POLICY BRIEF

AMERICAN ECONOMIC LIBERTIES PROJECT

The Dirty Secret of Drug Shortages

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Every hospital needs to have lidocaine injection in stock. Doctors use this local anesthetic to relieve the pain of patients who are in labor, receiving stitches, or having a catheter inserted. First discovered in the 1940s, lidocaine has been deemed so crucial that the World Health Organization includes it in its List of Essential Medicines.[1] Yet in the U.S., lidocaine has been in continuous shortage since 2011. Many pharmaceutical companies are approved to make lidocaine, including Fresenius Kabi, Hikma, and Pfizer, but they often have the anesthetic on backorder, blaming delays on increased demand while hospitals every day are rationing what little stock they have.

This situation doesn't add up. The high demand for lidocaine should incentivize manufacturers to expand their production lines to guarantee consistent supply. But they are not doing so for lidocaine, nor for scores of other basic drugs that consequently have persistently gone into shortage for more than a decade. And despite years of Congressional inquiry and regulation of medical supply chains, the situation has only worsened. Today, a record number of treatments, for everything from lead poisoning to cancer, are unavailable.[2] This includes new shortages of generic cancer treatments called carboplatin and cisplatin, forcing doctors to ration for their sick patients.[3] According to a recent report by the Senate Committee on Homeland Security and Governmental Affairs, there was a record five-year high of 295 active drug shortages at the end of 2022, with sterile injectables commonly used in hospitals at increased risk.[4] The Covid-19 pandemic certainly put

1 "WHO model list of essential medicines – 22nd list, 2021," World Health Organization, September 30, 2021, https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

2 "Drug Shortages," U.S. Food and Drug Administration, https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages.

3 Yuki Noguchi, "Some cancer patients are in short supply, putting patients' care at risk. Here's why," NPR, June 15, 2023, https://www.npr.org/sections/health-shots/2023/06/15/1181876655/cancer-drugs-cisplatin-carboplatin-shortage.

4 "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/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.

pressures on the industry and exposed the fragility of U.S. supply chains, but the shortage dilemma long predates the global epidemic.

At a March 22 hearing of the Senate Homeland Security and Governmental Affairs Committee this year, Democrats and Republicans tried to diagnose the problem. Many recognized that producers leave the market because many generic drugs have low profit margins despite an expensive and complex manufacturing process. Ranking Member Rand Paul (R-KY) blamed federal government regulations, while Chairman Gary Peters (D-MI) targeted drug makers' offshoring of production and the government's poor visibility into supply chain risks.[5] Unfortunately, with few exceptions, most members on both sides overlooked a core driver of the problem.

The primary driver of the problem is not a lack of regulation, but a set of consolidated middlemen who drive producers out of business. A group of firms known as group purchasing organizations (GPOs), who do not physically manage product but operate as buyer cartels for hospitals, have immense control over medical supply markets. The three main GPOs are Vizient, Premier, and HealthTrust Purchasing Group. As former generic drug executive Bill Simmons told *60 Minutes* in May 2022, "We are systematically shutting down all of our U.S. manufacturing because we do not pay enough money for the drugs to the manufacturers, and not enough money is paid because of the middlemen."[6]

GPOs control access to the market, and charge drugmakers and medical supply manufacturers high fees to access it. GPOs use a variety of business practices, such as long-term supply contracts and kickbacks from the largest manufacturers, which end up consolidating production and fostering a more brittle supply chain prone to collapse. These middlemen put so much pressure on manufacturers that manufacturers often discontinue production of unprofitable drugs, underinvest in factories, leading to FDA compliance problems, or go bankrupt. All of these lead to shortages.

This brief explains the medical shortage problem and the multiple roles that GPOs play in medical supply markets. It then outlines a series of common-sense reforms to rein them in: repealing GPOs' exemption from the Anti-Kickback Statute, breaking up the largest GPOs, and requiring medical providers to use multi-source contracts when more than one manufacturer is available.

5 International trade and investment policies and agreements and the offshoring of production of Active Pharmaceutical Ingredients and medicines has also contributed to shortages, but is beyond the scope of this paper.

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

WHAT ARE GROUP PURCHASING ORGANIZATIONS (GPOS)?

GPOs are middlemen who set up contracts with manufacturers, which hospitals can use to buy supplies they need. They, in theory, are like Costco for hospitals, aggregating the buying power of their hospital members to obtain volume discounts for supplies ranging from surgical masks and tracheal tubes to cafeteria food and even staff. GPOs do not buy or move products themselves, but the vast majority of the 6,000-7,000 hospitals in the United States belong to at least one GPO and use GPO contracts to purchase medical supplies.

GPOs were initially conceived in the early 20th century as small nonprofits representing hospitals in a given region. Several GPOs emerged with for-profit models and subsequently consolidated into nation-spanning purchasing consortia in the 1970s and 1980s. At the time, the large number of GPOs meant that domestic producers of medicines and medical supplies could sell to many buyers. If a GPO refused to carry one's products, there were always several others who might. Additionally, GPOs had to offer good service to hospitals. If one GPO didn't have all the products a hospital might need, a hospital could buy from another.

In the 1990s, a wave of mergers and acquisitions resulted in the six largest GPOs arranging procurement contracts for at least 80% of the acute care hospitals in the U.S. Today, just three GPOs control most of the industry: Vizient, Premier, and HealthTrust Purchasing Group. Vizient alone manages procurement for more than 450,000 staffed beds, representing more than $130 billion in yearly purchasing volume, roughly equal to the Department of Defense's entire procurement budget in 2020, though without the same oversight and transparency.[7] 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.[8]

Traditionally, GPOs were financed by member dues from the hospitals they represented, aligning the incentives of buyers and their GPO buying agents to both lower costs and assure reliable supply. But that changed in the late 1980s. Rather than accepting dues from their members, today, GPOs primarily generate revenue by charging fees and rebates to suppliers, a portion of which they distribute back to the hospitals.

7 "FY2021 Defense Appropriations Act: Context and Selected Issues for Congress, Congressional Research Service, June 7, 2021, https://sgp.fas.org/crs/natsec/R46812.pdf.
8 "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.

The process consists of a few steps. First, the GPO awards a contract to a manufacturer for a given product, like saline solution. Then, its hospital members can then buy saline from a designated wholesaler at the price set in the contract. Periodically, the manufacturer will send the GPO rebates and fees, a portion of which the GPO keeps for itself, before remitting the remainder to its hospital members.

LONG-TERM CONTRACTS UNDERMINE COMPETITION

A common practice used by GPOs is long-term contracts. When negotiating with manufacturers on behalf of hospitals, GPOs award near-exclusive contracts to a single supplier, and then they steer member hospitals use that supplier. GPOs can enforce the terms of these contracts on hospitals, which in effect guarantees that a single manufacturer dominates the customer base, leaving new and smaller companies out of the market and increasing the likelihood of shortages.

These multi-year contracts often also 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. For example, GPOs are known to withhold rebates if a member does not purchase a large enough volume from the preferred contractor.[9] In its financial disclosures last year, medical device maker ZimVie spelled out how these exclusionary 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."[10]

Likewise, GPOs also bundle key products together in contracts, meaning a hospital can lose out on a rebate for certain products if it does not also buy the GPO's linked items from the designated manufacturer. In February, for instance, small surgical device maker Applied Medical Resources filed a lawsuit accusing the established manufacturing giant Medtronic

9 *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 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/.

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

of making rebates in GPO contracts for its "bipolar energy" cutting device conditional on purchases of its other products.[11] This arrangement has made it nearly impossible for Applied Medical to enter the market.

GPO MARKET POWER SQUEEZES MANUFACTURERS OUT OF THE MARKET

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. Even Teva Pharmaceuticals, one of the largest generic drug manufacturers whose 2019 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.[12]

Failure to win a contract with one of the major GPOs can also mean exclusion from the market. Amphastar Pharmaceuticals, maker of the currently-in-shortage cardiac arrest emergency treatment, sodium bicarbonate injection, has written in recent financial filings that GPO pressure has excluded suppliers from important market segments.[13]

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. Amphastar has also 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.

11 *Applied Medical Resources Corporation v. Medtronic, Inc.*, https://fingfx.thomsonreuters.com/gfx/legaldocs/mopakdqwdpa/Applied%20Medical%20v%20Medtronic%20-%20complaint%20-%202023.pdf.

12 Form 10-K, Teva Pharmaceutical Industries, 2022, https://www.sec.gov/Archives/edgar/data/818686/000119312523031250/d443725d10k.htm.

13 Form 10-K, Amphastar Pharmaceuticals, Inc, 2022, https://www.sec.gov/Archives/edgar/data/1297184/000129718423000019/amph-20221231x10k.htm.

GPO PAYMENT STRUCTURE CREATES CORRUPT, PAY-TO-PLAY MARKET

The way GPOs make money, through fees paid by manufacturers, both further amplifies consolidation and reduces the bargaining leverage that manufacturers have to maintain productive capacity.

Originally, GPOs were funded with dues from their hospital members, which meant that GPOs were agents 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.

Under regulations established by the Health and Human Services Department (HHS) in 1991, GPOs could accept fees and rebates from manufacturers that previously would have been illegal. In the time since, these payments became GPOs' primary source of revenue. These "administrative fees" are typically calculated as a percentage of the revenue from each contract. 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.

Today, manufacturers pay GPOs for access to the market, 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.[14]

In addition to these perverse incentives, these GPO fees can also sometimes be an excessive burden for manufacturers to pay for access to the market. For example, a 2003 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.[15] It's virtually impossible to retain any sort of profit margin if 56% of your revenue is coming off the top to a middleman.

These kinds of fees put financial pressure on companies making drugs that already generate slim margins, like lidocaine, sterile water, and vincristine. Larger and more

14 Form 10-K, Eagle Pharmaceuticals, 2018, https://www.sec.gov/Archives/edgar/data/827871/000082787119000008/egrx_10kx2018.htm.
15 "How GPOs Inflate Healthcare Costs," Physicians Against Drug Shortages, Accessed September 12, 2023, https://www.physiciansagainstdrugshortages.com/gpos-inflate-hc-costs.html.

established providers are compelled to discontinue certain product lines, while smaller ones and startups can hardly afford to stay in business. 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.

Given these problems, one might expect hospital members to protest these arrangements and seek deals with manufacturers on their own. But executives from the largest hospitals in the U.S. are on the GPOs' board of directors and themselves receive part of the kickbacks and fees from manufacturers, creating an inherent conflict of interest. In 2013, Thomas Finn, principal editor of *Healthcare Matters*, acknowledged, "many hospital executives who are part of the Premier alliance have learned to rely on that [payment from GPOs] as an integral part of their annual compensation."[16] Today, Premier's board includes the presidents of Advent Health and CommonSpirit Health, while Vizient's board includes the presidents of Froedtert Health, Stanford Health Care, UCLA Health, and more.[17]

WHOLESALERS ADD EVEN MORE PRESSURE

While the focus of this brief is GPOs, these problems are made worse by the wholesalers who distribute medical supplies and drugs to hospitals, fulfilling the terms of GPO contracts. The idea behind these intermediaries is to put downward pressure on price by purchasing supplies from a manufacturer in bulk at a discount. They then distribute the supplies for a fee to a variety of local customers in smaller quantities. However, when the industry is highly consolidated, wholesalers have outsized bargaining power to extract more money from manufacturers without necessarily passing on those savings to hospitals. This dynamic exacerbates the GPOs' pay-to-play schemes that benefit wealthy, incumbent manufacturers and harm low-profit newcomers.

Indeed, as with GPOs, the healthcare wholesaler industry is dominated by just a few companies. AmerisourceBergen, Cardinal Health, and McKesson together own about 95% of the pharmaceutical distribution industry, while Cardinal, Medline, and Owens & Minor control about 85% of the medical surgical device distribution market.[18]

16 "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics," FTC, November 8, 2017, https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.
17 "Operating with integrity," Vizient, https://www.vizientinc.com/about-us/governance; "Board of Directors," Premier, https://premierinc.com/about/our-people/board-of-directors.
18 "Healthcare Distribution," Credit Suisse, April 22, 2020, https://research-doc.credit-suisse.com/docView?language=ENG&format=PDF&sourceid=csplusresearchcp&document_id=1082431491&serialid=XZZbsnnK65oOkuLT%2fVnfZGwJfxA775PWmdxCLrsks30%3d.

Like GPOs, wholesalers are in a unique position to act as enforcers of exclusionary contracts and exacerbate barriers for small or new manufacturers. For example, wholesalers often have control over the markups they charge hospitals. As buyers, wholesalers will frequently recoup "chargeback" fees from manufacturers if their 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.

In the syringe market, large incumbent Becton Dickinson has long had dominant market share despite the presence of innovators like Retractable Technologies. 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.[19] If the healthcare providers did not buy as large a volume as the previous year, the wholesalers would raise syringe prices in retaliation. While also taking bonuses and other payoffs from Becton, Cardinal and McKesson pressured providers to purchase more products than even necessary under their GPO contract, increasing delivery fees if providers do not comply.

Wholesalers cause similar problems for generic pharmaceutical manufacturers. Generic drug company Akorn Inc. went out of business earlier this year, worsening shortages of an asthma medication called albuterol. It was also the sole maker of a lead poisoning treatment. The company was paying exorbitant fees to middlemen. Akorn specifically warned its investors 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]

This problem is not unique to Akorn. Drug company Amneal laid out the harms of both wholesalers and GPOs as well 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

19 *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.

20 Form 10-K, Akorn, Inc, 2019, https://www.sec.gov/Archives/edgar/data/3116/000162828020002314/akorn10k12312019.htm.

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

SOLUTIONS

In trying to resolve the medical shortage crisis in America, the federal government must not resort to convoluted measures filled with loopholes and carveouts. There are straightforward and practical solutions targeting the underlying problems that they can enact instead.

Repeal Anti-Kickback Safe Harbor. GPOs enjoy an effective exemption from the Anti-Kickback Statute, which prohibits payments to induce the referral of any business reimbursed by federal health programs like Medicare. Without this exemption, GPOs would need to be paid by hospitals, eliminating the pay-to-play system with manufacturers that blocks many entrants from the market.

Require Multi-Source Contracts for GPOs. One of the greatest harms from GPOs is that they provide large, near-exclusive contracts to manufacturers, consolidating the market and creating less resilient bottlenecks. GPOs should be required, as a condition for their hospital members to receive Medicare and Medicaid funding, to multi-source contracts that are over a certain size.[22] This would allow more competing suppliers to remain in business, continue competing for business, and mean that shortages would be avoided if one supplier fails.

Prohibit Minimum Purchasing Volumes and Bundled Rebates. Both GPOs and wholesalers often require hospitals to buy medical supplies and drugs in minimum volumes each year in order for the hospital to get rebates, and those minimum amounts sometimes increase year-to-year. As a result, the supplier with the contract has more guaranteed business, and prevents hospitals are dissuaded from looking for other suppliers. And since this often happens via bundled rebates, hospitals are often trapped into using suppliers they do not want in order to get reasonable prices for supplies they need. If this was not allowed, new suppliers would be able to enter the market.

21 Form 10-K, Amneal Pharmaceuticals, 2021, https://www.sec.gov/Archives/edgar/data/1723128/000172312822000006/amrx-20211231.htm.
22 Exceptions to this rule will apply when there is only one manufacturer of a given product.

Break Up the Largest GPOs. The bargaining power of the three biggest, monopolistic GPOs over suppliers puts undue downward pressure on price. Their sheer size of the largest GPOs – Vizient, Premier, and HealthTrust Purchasing Group – creates a deeply imbalanced bargaining position between GPOs and manufacturers, pushing many to drop key product lines or pushing them entirely out of business. If these monopolists were broken up, this bargaining disparity would be reduced, and manufacturers producing these essential medicines could remain in business.

Prohibit Hospital Executives from Sitting on GPO Boards. Hospitals should look for alternative sources of supply given the problems created by GPOs, but many hospital executives sit on the boards of the major GPOs, profiting from the GPO system. This creates a clear conflict of interest and should be prohibited.

CONCLUSION

Hospital supplies are too crucial to leave in the hands of powerful, rebate-driven gatekeepers. As U.S. Food and Drug Administration Commissioner Robert Califf testified in May 2022 during a hearing in the House of Representatives on the baby formula crisis: "We are seeing this across the entire device and medical supply industry with frequent failures . . . We have gone to just-in-time, large, single-source contracts that lead to a lack of diversification in the industry, and the industry has fought us tooth and nail on requiring that there be insight into their supply chains."

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