying Causes and Needed Reforms," United States Senate, March 22, 2023, available at: https://www.hsgac.senate.gov/hearings/drug-shortage-health-and-national-security-risks-underlying-causes-and-needed-reforms/.

[7] United States Government Accountability Office Report to Congressional Committees, "Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge," July 2016, pp. 37-38, https://www.gao.gov/products/gao-16-595.

representing more than $130 billion in yearly purchasing volume.[8] It serves more than 60% of the U.S.'s acute care providers – including 97% of the country's academic medical centers – giving it access to and control over an extraordinary amount of highly coveted hospital data.[9] Premier, the second-largest GPO, manages at least $69 billion in purchasing volume,[10] while third-place HealthTrust handles more than $20 billion in purchasing volume.[11] Although there are hundreds of GPOs in the United States, hospitals on average have membership in two to four companies.[12] The data and market power that Vizient, Premier, and HealthTrust have in the highly concentrated GPO industry give them significant leverage in negotiations with manufacturers, and they use this to squeeze prices and the profit margins of manufacturers, likely pushing many manufacturers out of the market.

The role of GPOs in drug shortages has been highlighted multiple times in recent years. Responding to an executive order in the fallout from shortages of drugs and other essential commodities during the pandemic, the White House 100-Day Supply Chain Report highlighted that the market power of the largest GPOs likely

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[8] "FY2021 Defense Appropriations Act: Context and Selected Issues for Congress, Congressional Research Service, June 7, 2021, https://sgp.fas.org/crs/natsec/R46812.pdf.
[9] "Vizient Announces 30 New, Renewed or Expanded Provider Agreements in Q4 2022," Vizient, April 13, 2023, https://newsroom.vizientinc.com/en-US/releases/releases-vizient-announces-30-new-renewed-or-expanded-provider-agreements-in-q4-2022.
[10] 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.
[11] "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.
[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.

put additional pricing pressure on generic manufacturers.[13] The U.S. Food and Drug Administration also reported in 2020 that in addition to GPO negotiating power, GPO contracting practices make it hard to increase prices when, for example, costs increase, such that generic prices will frequently fall below the cost of production.[14]

While this pricing pressure from GPOs does bring down the selling price for generic manufacturers, it also undermines competition by eliminating many suppliers and leaving the remaining few in near-monopoly positions. The resulting concentration of production in the hands of just a few companies makes shortages far more likely in the event of contamination, bankruptcy, or some other supply shock at one of the remaining manufacturers. Amphastar Pharmaceuticals, maker of the recently-in-shortage cardiac arrest emergency treatment, sodium bicarbonate injection, has written in recent financial filings that GPOs pressure has excluded suppliers from important market segments.[15] Amphastar has acknowledged that it was able to greatly hike prices in 2022 as a result of its competitors' shortages of epinephrine, which is used to treat life-threatening allergic shocks. The company raised prices enough to generate $7.7 million more in revenue off the drug than in 2021, on top of a $9 million increase from a larger quantity of sales – leading to a nearly 30% one-year rise in revenue from epinephrine.

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[13] "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.
[14] "Drug Shortages: Root Causes and Potential Solutions," U.S. Food and Drug Administration, February 21, 2020, https://www.fda.gov/media/131130/download, page 22.
[15] Form 10-K, Amphastar Pharmaceuticals, Inc, 2022, https://www.sec.gov/Archives/edgar/data/1297184/000129718423000019/amph-20221231x10k.htm.

However, the business model of GPOs is based on distorted incentives, whereby GPOs earn most of their revenue from the suppliers with whom they negotiate, rather than revenue from the members they represent. These "administrative" fees are typically calculated as a percentage of a given product's price, which by HHS regulations should not exceed 3%.[16] The manufacturer pays the administrative fees to the GPO when a purchase is made off of a contract negotiated for the GPO's members. This means that over the course of a GPO contract, a manufacturer will periodically send the GPO rebates and fees, a portion of which the GPO keeps for itself, before remitting the remainder to its hospital members.

That begin said, there have been documented instances when these fees are far higher than permitted, or which are effectively retained in the form of other expenses. They have effectively risen above 50% through a chain of ancillary fees. 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.[17] For example, a 1998 whistleblower lawsuit alleged Vizient, then known as Novation, charged more than 56% to Ben Venue Laboratories so that its blood pressure medication Diltiazem could get access to the market. It's virtually impossible to retain any sort of profit margin if 56% of your revenue is coming off the top to a middleman. Beyond

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[16] 42 CFR 1001.952(j)(1)(i).
[17] 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, https://nebula.wsimg.com/cd1702b03dd5bdcbf25da39704c4045c?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

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. 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.

Regardless of their scale, this source of revenue creates an intrinsic conflict of interest: as a representative of buyers—its hospital and other provider members—GPOs are paid instead by the sellers with whom they are bargaining. As a result, GPOs are incentivized to select vendors based which supplier has higher prices or excess revenue and can thus afford to pay more. For these and related reasons, such arrangements are normally considered illegal kickbacks under the Anti-Kickback Statute.

Not only do these incentives misalign GPOs preferences away from those of the hospitals and providers they represent, they also distort competition between drug and medical supply manufacturers. For suppliers, failure to win a contract with one of the major GPOs can also mean exclusion from the market. Manufacturers pay GPOs for access to the market, and GPOs tend to favor the suppliers that will give them higher margins, further advantaging the largest incumbent manufacturers. This is a well-known industry dynamic. For instance, Eagle Pharmaceuticals wrote in its 2018 annual financial disclosure that sales of its products could decline because "GPOs may earn higher margins from [competitors'] products or combinations of

competing products.[18] Or, for example, 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.[19] The vendor-based revenue setup creates perverse incentives for GPOs to locking members into long-term contracts with incumbent suppliers who are able to pay such fees.

The financial filings of generic drug manufacturers are rather clear about these problems. Generic drug company Akorn Inc., which generated shortages of albuterol when it went out of business in 2023, noted in its 2019 10-K: "Drug wholesalers, drug retailers, and group purchasing organizations have undergone significant consolidation. Such consolidation has provided and may continue to provide them with additional purchasing leverage, and consequently may increase the pricing pressures that we face."[20] Drug company Amneal laid out the problems caused of both wholesalers and GPOs in its 2021 10-K:

> Additionally, consolidation among wholesalers and retailers and the formation of GPOs has caused increased price competition in the generic pharmaceutical market. The downward price adjustments demanded by distributors of generic pharmaceutical products have reduced revenue and average product gross margin across the industry. Should these price reductions continue or even increase, it could have a material adverse effect on our revenue and gross margin. Further, even if we

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[18] Form 10-K, Eagle Pharmaceuticals, 2018, https://www.sec.gov/Archives/edgar/data/827871/000082787119000008/egrx_10kx2018.htm.
[19] "New York Times Series On GPO's," Masimo, https://www.masimo.com/company/news/media-room/nyt-series/.
[20] Form 10-K, Akorn, Inc, 2019, https://www.sec.gov/Archives/edgar/data/3116/000162828020002314/akorn10k12312019.htm.

> reduce the prices we charge our customers, that does not ensure that the prices consumers pay for those drugs will be similarly reduced.[21]

Even Teva Pharmaceuticals, one of the largest generic drug manufacturers whose August 2022 decision to discontinue generic chemotherapy vincristine led to a shortage, writes in its financial filings that group purchasing organizations significantly erode prices and their ability to stay in certain lines of business.[22]

III. Contracting Practices

A GPO contract is ideally supposed to work whereby a GPO awards a contract to a manufacturer for a given product, like saline solution. Once that is done, its hospital members can then buy saline from a designated wholesaler at the price set in the GPO contract for the duration of that contract. Then, the wholesaler is responsible for delivering supplies and drugs to the hospital or other medical provider. But GPOs' bargaining power and conflicts of interest are combined with additional layers of contracts that restrict competition, favor incumbent suppliers, prevent hospitals and providers from seeking alternative suppliers, and worsen the risks of shortages:

Sole-Sourcing: GPOs generally lock their members into sole-sourced purchases and vendors into fixed prices. When negotiating with manufacturers on behalf of hospitals, GPOs award contracts to a single supplier, and then they require that the member hospitals use only that supplier. This creates a dangerous bottleneck, as the

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[21] Form 10-K, Amneal Pharmaceuticals, 2021, https://www.sec.gov/Archives/edgar/data/1723128/000172312822000006/amrx-20211231.htm.
[22] Form 10-K, Teva Pharmaceutical Industries, 2022, https://www.sec.gov/Archives/edgar/data/818686/000119312523031250/d443725d10k.htm.

failure of that single supplier will prevent the provider from getting the necessary drugs. Furthermore, because a comparatively small number of GPOs structure most of the market this way, means that there is little room in the market for more than a few drug manufacturers, further embrittling the supply chains and concentrating manufacturing to make shortages more likely.

Long-Term Contracts: The use of long-term contracts by GPOs often limits the ability of newer or different suppliers to enter the market. GPOs can enforce the terms of these contracts on hospitals, preventing hospitals from switching suppliers mid-contract should the supplier turn out to be unreliable or low-quality. This contracting practice likewise leaves very narrow windows of time—the expiration of existing GPO contracts—during which new and smaller companies are able to enter the market at all.

Penalty Pricing Rebates: These multi-year contracts often condition discounts and rebates on hospitals purchasing a set percentage of a given product from a specific vendor. They claim these deals are voluntary, but they use a variety of anti-competitive tactics to steer or retaliate against member hospitals that do not follow the terms of the deal. GPOs are known to withhold rebates if a member does not purchase a large enough volume from the preferred contractor.[23] In its financial

[23] See allegations in *Marion HealthCare, LLC, et al., v. Becton Dickinson & Company, et al:* https://nebula.wsimg.com/a30fcb11b316d2c09f1325a9dd39e9d6?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=*1*; Christian Deroo, "Pay-to-Play: The Impact of Group Purchasing Organizations on Drug Shortages," American University Business Law Review, 2013, https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1033&context=aublr; Patricia

disclosures last year, medical device maker ZimVie spelled out how these exclusive contracts can cut it out of the market: "if the group purchasing organization has negotiated a strict compliance contract for another manufacturer's products, we may be precluded from making sales to members of the group purchasing organization for the duration of the contractual arrangement."[24] A 2018 lawsuit likewise notes that so-called "Net dealer contracts" used by both Vizient and Premier contain a "penalty pricing" rebate system such that providers get no rebates at all if they do not purchase 80-95% of their prior volume from the same preferred supplier.[25]

Bundled Rebates: GPOs bundle the rebates for key products together, conditioning rebates for one product on the purchasing of sufficient volumes or other, unrelated products. This means that a hospital can lose out on a rebate for certain products—and effectively most of the savings they earn from being a GPO member in the first place—if it does not also buy the GPO's linked items from the designated manufacturer. In February 2023, for instance, small surgical device maker Applied Medical Resources filed a lawsuit accusing the established manufacturing giant

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Earl 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/.

[24] Form 10-K, Zimvie, 2022, https://www.sec.gov/Archives/edgar/data/1876588/000095017023005542/zimv-20221231.htm.

[25] *Marion Diagnostic Center, LLC v. Becton, Dickinson, and Co*., 3:18-cv-01059-NJR, SAC, Document 52, (S.D. Ill., June 15, 2018), graf 42-3

Medtronic of making rebates in GPO contracts for its "bipolar energy" cutting device conditional on purchases of its other products.[26]

Staggered Contracts: GPOs also frequently "stagger" their long-term contracts across product lines, arguably intentionally, such that they all end at different times. In conjunction with the penalty pricing and bundling, this makes exiting the GPO's procurement system very costly for a medical provider.[27] In such a system, if a provider were not renew a contract for just one of its products or product categories, for the remaining duration of the remaining GPO contracts, the provider would lose significant rebates, because they were conditioned on purchasing volumes on the contract that just expired.

Distributor Agreements: GPOs enlist wholesalers to separately enforce and monitor their contracts. As reported in a 2018 lawsuit involving Vizient and Premier: "Distributor Agreements typically require that distributors enforce the requirement that the healthcare providers buy a certain volume of [a vendor's] products or else pay the penalty pricing set forth in the Net Dealer Contract."[28] Not only does the GPO obligate purchases from a specific and narrow set of vendors, but the wholesaler delivering the drugs does as well.

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[26] *Applied Medical Resources Corporation v. Medtronic, Inc.*, https://fingfx.thomsonreuters.com/gfx/legaldocs/mopakdqwdpa/Applied%20Medical%20v%20Medtronic%20-%20complaint%20-%202023.pdf.
[27] See *Endure Industries, Inc. v. Vizient, Inc.*, 3:20-cv-03190, SAC (N.D.T., March 22, 2022), graf 56
[28] *Marion Diagnostic Center, LLC v. Becton, Dickinson, and Co*., 3:18-cv-01059-NJR, SAC, Document 52, (S.D. Ill., June 15, 2018), graf 44

Dealer Notification Agreements: "Dealer notification agreements" between manufacturers and distributors require that distributors agree to enforce the terms of the suppliers' contracts with the GPOs and enforce the penalty rebate system.[29] A 2020 complaint from a group of healthcare providers alleged that wholesalers Cardinal and McKesson used their leverage to punish hospitals not sufficiently abiding by a contract which obligated them to buy large quantities from incumbent Becton.[30] Furthermore, these dealer notification agreements also require that the distributors pay GPOs additional amounts based on the volume of goods delivered.[31]

Chargeback Clauses: Wholesalers often have control over the markups they charge hospitals. As buyers, wholesalers will frequently recoup "chargeback" fees from manufacturers if the wholesalers' costs were greater than the prices set in a GPO contract, essentially requiring the manufacturer to cover the losses from any price or cost change. With already low prices, this can make the revenue for generic manufacturers unpredictable, undermining one of the ostensible benefits of the GPO ecosystem, predictable prices.

Generic Compliance Ratios: In the commercial pharmacy market even outside of the GPO ecosystem, wholesalers impose contract terms on pharmacies based off of their "generic compliance ratios" (GCRs), such that the price of brand drugs is tied to

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[29] *Marion Diagnostic Center, LLC v. Becton, Dickinson, and Co*., 3:18-cv-01059-NJR, SAC, Document 52, (S.D. Ill., June 15, 2018), graf 45

[30] *Marion Diagnostic Center LLC and Marion Healthcare LLC v. Becton Dickinson, Cardinal Health, and McKesson Medical-Surgical,* https://nebula.wsimg.com/a30fcb11b316d2c09f1325a9dd39e9d6?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

[31] *Marion Diagnostic Center, LLC v. Becton, Dickinson, and Co*., 3:18-cv-01059-NJR, SAC, Document 52, (S.D. Ill., June 15, 2018), graf 45

the volume of generic drugs purchased by the pharmacy. In short, wholesalers will offer pharmacies larger discounts from their wholesale acquisition cost of brand drugs in return for the pharmacy purchasing larger volumes of generic drugs from the same wholesaler, presumably all from that wholesaler's favored vendor. These arrangements financially pressure pharmacies to purchase an overwhelming majority of the generic stock from a single wholesaler. Because the discounts on expensive brand products are so important for pharmacies, this gives wholesalers extraordinary power to raise the prices on Generic products, as pharmacies must by the generic products to meet the volume requirements needed to retain the lower brand purchase prices.

Prime Vendor Agreements: Under prime vendor agreements, a wholesaler requires a pharmacy to use only that one exclusive wholesaler and purchase most or all of their inventory from them. Pharmacies are not allowed to have more than one Primary wholesaler, which means a pharmacy would not be allowed to buy products from multiple wholesalers at the same time.

IV. Vizient's Ecosystem

Any one of these contract terms would be problematic on their own terms, but it helps to illustrate how many of them interact collectively within the ecosystem of Vizient, the largest GPO. Vizient maintains multiple tiers of procurement programs for different types of providers and different categories of products. In almost all of them, member hospitals are trapped in Vizient's procurement system on fixed contracts with favored suppliers. Vizient's own marketing materials to suppliers tout

their program's ability to reduce competitive threats for suppliers and to increase product homogeneity and sourcing among member hospitals.

One such program, Vizient's "Impact Stabilization Program" requires that member hospitals purchase 75% of their overall purchasing from preferred suppliers, additionally requiring 90% of their purchasing in any individual category of supplies defined by Vizient.[32] Those categories are "(1) Adhesive Tapes; (2) Bowel Management; (3) Disposable Patient Positioners; (4) Disposable Sharps Containers; (5) Monitoring Electrodes; (6) Nonsterile Kits; (7) Patient Care Plastic and Steel Products; (8) Patient Skin Care; (9) Transparent Dressings; (10) Urinary Catheters and Related Products; and (11) Bonus: Disposable Stethoscopes."[33] So, a member hospital needs to satisfy 90% of its procurement within a category to be eligible for rebates for that category. Additionally, they need to satisfy 75% of their procurement in patient care overall to be eligible for any rebates in any of these categories.

Contracts are staggered under Vizient's ISP program, so that providers must lose out on rebates for the products associated with the longer-lasting contracts in order to terminate its participation in the ISP for the contracts are currently ending. So if a provider wanted to go to an alternative supplier for one category—say, monitoring electrodes—not only would it obviously lose out on rebates for that category as its procurement fell below 90%, if its purchasing volume across all

[32] *Endure Industries, Inc. v. Vizient, Inc.*, 3:20-cv-03190, SAC (N.D.T., March 22, 2022), grafs 6, 51
[33] *Endure Industries, Inc. v. Vizient, Inc.*, 3:20-cv-03190, SAC (N.D.T., March 22, 2022), graf 47

Vizient's patient care categories fell below 75% for the duration of the remaining contracts, the provider would get no rebates at all, for any category.

Another Vizient program, the "Vizient Achieve Committed Program," operates under similarly restrictive premises. It requires:

- "Compliance at the individual contract level
- Compliance at the segment level
    - 90% commitment in the commodity contract segment
    - 80% commitment in the clinical preference contract segment
- Compliance at the program level
- Submit data in an automated fashion on a monthly basis
- Provide advanced notice for termination
- Decline to locally negotiate contracts in any of the categories offered through Achieve
- Pay increased fees for non-compliance"[34]

These rebate terms lock hospitals into a dependent relationship with Vizient, relying on non-diversified suppliers to obtain maximal rebates. As the rebate savings are the major purpose of participating in a GPO contract, any non-compliance by the hospital calls into question the entire purpose of GPO participation.

Vizient's practices with respect to pharmaceuticals are similar. Vizient organizes drug procurement for member hospitals and providers within "Pharmacy Aggregation Groups" (formerly known as Vizient's "Pharmacy Network Program"). Within this program, Vizient RxCommit is a program for providers willing to "standardize their formulary preferences", enter into "a longitudinal commitment of

[34] Solvent Networks, "Vizient Achieve Committed Program," November 13, 2023 https://solventnetworks.com/vizient-achieve-committed-program/ (accessed 3/26/2024).

their pharmaceutical spend," and "to uphold RxCommit contract commitments."[35] This, like Vizient's ISP, is a commitment to make purchases exclusively from Vizient's preferred drug supplier or manufacturer, that purchases are made in committed volumes amounting to sole- or dual-sourced contracts, and that providers will be penalized for noncompliance. "Standardized formulary preferences," to be clear, means that this program restricts physicians ability to use products that they prefer, prioritizing the financial cost of therapies ahead of the clinical benefit of the therapies in terms of how formulary decision are made. If an item isn't on a hospital's formulary as a result of Vizient's RxCommit program, then patients admitted to that hospital are not going to receive that product. The Vizient Oncology Network (VON) provides similar arrangements for branded oncology drugs.[36]

In its own marketing materials, Vizient extolls many of its most problematic contracting practices. Vizient, in attracting suppliers to its programs, has described them as "protection from competitive threats."[37] Or, for example, from 2016 to 2022, Vizient's pharmacy procurement had a sole award for high dose IV iron. When it went out to bid for a new contract, Vizient opted "to award one supplier that provided positive reimbursement margins across all account types, as well as delivering $41M

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[35] Vizient Marketing Materials, "Vizient RxCommit," https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/0eab875eb75c47bb87dbf3603ce4da18 (accessed 3/26/2024)
[36] Vizient, "Vizient Oncology Solutions Resource Guide," November 2022, https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/933819b54443499887451af5a33d94f0 (accessed 4/2/2024).
[37] *Endure Industries, Inc. v. Vizient, Inc.*, 3:20-cv-03190, SAC (N.D.T., March 22, 2022), paragraph 7.

in estimated value for direct match and conversions."[38] It separately noted awarding a single contract for plasma products to a large supplier, noting that "Members from the participating aggregation groups" would receive "priority access when supply constraints have tightened in the market."[39]

Rather than operating as a service for providers, GPOs like Vizient have inserted themselves into the core of the delivery of most medical supplies, including pharmaceuticals. They operate on behalf of incumbent suppliers when it suits their interests, and they operate against the interests of their own members when it would mean more income for them. And because the market for generic pharmaceuticals is structured such that GPOs have little to no preference for a healthy and competitive market, we don't have one.

V. How HHS Can Act

To resolve these problems, the Department of Health and Human Services can act to prevent shortages in several ways, including by narrowing the safe harbor from the Anti-Kickback Statute granted to GPOs, and by updating the Medicare Conditions of Participation to require that medical providers and GPOs dual- or multi-source their contracts for the types of generic drugs and other medical supplies that have fallen into shortage in recent decades.

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[38] Vizient Pharmacy Aggregations Groups, 2022 External Annual Report, https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/3b7bee607b3c484794b47d24a450dfbe, page 4 (accessed 3/27/2024).
[39] Ibid.

A. The Anti-Kickback Statute

Originally, GPOs were funded with dues from their hospital members, which meant that GPOs were agents, contractually *and* financially, working on behalf of the buyers who paid them. Accepting kickback payments from suppliers was illegal. But the Omnibus Budget Reconciliation Act of 1986 and Medicare and Medicaid Patient and Program Protection Act of 1987 granted GPOs a safe harbor from the Social Security Act's Anti-Kickback Statute. The HHS OIG issued its final rules in July 1991, allowing GPOs to accept fees and rebates from manufacturers that previously would have been illegal, also establishing 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. [40]

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%.[41] 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

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[40] "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.

[41] 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, https://nebula.wsimg.com/cd1702b03dd5bdcbf25da39704c4045c?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

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.[42]

HHS could open a rulemaking to substantially narrow the safe harbor for GPOs, eliminating many of the conflicts of interest for GPOs that depend on supplier revenue. GPOs—and particularly larger, for-profit GPOs, should operate by being paid fees by their member providers for the services they provide. If these savings and benefits are real, GPOs would be able to work for a service fee from providers.

B. Medicare Conditions of Participation

Another way to reduce the incidence of shortages, and limit the harms of GPOs, would be for HHS to require that medical providers multi-source their suppliers, particularly for the generic medications that frequently fall into shortage. Whether individually, or collectively through their GPOs, providers should be required to multi-source contracts that are over a certain size. This would allow more competing suppliers to remain in business, and it would mean that shortages would be avoided if one supplier fails.

This can be accomplished by revising the Medicare Conditions of Participation ("CoPs") that set the standards that medical providers must meet to be eligible for reimbursement under Medicare. Section 1861(e) gives HHS broad authority to adopt "such other requirements" that they "find[] necessary in the interest of the health and

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

safety of individuals who are furnished services in the institution."[43] Shortages present a clear risk to the health and safety of patients, where their lives or their long-term well-being is put at risk for lack of the essential drug for the course of treatment they are undergoing is unavailable, or where they receive lesser care because only an inferior substitute drug was available as the result of a shortage.

The CoPs already include similar and extensive requirements for contracted external services under this authority, such as for food delivery and procurement for organ and tissue transplants.[44] For example, 42 CFR 482.45 includes requirements that hospitals must have sufficient protocols to have at least one tissue bank and one eye bank for organ transplants.[45] 42 CFR 482.27(b)(3) has extensive conditions on the terms of any contracted agreement for blood or blood components.[46]

We urge HHS to revise the Medicare Conditions of Participation to require that medical providers, and the GPOs that represent them, multi-source their contracts to multiple suppliers. Given the health and safety risks imposed by drug and medical supply shortages, such a rule likely would fall under this authority, and such action would help to diversify the supply base and mitigate the risk of drug shortages.

VI. How the FTC Can Act

The FTC can likewise act in multiple ways, most especially according to the prohibitions on tying and exclusive dealing under Section 3 of the Clayton Act and

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[43] 42 U.S.C. § 1395x(e)(9); *see also* 42 C.F.R. § 482.1(a)(1)(ii) ("The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.").
[44] 42 CFR Part 400 – 699.
[45] 42 CFR 482.45.
[46] 42 CFR 482.27(b)(3).

the prohibitions on commercial bribery under Section 2(c) of the Robinson-Patman Act.

A. Section 3 of the Clayton Act

Section 3 of the Clayton Act prohibits contract terms and conditions on the sale of goods or services, including several of the most problematic aspects of wholesaler and GPO contracts, such as tying, exclusive dealing, and exclusionary rebates. Specifically, Clayton 3 prohibits sale, lease, discounting, or rebates on the "understanding that the lessee or purchaser thereof shall not use or deal in the [goods or services] of a competitor or competitors of the lessor or seller," where the effect of that contract "may be to substantially lessen competition or tend to create a monopoly in any line of commerce."[47]

Many of the contract terms outlined above fit these criteria of illegal and prohibited behavior. Many GPO and wholesaler contracts both (a) are exclusionary and/or tying and (b) substantially lessen competition. For the first, many of the contract terms, such as bundling rebates, generic compliance ratios, and penalty pricing systems, are explicitly exclusionary ties or exclusive dealing. For the second, the GPOs themselves often extol the anticompetitive effects of these contract terms, for example Vizient's marketing to suppliers that its programs are "protection from competitive threats." The wholesaler practice of tying the price of branded drugs to generic purchase volume is a classic case of tying the purchase of a product over which the seller has market power (the brand drug) to the purchase over a good where the

[47] 15 U.S. Code § 14

seller does not have market power (generic drugs), meeting the requirements for a tying claim.[48]

B. Robinson-Patman

The Robinson-Patman Act ("RPA") was passed in 1936 to limit the unfair advantages that large retailers had in pressuring suppliers for lower prices than their smaller competitors could get. Of most interest for the purposes of GPOs and wholesalers, the Robinson-Patman Act includes similar prohibitions to the Clayton Act in prohibiting various forms of payments to improperly induce business in ways that would unfairly advantage certain sellers or buyers over others.

Section 2(c) of the RPA prohibits paying, receiving, or accepting any "commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, … either to the other party to such transaction or to an agent, representative, or other intermediary."[49] Generally speaking, 2(c) is designed to prohibit commissions, rebates, or other side payments by a seller either to a buyer or some intermediary acting on their behalf (like a broker, or in this case, a GPO). In short, it would prohibit the sorts of "administrative fees" on which GPOs have come to rely on as a source of revenue, and which would also otherwise be illegal under the Anti-Kickback Statute were it not for the safe harbors granted.

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[48] See, for example, *Eastman Kodak v. Image Technical Services, Inc.*, 504 U.S. 541 (1992).
[49] 15 U.S. Code § 13(c).

VII. Conclusion

Shortages of generic drugs and a range of other medical supplies have become an endemic feature of the American medical system in recent decades. These shortages, however, have deep roots in dysfunctional and broken market dynamics between multiple layers of middlemen who bottleneck the market for generic drugs, reducing the number of manufacturers and keeping medical providers trapped into contracts with incumbent suppliers. We urge the FTC and HHS to act swiftly.