Documents for the Record – Health Hearing 09/14/23

Majority:

- September 14, 2023, Association for Clinical Oncology Letter
- September 5, 2023, Rep. Harshbarger Letter to Commissioner Califf
- November 22, 2022, Letter to FTC and FDA

Minority:

- July 31, 2023 article from Pink Sheet, Citeline Regulatory
- August 23, 2023 article from Edwin Park, Georgetown University McCourt School of Public Policy's Center for Children and Families

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Association for Clinical Oncology

Statement prepared for:
U.S. House Committee on Energy and Commerce Subcommittee on Health

Legislative Proposals to Prevent and Respond to Generic Drug Shortages
September 14, 2023

The Association for Clinical Oncology (ASCO) appreciates the opportunity to provide this statement for the record regarding the timely and crucial hearing on "Legislative Proposals to Prevent and Respond to Generic Drug Shortages." ASCO is grateful that the subcommittee continues to elevate the conversation on drug shortages through their legislative activities and collaborates with stakeholders to ensure the impact on patients with cancer and their providers is considered as legislative solutions emerge.

ASCO is the national organization representing nearly 50,000 physicians and other health care professionals who care for people with cancer. ASCO members are dedicated to conducting research that leads to improved patient outcomes, and we are also committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans.

The shortage of generic drugs, including vital oncology medications, poses a grave threat to the health and well-being of patients with cancer across the nation. These shortages can result in treatment delays, compromised therapeutic regimens, and increased health care costs, all of which can exacerbate the already daunting challenges that patients face. The consequences of drug shortages extend far beyond mere inconveniences; they can directly affect treatment outcomes and patient quality of life. Moreover, drug shortages highlight a break down in the U.S. pharmaceutical supply chain and can pose significant national security threats.

As noted in our past statements and response to requests for information [1][2][3][4][5][6], ASCO firmly supports legislative efforts to prevent and respond to

[1] http://old-prod.asco.org/sites/new-www.asco.org/files/RFI-Reponse-House-EandC-Drug-Shortage-Discussion-Draft.pdf
[2] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2023-07-06-RFI-EC-Finance-Drug-Shortages.pdf
[3] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/practice-patients/documents/2023-JG-CEC-Testimony.pdf
[4] https://old-prod.asco.org/sites/new-www.asco.org/files/SFTR-House-EandC-Drug-Shortages-Hearing-5.11.23.pdf
[5] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2023-03-29-RFI-Senate%20HELP-PAHPA-Reauthorization.pdf

generic drug shortages, recognizing the urgency of this issue in the context of cancer care. We believe that a comprehensive approach to mitigating drug shortages must encompass the following key recommendations, but encourage broad consideration of all our recommendations[7][8][9]:

- Enhance transparency in the drug supply chain.
- Streamline regulatory processes, including approvals to expedite access.
- Diversify manufacturing, including active pharmaceutical ingredient sourcing.
- Develop strategic reserves to offset supply interruptions.
- Stabilize the market by Incentivizing investment.
- Enhance reporting and manufacturing accountability.

The bills highlighted in this hearing incorporate some of the above recommendations and we commend you and your colleagues for further considering and advancing these proposals. ASCO specifically endorses the following:

- The *Drug Shortage Prevention Act of 2023* (H.R. 3008) introduced by Reps. Sara Jacobs (D-CA) and Cory Mills (R-FL) requires manufacturers to report when they are experiencing increases in demand, permanent discontinuance, or an interruption in manufacturing of a drug that is likely to have a meaningful disruption in the U.S. drug supply.
- The *Drug Origin Transparency Act of 2023* (H.R. 3810) introduced by Rep. Anna Eshoo (D-CA) requires manufacturers to report supply chain information, including origin details, to increase transparency in the supply chain.
- The *Ensuring Access to Lifesaving Drugs Act of 2023* (H.R. 3793) introduced by Rep. Elissa Slotkin (D-MI) requires manufacturers of life-saving drugs to submit data to assess drug stability and determine their longest supported expiration date.

ASCO also supports many provisions included in the *Stop Drug Shortages Act* (H.R. ___) drafted by Chair Cathy McMorris Rodgers (R-WA) as outlined in our discussion draft response[10]. We appreciate the strides taken to put forth a comprehensive legislative solution to this complex issue.

In closing, addressing drug shortages is a top priority for ASCO, our members and the thousands of cancer patients impacted. We urge this subcommittee to take decisive action to develop and enact legislation that effectively prevents and responds to generic drug shortages. By doing so, we can safeguard access to critical medications that cancer patients depend on for their treatment and ultimately improve the outlook for those battling this devastating disease.

Thank you for holding this legislative hearing and for the opportunity to provide ASCO's comments, concerns, and solutions to address drug shortages. We stand ready to work collaboratively with you and your colleagues to find meaningful solutions to this ongoing health care challenge. Please contact Megan Tweed at Megan.Tweed@asco.org with any questions.

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[6] https://old-prod.asco.org/sites/new-www.asco.org/files/Statement-Senate-Homeland-Security-Committee-Drug-Shortages-Hearing-03.2023.pdf
[7] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/practice-patients/documents/2023-JG-CEC-Testimony.pdf
[8] https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-security.ashx)
[9] https://www.ashp.org/-/media/assets/news-and-media/docs/Healthcare-Supply-Chain-Recommendations
[10] http://old-prod.asco.org/sites/new-www.asco.org/files/RFI-Reponse-House-EandC-Drug-Shortage-Discussion-Draft.pdf

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HOUSE COMMITTEE ON HOMELAND SECURITY
HOUSE COMMITTEE ON EDUCATION AND LABOR

Congress of the United States
House of Representatives
Washington, DC 20515

September 5, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

I am writing with respect to a legislative proposal in the U.S. Food & Drug Administration's [FDA, or Agency] fiscal year (FY) 2024 budget request that would provide the Agency with authority to mandate that drug manufacturers and repackagers of active pharmaceutical ingredients (APIs) include information regarding the original manufacturer and unique facility identifier of APIs on finished drug products and on the label of bulk drug substances. Products that do not include this information would be deemed misbranded. We have a shared commitment to ensuring the safety of the U.S. drug supply chain, and I am writing to clarify and better understand how existing Agency authorities relate to this FY2024 legislative proposal.

Existing Information Available to the Agency

According to the FDA FY24 budget proposal, this policy would improve supply chain accountability and transparency, but I understand **that FDA already has access to much of the information as a result of various regulations and reporting requirements**. For example, FDA currently has access to API and supply chain information through the Drug Registration and Listing System. Current regulations (21 CFR Part 207) require companies to provide the following information for each drug bearing a National Drug Code (NDC):

> *"The name and Unique Facility Identifier of every other establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment.* ***This includes all establishments involved in the production of each unfinished drug received by the registrant for use in the production of the drug being listed. The names, Unique Facility Identifiers, and type of operations for establishments involved in production of each unfinished drug received by the registrant for use in the production of the drug being listed may be provided by including the properly assigned and listed NDC for such unfinished drug****."*

API repackagers must also register their products with the FDA and must disclose the original manufacturer of the drug within their application. According to 21 CFR 207.53(b):

> *"Each registrant must provide the following listing information for each drug it repacks or relabels:*
>
> *(b)* ***Source NDC.*** *The NDC assigned to each finished drug received by the registrant for repacking or relabeling, with the exception of medical gases.* ***Each such NDC must be associated with the corresponding NDC(s) for repacked or relabeled drugs, reported under paragraph (a) of this section.*** *"*

Additionally, foreign manufacturers of API are already required to report an "Importer of Record" to the FDA through their NDC Drug Listing Application. The Agency deems products misbranded if the importer of record or manufacturer are not listed with the FDA. The specific requirement, according to the Agency, states "foreign drug establishments that manufacture, repack, re-label or salvage drug products and whose drugs are imported or offered for import into the United States are required to register with the FDA before offering a drug for import and renew annually. **These regulations also requires (sic) foreign drug establishments to identify** a U.S. Agent and include **all known importers in their drug registration.**" The regulations (21 CFR 207.25(h)) further require:

> *"with respect to foreign establishments subject to registration, the name, mailing address, telephone number, and email address must be provided for:*
>
> *(1) The United States agent, as provided in § 207.69(b);*
>
> *(2) Each importer in the United States of drugs manufactured, repacked, relabeled, or salvaged at the establishment that is known to the establishment; and*
>
> *(3) Each person who imports or offers for import such drug to the United States."*

Finally, FDA reviews "Affirmation of Compliance" (A of C) codes, submitted by importers, to verify that imported drug products are in compliance when entering the United States. According to the FDA, some A of C codes require a product manufacturer's registration number, unique to the facility, or a product's approval number, specific to the product." Imported drug products that are appropriately classified are thoroughly reviewed by FDA inspectors before entering the country. The Agency's website notes that:

> *"FDA entry reviewers are trained to verify compliance with applicable product requirements. The FDA entry reviewers use the information provided to FDA in the importer's entry transmission, such as:*
>
> - *Declared Manufacturer*
> - *Declared Importer/Consignee*
> - *Product Description*
> - *Affirmations of Compliance (A of C)*
> - *Intended use code*
>
> *These entry declarations are compared to information in FDA's internal data systems. If the information matches, then compliance is verified; if the information does not match, FDA may need to gather additional information or may detain the product. The FDA also conducts field examinations and analyzes samples of drug products to ensure they comply with applicable standards and/or label requirements."*

Questions to Better Understand the FDA Budget Request

I am writing to better understand the Agency's desired policy goal, so that we can work together on potential workable solutions. To that end, please respond to the following questions by September 29, 2023:

1. What steps can be taken to improve the FDA's internal systems to better access and utilize the supply chain information that is already collected by the Agency?
2. What would the requirement for full transparency of the original manufacturer on labels do to improve the supply chain or its quality, given that the FDA currently has this information or could easily gather it?
3. What resources does FDA provide that would allow the end user to know if the API manufacturer has met current good manufacturing requirements?
4. What actions does FDA expect end users to take upon receipt of product, once the API manufacturer information is provided to them?
5. To what extent is this proposal driven by API manufacturers — especially those in foreign countries — failing to meet appropriate manufacturing practice requirements?
6. The information the Agency is seeking to disclose has historically been considered confidential commercial information (CCI) and trade secrets. Many companies have made an investment in vendor qualification so that their customers can trust the products they use and provide for their patients. Does the Agency's effort to publicly disclose the API manufacturer devalue the vendor qualification investment by companies that has historically been considered CCI and trade secret?
7. What are some meaningful steps that Congress and the FDA can take to improve API manufacturing quality overseas, or encourage domestic API manufacturing?

Thank you for your timely attention and response to these issues and questions. If you have questions about this inquiry or are unable to reach me, please contact Peter Stein on my staff at peter.stein@mail.house.gov.

Sincerely,

Diana Harshbarger
Member of Congress

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

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[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?AccessKeyId=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.[8] 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.[9]

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, 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, 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.[13] 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.[14] HealthTrust is the third largest, boasting more than $20 billion in purchasing volume.[15] 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

[11] Ibid.
[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.
[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, 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.
[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.

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[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, 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]

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[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] "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

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

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]

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[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=jchlp.
[35] Ibid.
[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

[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/ .

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.[44] In January 1996, American Healthcare Systems, SunHealth Alliance, and Premier Healthcare Alliance merged to form Premier Inc.[45] Premier oversaw purchasing for approximately 33% of hospitals in the U.S.[46] In January 1998, VHA and University HealthSystem Consortium merged to form Novation. By 1998,

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[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.
[45] "Connecting the Dots: How Anticompetitive Contracting Practices, Kickbacks, and Self-dealing by Hospital 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

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

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All Carrots, No Sticks: House Republican Drug Shortage Plan Ups Reimbursement But Lacks Supply, Quality Commitments

31 Jul 2023 | **ANALYSIS**

by Sarah Karlin-Smith | @sarahkarlin | Sarah.Karlin-Smith@citeline.com

Executive Summary

New Republican House Energy and Commerce shortage plan is seen as reasonable starting point, though in need of much strength to address root causes of supply troubles. Most changes apply to generic drugs, but a few could impact brands.

REPUBLICAN DRUG SHORTAGE PLAN CONTAINS LOTS OF CARROTS FOR DRUG MANUFACTURERS *Source: Shutterstock*

A House Republican plan to tackle drug shortages focuses on increased reimbursement to shore up the US supply chain, relying on manufacturer's good will rather than mandates to use those additional resources to prevent and mitigate drug shortages.

The bill's failure to extract supply chain commitments from drug companies or other health care entities in exchange for new government funding is unlikely to lead to the enhanced drug marketplace lawmakers are aiming for, experts said.

"Just paying more is not enough," said Marta Wosinska, a senior fellow in economic studies at the Brookings Schaeffer Initiative on Health Policy. "We need to pay more yes, but we need to pay more for having product made to specification reliably."

The draft is "missing any mitigating factors that get at the root cause of shortages – quality," said Erin Fox, associate chief pharmacy officer and the University of Utah Health. "Right now, generic drug companies only have price to compete on, even though FDA sees differences between the manufacturing facilities and their reliability and quality."

Key Takeaways

Financial perks in Medicaid, 340b and Medicare for drugs at risk of shortages (mostly generics) would be awarded under a new Republican plan.

Experts say the root cause of shortages won't be solved by this plan because payments are not tied to drug reliability and quality.

A MedPAC study on getting rid of percentage-based add on payments for Part B drug reimbursement may be key item to watch for brands.

Brands would also qualify for a new IRA inflation rebate reprieve and a potential 1-month exclusivity extension for requested stability studies.

House Democrats and other health policy experts also worried that some of the payment provisions in the bill may create perverse incentives that would encourage companies to keep some products in shortage. Energy and Commerce Democrats have been pushing for FDA-centric reforms in the must-past pandemic prep bill reauthorization. (Also see "US FDA Gets Wanted Pathogen Program, Manufacturers Get Longer BARDA Contracts In Competing Pandemic Prep Bills" - Pink Sheet, 20 Jul, 2023.)

The generic industry, on the other hand, is pleased with the plan.

"We commend Chair Rodgers for this proposal that takes a comprehensive approach to reducing drug shortages by improving the long-term sustainability of generic competition," the Association for Accessible Medicines Interim President and CEO David Gaugh said.

Comments on the plan are due by 25 August to drugshortages@mail.house.gov.

Medicare, Medicaid & 340B Tackled

The Stop Drug Shortages Act would alter reimbursement policies in Medicare, Medicaid and the 340B health program that are designed to penalize companies for raising the prices of drugs above the rate of inflation with a focus on sterile injectable generics.

For Medicaid, the discussion draft released on 28 July by House Energy and Commerce Chair Cathy McMorris Rodgers suspends inflationary rebates for generic sterile injectable drugs with at least one indication for a serious disease or condition made by more than one manufacturer. The inflationary rebate would also be suspended for all generic drugs in shortage or at risk of experiencing shortage.

In Medicaid, generic drugs pay a rebate of 17.1% of AMP plus an inflationary penalty equal to the amount by which the drug grows faster than inflation. Generic drugs that are in shortage or at risk of experiencing shortages could not have total Medicaid rebates exceeding 100% of the drug's average manufacturer price (AMP) under the bill.

For 340B, the bill would exempt generic sterile injectable drugs with at least one indication for a serious disease or condition that are made by more than one manufacture from the program.

Tweaks to programs designed to provide some of the neediest Americans access to affordable medicines were met with skepticism.

“This bill to me leans too heavily on solutions relating to carving drugs out of some of the statutory provisions that ensure that the government receives a fair deal on prescription drugs, particularly older ones that have been on the market for decades,” said Aaron Kesselheim, a professor of medicine at Harvard and director of the Program On Regulation, Therapeutics, and Law.

“Creating exemptions to the 340B program or to the effective Medicaid drug rebate program could open up the door to those exceptions being gamed or staying in place too long or being expanded further,” he added.

For example, Kesselheim said shortages might be “manufactured” so a drug qualifies for these rebate exemptions if companies realize such exemptions might be profitable.

House Energy and Commerce Ranking Member Frank Pallone, D-NJ, made a similar comment.

“I’m concerned that some of the Republican proposals are just handouts to pharmaceutical corporations that would increase costs for patients and potentially lead to more shortages,” Pallone said.

Changes To Inflation Reduction Act

In Medicare, the Republican bill seeks to modify a provision in the Inflation Reduction Act that requires Medicare to reduce or wave inflation rebates if those drugs are in shortage. The provision requires that the Center for Medicare and Medicaid Services gradually phase out the waiver once the shortage resolves with step downs in their inflation rebate penalty reductions each quarter for a year post-shortage. This provision applies to brands and generics. (Also see "Inflation, Biosimilars, And The Wizard Of Oz: An Interview With Teva’s Christine Baeder" - Pink Sheet, 14 Feb, 2023.)

The provision also prohibits HHS from conditioning waivers or reductions of rebate penalties on the duration of a supply chain disruption or shortage.

Exclusivity For Shelf-Life Extensions

Another provision in the bill would an extra one month of exclusivity to already marketed drugs for shelf-life extension studies conducted and completed in response to a request from the government.

Brookings’ Wosinska said it will be important to look at the costs and unintended consequences of this provision.

“A one-month exclusivity could be a lot of money,” and it might be more efficient for the government to simply reimburse companies for conducting certain stability studies, she said.

This idea could also incentivize manufacturers “in the wrong way,” Wosinska added, encouraging them to initially conduct shorter stability studies in order to later get the exclusivity extension from the government.

Part B Formula Back In Spotlight

Rodger’s bill calls for a variety of studies and transparency reports, an aspect of the legislation which drew praise from Kesselheim.

“There isn’t a lot of good information about how the drug supply chain can exacerbate or help prevent shortages, so it was good to see a lot of attention to studies and reports that would hopefully help shed some

light on the idea," he said.

For Medicare, one study asks the Medicare Payment Advisory Commission to make recommendations to move the reimbursement systems for Part B away from the average sales price plus 6% reimbursement methodology to a flat fee instead of the percentage add-on payment. Any change should hold physicians harmless.

Reforms to the Part B reimbursement formula have long been a focus of Democrats as well. (Also see "Medicare Drug Payment Demonstration May Advance In 2023 Under Executive Order" - Pink Sheet, 14 Oct, 2022.)

The bill also includes a study on Medicare reimbursement of sterile generic injectable drugs and other Part B drugs in shortage for the purpose of recommendations on how to transition these drugs to market-based pricing. The bill requires a Medicare Innovation Center model to test market-based pricing of generic sterile injectables.

Medicare is also asked to study coding policies for generic sterile injectables and other Part B drugs in shortage and provide billing and coding recommendations to mitigate shortages.

For, 340B, the Republican draft asks the Health Resources and Services Administration which runs 340B – the drug program that provides nonprofit hospitals and other safety net health care providers steep discounts on drugs – to issue guidance that would provide covered entities with ways to share drugs during shortages without violating prohibitions on diverted drugs purchased through 340B to patients not eligible for the program.

And the bill would call for a Government Accountability Office study on the number of generic drugs that are subject to 340B "penny pricing" or have costs of $1 or less and ask GAO to look at the number of these drugs that have experienced shortages within a decade. Penny pricing for 340B drugs occurs when the 340B ceiling price would otherwise dip below zero when price increases trigger a Medicaid inflation rebate on top of the standard Medicaid rebate.

Transparency provisions in the bill aim to shine a light on the role of group purchasing organizations and shortages, including by requiring reporting of hospital renumeration from GPOs as a condition of Medicare participation. This includes reporting on renumeration tied to an ownership stake in a GPO.

What's Missing: Hospitals, Definitions And Public Manufacturing

To ensure a redundant, robust supply chain, experts said policymakers will need to go further than this package and that may mean looping in other parts of the US health system.

"What I don't see in bill is an acknowledgement or an attempt to get hospitals to buy differently," said Brookings' Wosinska.

She believes additional payments should be tied to quality, but that many of the quality incentives should target hospitals instead of manufacturers, rewarding hospitals for purchasing from higher-quality, more reliable manufacturers. (Also see "AAM Calls For Congress And FDA To End Shortages By Easing Up On Generics Quality, Pricing" - Pink Sheet, 4 Jul, 2023.)

"There's a presumption that if we just pay manufacturers more that somehow the problem would go away, which isn't the case. Quality is difficult to observe. And hospitals are not, even if they could, putting nearly as much weight on manufacturing quality and reliability. And that's why we have a problem," Wosinska said. "Hospitals consider that every product to be therapeutically equivalent. It's FDA approved, why would you pay attention to anything else?"

"The reason why we think that we need to go beyond FDA and manufacturing oversight to hospitals is because FDA basically can't assure [quality] to the level that to the extent that we would like to have it," Wosinska said.

“Number one, they're not at these facilities at all times. The probability of being caught … and the consequences of being caught are also not as severe. I mean, think about it. None of us – Congress, FDA – wants shortages when push comes to shove, right?” (Also see "AAM Calls For Congress And FDA To End Shortages By Easing Up On Generics Quality, Pricing" - Pink Sheet, 4 Jul, 2023.)

CMS on the other hand, has the levers to push hospitals and GPOs to purchasing systems that reward quality and stability of production.

Kesselheim said the draft could benefit from thinking more from defining shortages and tailoring solutions to different shortage situations.

“We need more transparency about this process to ensure that a shortage is actually a real shortage, and to ensure that resolution of shortages can also be acted on. Also, there’s a difference between a shortage caused by a natural disaster in the world somewhere and a shortage caused by business dealings in the drug market. The former are reasonable to adjust to – the latter suggest that there are larger problems that we should be addressing.”

For instance, Kesselheim said solutions to shortages should be different when they occur because a merger between two companies reduces supply, for example.

Kesselheim would like to see more efforts in to invest in public manufacturing of essential medicines through efforts akin to Civica to help the US maintain a supply of older, off-patent drugs. (Also see "Civica’s $27.8m New Facility Expands Virginia Drug Hub Vision" - Generics Bulletin, 21 Sep, 2022.)

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Medicaid Provision of Draft House Drug Shortages Bill Raises Concerns

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This year, there has been renewed focus in Congress on how to address the ongoing problem of drug shortages, especially with cancer patients now facing severe **shortages** of widely used generic chemotherapy drugs. On July 28, 2023, House Energy and Commerce Committee Chair Cathy McMorris Rodgers **unveiled** a draft bill intended to address the "root causes" of drug shortages.

The draft bill includes a provision that would exempt manufacturers of certain generic drugs from having to pay any inflation-related rebates under the highly effective Medicaid Drug Rebate Program (MDRP), which, for example, ensures Medicaid obtains the **lowest net prices** for brand-name drugs compared to other federal programs and agencies. This Medicaid exemption provision, however, raises concerns. The provision is not well targeted, extending to many generic injectable drugs not in shortage. By reducing the rebates paid by generic manufacturers for many generic drugs, the provision could substantially increase federal and state Medicaid prescription drug costs. At the same time, it is unclear whether this exemption provision would have any significant impact in reducing critical drug shortages. The provision also would create troubling incentives for manufacturers to game the Food and Drug Administration (FDA) shortage reporting process. Instead, any exemption from the Medicaid inflation-related rebate to address critical drug shortages should be designed more narrowly: it should be highly targeted, temporary, and limited in size. It should also be explicitly tied to manufacturer improvements and production increases to ensure that it would actually reduce drug shortages.

Under the MDRP, in order for their generic drugs to be covered under Medicaid, manufacturers must pay rebates to state Medicaid programs, with the federal government and the states sharing in the savings. These generic drug rebates consist of two elements: (1) a basic rebate equal to 13 percent of the Average Manufacturer Price and (2) an inflation-related rebate equal to the amount by which annual increases in Average Manufacturer Price outpace general inflation. The inflation-related rebate, which has applied to brand-name drugs since the MDRP's inception, was extended to generic drugs as of 2017.

Section 101 of the draft bill would entirely exempt manufacturers from having to pay the Medicaid inflation-related rebate for certain generic drugs starting on January 1, 2024. The first group of exempted drugs would include generic drugs that are either on the FDA's drug shortage list or that are suffering from a severe supply chain disruption due to a natural disaster or other unique or unexpected event, as determined by the Secretary of Health and Human Services. The second group of exempted drugs would include any sterile, injectable drug with at least one indication for a serious disease or condition and with at least two manufacturers. In addition,

the draft bill would reinstate a cap on total rebates paid by manufacturers for both groups of generic drugs. Prior to January 1, 2024, total rebates for both brand-name and generic drugs may not exceed 100 percent of Average Manufacturer Price. As we have previously **explained**, that cap was eliminated under the American Rescue Plan Act in order to discourage manufacturers from imposing excessive annual price increases over time. Lifting the Medicaid rebate cap was likely a **key factor** in recent price reductions by insulin manufacturers.

The Medicaid provision of the draft drug shortages bill raises numerous concerns:

1. The provision is not well targeted. For the second group of generic drugs exempted, the bill defines an indication for a serious disease or condition by referencing 21 C.F.R. § 312.300. However, paragraph (b) of such regulation very broadly defines a serious disease or condition as "a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one." This would seem to encompass many — possibly most — sterile, injectable generic drugs, even if they are not actually in shortage or suffering from a severe supply chain disruption.The exemption for the group shortage drugs appears overly expansive as well. For comparison, some aspects of the exemption go beyond similar provisions included in the Inflation Reduction Act (IRA) related to the new Medicare inflation-related rebates. For example, under the IRA, the Secretary "shall reduce or waive" inflation-related rebates for Part D drugs if they are currently in shortage on the FDA shortage list, the Secretary has determined there is a severe supply chain disruption in the case of generic or biosimilar drugs, or the Secretary has determined that without such reduction or waiver the drug is likely to be in shortage on the FDA shortage list. The discussion draft, in contrast, would require a 100 percent exemption from Medicaid inflation-related rebates, rather than giving the Secretary the option of allowing only a rebate reduction. Also, in its February 2023 implementation **memo** for the Medicare inflation-related rebates, the Centers for Medicare and Medicaid Services (CMS) indicated that it was considering either a variable reduction in rebate amounts based on the length of time a drug was on the shortage list or a limited standard deduction, which could be adjusted based on manufacturer request, rather than full waivers for any drug in shortage. Moreover, CMS also indicated its intent to limit the definition of severe supply chain disruptions to those due to factors outside of a manufacturer's control, rather than to issues like failure to comply with good manufacturing practice requirements.
2. The provision would increase federal and state Medicaid prescription drug costs. Researchers from Brigham and Women's Hospital and Harvard University recently **estimated** that the inflation-related rebates reduced federal and state Medicaid generic prescription drug costs by between 2 and 12 percent — $516 million to $6.5 billion — over the period 2017-2020. (The researchers estimated a range of savings due to data limitation issues.) Similarly, when the Medicaid inflation-related rebates for generic drugs were enacted in 2015, the Congressional Budget Office **estimated** that the provision would reduce federal Medicaid spending by $1 billion over ten years and by $156 million in the tenth year. Moreover, while it is unclear how many generic drugs, if any, would have rebate obligations in excess of 100 percent of Average Manufacturer Price when the rebate cap is eliminated starting in 2014, lifting the cap was likely a **key factor** in price decreases instituted by brand-name insulin manufacturers earlier this year. As a result, any exemption, especially a broad one exempting many injectable drugs, would reduce generic inflation-related rebates and thereby increase net federal and state Medicaid prescription drug costs, possibly substantially. Notably, the same Brigham and Women's Hospital and Harvard University researchers previously **found** that one in five generic drugs experienced a price spike from at least one manufacturer between 2014-2017, with nearly half of generic injectable drugs experiencing a price spike over the period. (A price spike was defined as price increases of 100 percent or more over the previous year or 50 percent or more over the previous quarter.) They also conclude that because of the generic inflation-related rebates, state Medicaid programs are now protected from these price spikes; "generic

drug spikes now have little or no impact on state Medicaid spending…." The draft bill, however, could considerably undercut that fiscal protection.

3. The provision may do little to address shortages of critical generic drugs. Since the Medicaid inflation-related rebates have been extended to generic drugs, the generic drug industry has repeatedly blamed the rebates as a key contributor to drug shortages (for example, **here** and **here**). Of course, shortages have been a persistent, serious problem well before the rebates first took effect in 2017. Moreover, like the **Government Accountability Office** and the **Assistant Secretary for Planning and Evaluation** (ASPE), in its 2019 **report** entitled "Drug Shortages: Root Causes and Potential Solutions," the FDA cites quality problems among manufacturers, intense price competition, the lack of purchaser incentives for good manufacturing practices and the complexity of the supply chain as the major contributors to ongoing drug shortages. While FDA acknowledged the manufacturer argument that the Medicaid inflation-related rebates "could erode the incentive for the manufacturer to continue marketing the drug and increase the likelihood of drug shortages," FDA noted that the "argument that the CPI-U rebate will make it difficult for manufacturers to recoup rising input costs may be weak, however. There is little evidence that manufacturing input costs are rising faster than the CPI-U, and they are likely to be captured in the rising costs of consumer goods that the CPI-U measures." Finally, it is notable that moving forward, high general inflation during the pandemic will be permanently built into the calculation of inflation-related rebates moving forward. This will effectively give manufacturers more "room" to raise prices without being subject to Medicaid inflation-related penalties, which could ostensibly pay for greater investments in good manufacturing practices and more stable supply chains over time as generic manufacturers claim.
4. The provision risks manufacturer gaming. In discussing the Medicare inflation-related rebates under the IRA, CMS **noted** that it did not want to "create incentives for misuse of" the FDA shortage reporting process or "for manufacturers to intentionally maintain their Part D rebate drug or biological in shortage for the purpose of avoiding an obligation to pay a rebate." CMS' concerns about manufacturer gaming in Medicare would similarly apply to an exemption from Medicaid inflation-related rebates. As ASPE **points** out, "because shortages often occur for reasons, such as quality manufacturing practices, under the manufacturer's control and because manufacturers have better information on market conditions and their production capacity that certain manufacturers could be incentivized to intentionally create a shortage or maintain a drug in shortage to avoid their obligation to pay a rebate." In other words, some manufacturers could reduce production just enough to remain in (or go into) shortage to avoid Medicaid rebate obligations if an exemption was from inflation-related rebates was available.

Any policy to provide an exemption from the Medicaid inflation-related rebate to address critical generic drug shortages should instead be designed far more narrowly. For example, it should be highly targeted to a limited number of generic drugs in shortage that are deemed critical high-need drugs. It should be temporary, available for only a very short duration. An exemption should also be limited in size, with a percentage reduction in rebate amounts, not a full waiver, that varies based on severity and duration of a shortage. It should also not include a reimposition of the rebate cap. Finally, any exemption should be explicitly tied to specific manufacturer actions that would reduce the risk of shortages such as improvements in compliance with good manufacturing practices and in supply chain management and benchmark increases in production capacity with clear timelines.

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MEDICAID PROVISION OF DRAFT HOUSE DRUG SHORTAGES BILL RAISES CONCERNS