Your Generics & Biosimilars Industry

May 30, 2024

The Honorable Lina M. Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages

Docket ID: FTC-2024-0018-0001

The Association for Accessible Medicines (AAM) is pleased to provide comments to the Federal Trade Commission (FTC) and U.S. Department of Health and Human Services (HHS) (the Agencies) in response to the Agencies' February 14, 2024 Request for Information (RFI) to understand how the conduct and practices of two types of pharmaceutical drug middlemen groups—group purchasing organizations (GPOs) and drug wholesalers (hereafter referred to as "Buying Groups") — are lessening competition and contributing to generic drug shortages.

AAM is the nation's leading trade association representing manufacturers of generic and biosimilar medicines. AAM's core mission is to improve the lives of patients by advancing timely access to safe, effective, and affordable prescription generic and biosimilar medicines. Generic drugs and biosimilar products account for 90% of all prescriptions dispensed in the U.S., but less than 18% of the costs of prescription drugs. America's patients and the U.S. health care system have saved nearly $3 trillion in the last 10 years due to the availability of safe and affordable generics and biosimilars.[1]

That said, the sustainability of competitive generic and biosimilar markets and the continuing supply of Food and Drug Administration (FDA) approved/licensed generic and biosimilar medicines for patients, uninterrupted by shortages, is in jeopardy. Although generic and biosimilar manufacturers have contributed to dramatically lower rates of health care spending, the ability to continue to provide affordable generic and biosimilar medicines is threatened by excessive consolidation of intermediary participants–GPOs (at both the retail and hospital levels)[2], wholesalers, and pharmacy benefit managers (PBMs). Consolidation in and among such intermediaries has: (1) adversely affected generic and biosimilar competition, (2) significantly reduced drug availability, and, in so doing, (3) greatly harmed patients. Perverse market dynamics caused by a limited number of entities driving distribution and reimbursement in the United States have allowed abusive contract practices and, combined with poorly designed Federal and State policies, driven generics

[1] AAM Report, The U.S. Generic & Biosimilar Medicines Savings Report (October 2021).

[2] AAM will refer to retail and hospital group purchasers, including GPOs, wholesalers and wholesale/pharmacy purchasing consortia as "Buying Groups" throughout.

and biosimilars to unsustainably low prices. The Agencies should act to reverse this trend by striking the right balance between affordability to the healthcare system and incentives to reinvigorate robust generic and biosimilar markets.

AAM previously suggested that FTC specifically study the impact of Buying Group consolidation in response to these concerns. Accordingly, we commend the Agencies for this RFI. Based on the urgent challenges discussed in this response, AAM requests that the FTC issue a section 6(b) Order to investigate the contracting practices of Buying Groups that contribute to the root causes of drug shortages.[3]

In addition, AAM suggests that the Agencies should undertake the following:

- Issue new Statements of Antitrust Enforcement Policy in Healthcare that lower the (now withdrawn) "market power" safe harbors for Buying Groups; and

- Revise/clarify the Anti-Kickback Statute safe harbor provisions to exclude anticompetitive fees and charges imposed by Buying Groups.

Without remedial action, the high concentration of buying power in the generic and biosimilar markets—combined with anticompetitive contractual terms—will continue to cause anticompetitive harm to patients and consumers in the form of terminated or abandoned products and drug shortages.

I. Generic Buying Groups Are Highly Consolidated

Generic Buying Groups are highly consolidated. In the retail generic market, three Buying Groups (WBAD, Red Oak, and ClarusOne), representing collaborations among the three leading wholesalers and pharmacies, now account for nearly 80% of generic drug purchases in the U.S.[4]

Red Oak Sourcing	38%
Walgreens Boots Alliance (WBAD)	21%
ClarusOne	19%
Top 3 Buying Group Control	**78%**

A similar pattern is found in the hospital GPO market that controls institutional purchasing of medical supplies and drugs where three major players dominate the market.

[3] The FTC issued a 6(b) Order regarding PBMs on June 6, 2022. AAM submits a similar Order should be directed at the large Buying Groups discussed in this submission.
[4] Fein, A. (2023). *The 2023-2024 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*. Drug Channels Institute.)

Collectively, Vizient, Premier, and HealthTrust control at least 80% of the hospital purchasing market.[5]

Organization name	Hospitals and health systems	Total staffed beds	Alternate sites and other providers	Estimated total purchasing volume (billions)
Vizient[1]	3,500	450,000	145,000	$130
Premier[2]	4,400	340,000	250,000	$82
HealthTrust Purchasing Group	1,800	175,000	57,000	$50

1. In 2015, Novation, University HealthSystem Consortium, and VHA formed Vizient. Vizient acquired MedAssets in 2016 and acquired Intalere (previously known as Amerinet) in 2021.
2. Includes Acurity, which Premier acquired in 2020.
Source: Drug Channels Institute research and estimates; Definitive Healthcare. Note that membership counts may not be comparable between organizations due to differences in methodologies and definitions.

If anything, the above figures understate the challenge. In the retail market, there has been extensive vertical integration between wholesale distributors and pharmacy chain Buying Groups with equally consolidated Pharmacy Benefit Managers (PBMs) – another market in which the three largest players (i.e. CVS Health, Optum Rx, and Express Scripts) control roughly 80% of the market.[6] As previously noted, and further described below, such consolidation results in harm to mature generic drugs and contributes extensively to the likelihood of drug shortages. Additionally, it undermines competition from new lower-priced medicines when PBMs (including those with integrated pharmacies) prefer high-priced innovator products long after generic entry.[7]

This type of consolidation (among what are known in antitrust parlance as "horizontal competitors") can and does have anticompetitive impacts on the market. Market power in few hands – be it buyers or sellers – raises anticompetitive concerns. Overly consolidated market power in the hands of a few buyers is known as "monopsony" power (or buyer-side monopoly power). As discussed further below, such monopsony power may lead to below-competitive pricing which, in turn, leads to reductions in output and shortages.

This consolidation among both generic Buying Groups and PBMs has permitted abusive contract terms and led to unsustainably low generic drug prices, which has led to volatile supply and drug shortages. These entities have been able to extract below-competitive prices and non-competitive, take-it-or-leave-it contract terms, such as most-

[5] *Id*.
[6] Those PBMs are CVS Health/Caremark at 32%, Cigna/ExpressScripts at 24%, and Optum RX/United Health at 21%. *Id*. (*see also PBM Chart below).*
[7] AAM White Paper, Access Denied: Why New Generics Are Not Reaching America's Seniors (September 2019).

favored-nation clauses (MFNs)[8], failure-to-supply (FTS) penalties[9], imbalanced returns provisions, and extended price restrictions discussed in detail below. Buyer consolidation has contributed to substantial generic price deflation and market exits. Moreover, the savings achieved by Buying Groups are often not passed on to patients.[10] In sum, the competitive landscape is disrupted because: (i) the concentrated market power of the Buying Groups by itself leads to below-competitive monopsony prices; and (ii) this market power permits the Buying Groups to impose further unsustainable deflation through onerous contract provisions such as MFNs, FTS penalties, and after-the-fact pricing adjustments that restrict output, limit capacity, and hinder competition.

The increasing consolidation in the supply chain is a key threat to sustainable generic markets and a major contributor to drug shortages. Compared to the fragmented and highly competitive generic market, consolidation in the retail, wholesale, institutional, and PBM markets (including contractual arrangements between pharmacy chains and wholesalers) has left generic manufacturers with only a small number of purchasers. The Buying Groups' sheer market size is, by itself and in combination with the other players, unsustainable. These Buying Groups: (1) control the buying experience and product movement/allocation; (2) have access to every company's pricing and all consumers' purchasing behavior; and (3) are moving upstream into private labelling and downstream into their own supply programs. Manufacturers are relegated to the role of contract commodity manufacturers.

These Buying Groups have been moving more and more toward single-source contracts for generic drugs.[11] As a result, it is often possible that only one to three generic manufacturers are able to market any given product. This puts reliable access to affordable generic medicines at risk for the patients who need them. This is problematic because FDA has found that generic prices (when looking at both average manufacturer's price (AMP)[12] and invoice prices) fall more than 95% when compared to the corresponding innovator product's prices when there are six or more competitors.[13] With the shift toward single (or limited) suppliers and below-competitive pricing, there is little incentive for

[8] A MFN (most-favored-nation) clause, inhibits competition by requiring a generic manufacturer to sell all product at the lowest price of any of its sales. For example, a generic manufacturer with excess capacity cannot sell product at a discount without retroactively incurring losses on other sales.

[9] A FTS (failure-to-supply) clause will penalize a generic manufacturer already offering low prices when capacity is restricted.

[10] USC Schaeffer Center, U.S. Consumers Overpay for Generic Drugs (May 31, 2022), https://healthpolicy.usc.edu/ research/ u-s-consumers-overpay-for-generic-drugs/#:~:text=Despite%20generic%20entry%20driving% 20down,the%20full%20savings%20to%20consumers.

[11] Deroo, C., Pay to Play: The Impact of Group Purchasing Organizations on Drug Shortages, Am. L. Bus. Rev. (2013), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1033&context=aublr

[12] AMP is the average price wholesalers and other large purchasers pay manufacturers for prescription drugs that are sold to retail pharmacies.

[13] *See* Food and Drug Administration: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, Dec. 13, 2019, available at: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

additional entrants and this, in turn, poses a serious risk of shortages should a single supplier have interruptions or exit the market.

And just as we see shortages in the generic market because of market concentration of Buying Groups, we predict that the consolidation in the PBM industry could eventually cause complex generics, including critical sterile injectables and cancer treatments, and biosimilars to have to exit markets due to low market penetration despite having lower net costs than their associated reference products.

A. Generic Buying Groups are Exercising Monopsony Power

Buying Groups exercise anticompetitive buyer-side monopoly power (known in legal precedent as "monopsony" power) that harms patients. This phenomenon has been previously recognized in other markets.[14] It is now occurring here.[15] This includes scarcities in cardiovascular, anti-infective, and cancer treatments as well as shortages in "old generic drugs," including intravenous ("IV") saline solutions, and others."[16] By driving prices below the competitive level (i.e., at marginal cost or at a loss), competition is harmed because output is driven lower and downstream pricing is less competitive. The resulting harm includes competitors abandoning certain products or smaller competitors being driven out of the market or out of business, thus potentially leading to drug shortages.

Buying Groups may violate the antitrust laws (just as sellers may) because "monopsony power is the mirror image of monopoly power."[17] As Judge Posner, an expert on antitrust law and a Seventh Circuit judge for more than 30 years, has explained: "Just as a sellers' cartel enables the charging of monopoly prices, a buyers' cartel enables the charging of monopsony prices; and monopoly and monopsony are symmetrical distortions of competition from an economic standpoint."[18] As the Supreme Court has recognized, there is a "close theoretical connection between monopoly and monopsony" and this "suggests that similar legal standards should apply."[19]

A Buying Group may force sellers to accept prices below what those sellers would receive in a competitive market because the members collectively exercise market power.[20] The anticompetitive effect of below-competitive pricing in the long run is that output will be restricted. Restricted output, in turn, will lead to shortages. And indeed,

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[14] *See, e.g., Arizona Hospital*, No. 07-10330 (D. Ariz. 2007); *Powderly v. Blue Cross*, No. 3:08-cv-0109 (W.D.N.C. 2008).

[15] Khan, R., Forbes, Unsustainable Low Prices Causing Generic Drug Market Failure Leading to Supply Chain Disruptions and Shortages (July 6, 2020), https://www.forbes.com/sites/roomykhan/2020/07/06/unsustainable-low-prices-causing-generic-drug-market-failure-leading-to-supply-chain-disruptions-and-shortages/?sh=73eb20db74d4.

[16] *Id*.

[17] *Improving Health Care: A Dose of Competition* at 13 (2004).

[18] *Vogel v. American Soc. of Appraisers*, 744 F.2d 598, 601 (7th Cir. 1984).

[19] *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 127 S. Ct. 1069, 1076 (2007).

[20] *See, e.g., Telecor Communications v. Southwestern Bell*, 305 F.3d 1124, 1134-36 (10th Cir. 2002).

generic products have been discontinued and shortages have already resulted, precisely for this reason.[21] Eventually, analysts have recognized that "mid-tier and smaller manufacturers likely will be acquired or forced out of business."[22] Output will be reduced by sellers being forced to consolidate, smaller sellers going out of business, or manufacturers leaving the market.[23]

In today's generic drug marketplace, the Buying Groups, respectively, wield significant monopsony power. Their collective dominance has led to unchecked and historically high levels of price deflation and shortages throughout the generic market. This leads to fewer generics being available and to manufacturers reconsidering production of lower-margin drugs.[24] Over the past five years, even as the quantity of generic drugs sold has increased, the total value of all generic sales, including new launches following reference product loss of exclusivity, has fallen by $6.4 billion.[25]

Further, these purchasers have increasingly utilized restrictive contract terms to reduce prices and margins, which has led to a reduction in the size of generic portfolios. Those restrictive contract provisions include contract terms such as: MFN clauses; imbalanced returns provisions and/or lack of cancellation notice periods in conjunction with FTS; administrative fees; service penalties; extended price restrictions; and extended payment terms. Such terms can and do directly harm competition.[26] For example, a service level penalty can create an anticompetitive incentive for a wholesaler who will earn money on the difference between the generic price and the price of the product it purchases when failure-to-supply occurs, in which a generic manufacturer contractually must pay a buyer the difference between the manufacturer's contracted-for price and the

[21] Forbes, at 2-3 ("unhealthy purchase prices are causing a dysfunctional business environment for the generic drug market" causing, among other things, discontinuation of "unprofitable older generic drugs" as well as "supply chain disruptions and shortages").
[22] *See* Blueshift Report, "Generic Drug Joint Purchasing Will Squeeze Manufacturers," May 7, 2014.
[23] *Id.*
[24] *See, e.g.,* Swetlitz, I., "Teva Plans to Cut Back Generic Drug Production Even as Shortages Intensity," Bloomberg (May 18, 2023), https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages.
[25] IQVIA Institute for Human Data Science. "The Use of Medicines in the U.S. 2023 Usage And Spending Trends And Outlook To 2027" (April 2023) Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/theuse-of-medicines-in-the-us-2023/the-use-of-medicines-in-the-us-2023.pdf
[26] By way of background, AAM offers the following additional examples of the most common onerous contract provisions. For example, return of goods or lack of cancellation notice periods, in conjunction with FTS, creates extreme price leverage whereby manufactures must accept lower pricing immediately or accept financial losses associated with returned goods and unsellable safety stock (finished goods / materials). Manufacturers do not control what/how much Buying Groups order or keep on hand. Typically, Buying Groups hold approximately 30 days of high cost, low margin product and use the threat of returns to further depress prices. If manufacturers refuse to build their safety stocks, they face FTS, and if they comply, they face return risk. In either case, Buying Groups are not held accountable for inventory management practices.

purchased product's price. These penalties leave the generic manufacturer with the choice of absorbing high penalties or abandoning the market, reducing competition.

Moreover, these tactics cause long-term harm to generic manufacturers. Such contract terms lead to an increased portion of portfolios sold at low to negative margins; a reduction in product portfolios; the curtailing of planned generic launches; product shortages; the inability to or difficulty in supplying larger concentrated volumes; and reduced production. Unsustainably low prices and margins, combined with harmful contract terms, have resulted in decisions to exit the market. Moreover, an increasing number of generic medicines approved by the FDA do not launch because of a lack of viable commercial market opportunity.[27]

Excessive consolidation of power among the major Buying Groups presents the risk of exerting undue market power over generic suppliers, driving wholesale prices below marginal cost and reducing output, all of which can lead to producers exiting the market, or reducing production of unprofitable drugs. This consolidation also poses a danger of stabilizing and elevating downstream costs to end users and payers because of the small number of competing Buying Groups (who extract large price concessions but are not compelled to pass those savings on through competition in the distribution channel). In short, as the FDA has observed, the ever-increasing market power of Buying Groups has an adverse effect on competition which inevitably leads to shortages.[28] Ultimately, this will be reflected in increased public health costs and higher prices for consumers, running counter to the overarching aim of ensuring affordable access to essential medications. In effect, while these Buying Groups may achieve immediate cost reductions, the broader implications undermine supply chain competition without producing tangible benefits to consumers, particularly at the pharmacy counter, where lower drug prices remain an elusive goal to many.

In sum, the Buying Groups have been successful in driving prices to less than competitive levels. While lower drug prices are typically the Agencies' goal, the supply savings are not reaching the patient. Instead, the buyer consolidation is causing supply side competitive damage (including risk of shortage) with no real demand side benefit (in terms of lower prices for patients at the pharmacy counter). Furthermore, this imbalance facilitates immediate gains for Buying Groups at the expense of consumers and the healthcare system, causes substantial indirect harm to consumers by discouraging market participation from generic manufacturers due to unsustainable profit margins or below-cost pricing pressures. Ultimately, the actions of the Buying Groups dampen the long-term viability of the generic market, to the detriment of consumer interests, as manufacturers

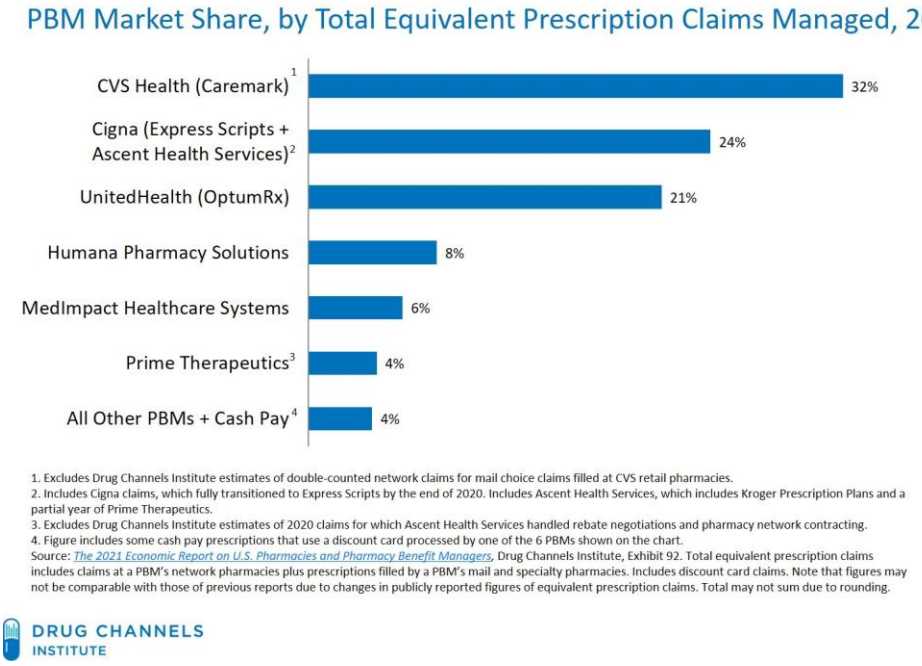
[27] AAM Report, Drug Shortages: Causes & Solutions (June 2023), https://accessiblemeds.org/resources/reports/aam-white-paper-shortages.
[28] AAM Report, The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report (2019).

are compelled to exit, diminishing competition and innovation in a sector critical for public health.

B. PBM/Payer Consolidation Exacerbates Buying Group Consolidation

The market imbalances challenging the sustainability of generic competition are exacerbated by the integration of health insurance plans with PBMs with retail and mail-order pharmacies.

Just three PBMs – CVS Health, Express Scripts, and OptumRx – control nearly 80% of the market. They exert this control over both the commercial as well as the Medicare Part D market. They also participate in the Medicaid market by managing Medicaid formularies where there is no state offering. In essence, these three entities – intermediaries with no fiduciary duty to patients – determine the formulary choices for almost all Americans. All three of the large PBMs operate their own mail-order pharmacies, and CVS owns the nation's largest retail pharmacy chain. PBMs limit competition in several ways, detailed below.



Each of the above PBMs owns or is owned by a major insurer, and each owns some kind of pharmacy while simultaneously determining reimbursements to its competitors. This consolidation and concentration have caused substantial harm to competition.

PBM consolidation threatens competition in numerous ways. It has allowed them to extract sizable rebates from reference manufacturers for reference medicines on formulary, limiting generic and biosimilar manufacturers' ability to gain market share when

a generic or biosimilar launch occurs.[29] PBMs often exclude low-priced generics from their formularies if the PBMs can collect more in rebates by using the reference version.[30] These rebate incentives lead to PBMs blocking or delaying coverage and formulary status for lower-cost generics.[31]

These behaviors have, in turn, caused increases in patient's prices at the pharmacy, both through the implementation of various fees and rebates and by controlling access to networks, which limit options for patients. Not only does PBM reliance on rebates and fees linked to list prices result in formularies that block patient access to new generic and biosimilar medicines, but when generics *are* covered, the cost of the product is often significantly less than the assigned copayment for the tier on which the product is placed. As a result, patients are made responsible for the full cost of the generic drug, thereby diminishing the value of their insurance benefit.[32]

PBMs are also not required by federal law to disclose rebates they receive from manufacturers or the difference between what they are paid by insurers to fill a prescription and how much they pay the pharmacy that fills it.

In this area, "[w]here a payor is also a provider, they can manipulate the relationship to raise health care costs."[33] The vertical consolidation in this area has resulted in an oligopoly of integrated health care companies controlling the pharmacy supply chain.[34]

The market conditions in the pharmacy supply chain make this sector ripe for competitive harm: "The health care sector exhibits textbook conditions of a market susceptible to consumer harm. Provider, payer, pharmaceutical, insurance, and intermediary management markets exhibit key pre-conditions for harm from vertical mergers: Most are highly concentrated, exhibit durable barriers to entry, and have historically performed poorly."[35]

II. Buying Group Consolidation Contributes to Drug Shortages

The significantly increased risk of drug shortages, an unfortunate yet foreseeable consequence, stems from the consolidated market power wielded by the Buying Groups.[36]

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[29] AAM, Hatch-Waxman Turns 40 (Feb. 2024), https://accessiblemeds.org/resources/press-releases/aam-white-paper-hatch-waxman-turns-40.
[30] Trish, E., Stat, PBMs Are Inflating the Cost of Generic Drugs (June 30, 2022).
[31] AAM Report, Middlemen Increasingly Block Patient Access to New Generics (January 2023).
[32] *Id.*
[33] Balto, D., Pharmacy Benefit Managers 101, March 20, 2017, available at http://www.pbmwatch.com/uploads/8/2/7/8/8278205/pbm_testimony.balto.pdf.
[34] Greaney, T., "Navigating the Backwater: Vertical Mergers in Healthcare," CPI Antitrust Chronicle at 3 (May 2019.
[35] Greaney, T., The New Health Care Merger Wave, 46 J. Law. Medicine & Ethics 918, 921 (2018).
[36] IQVIA Institute, Drug Shortages in the U.S. 2023: A Closer Look at Volume and Price Dynamics (Nov. 23), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023.

"Prices are so low that some generic manufacturers are deciding to exit, stop producing and marketing certain drugs that are no longer profitable….If prices are pushed down too low, generics may be forced to stop producing certain drugs and launching other drugs that are critical to patients and consumers."[37] Evidence suggests that generic drugs are particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement.[38] Because of the extreme price competition with almost "auction style" bidding, wholesalers can switch suppliers and reduce prices quickly. This lowers incentives for generics to commit capacity to older low-margin products or to address supply disruptions in the market.[39]

In fact, a recent study by the IQVIA Institute commissioned by AAM confirmed that drug shortages are increasing.[40] The analysis (attached) brings important facts to a discussion often marked by self-serving theories that are short on data:

1. Most shortages are found in generic drugs;

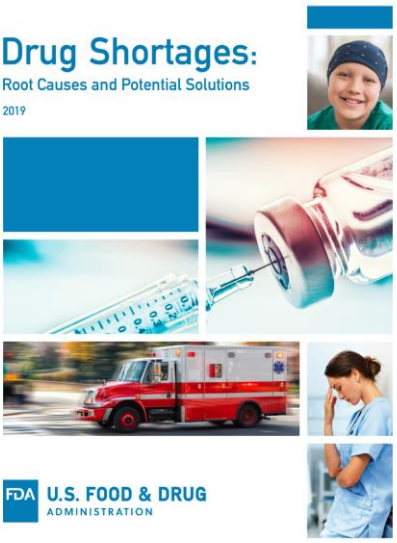
2. Most shortages are found in generic drugs with a per unit price of less than $1; and

3. Unlike past shortages, single-source generic markets are *less likely* to see a shortage compared to multi-source markets.

Such shortages have a serious effect on patient care. Many such shortages were a direct result of low reimbursement for older, low-margin products, with the result being that patients were unable to obtain needed medicines.[41] Generic product discontinuations have numbered over 3,000 since 2010 and appear to be on the rise.[42]

[37] Barlow, A., "Fair Competition Is Needed to Keep Generic Prescription Drugs Affordable," Antitrust Lawyer Blog, May 30, 2018.
[38] Stromberg, C. (May 2014), Drug Shortages, Pricing, and Regulatory Activity, National Bureau of Economics Working Paper, http://www.nber.org/chapters/c13102.pdf.
[39] *Id.*
[40] IQVIA Institute, Drug Shortages in the U.S. 2023: A Closer Look at Volume and Price Dynamics (Nov. 23), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023.
[41] Sirota, S., American Economic Liberties Project, The Dirty Secret of Drug Shortages (October, 2023).
[42] Raffat, U. Evercore ISI Research. (July 16, 2018)

A 2019 FDA task force that included participation from the Centers for Medicare and Medicaid (CMMS), the Department of Defense (DoD), FTC and HHS concluded that a primary "root cause" of drug shortages was the "lack of incentives to produce less profitable drugs."[43] The study also found: "When market conditions limit manufacturers' profitability, they reduce a firm's motivation to maintain a presence in, or enter the market for, older prescription drugs, and to invest in manufacturing quality and redundant capacity." The task force went on to conclude that "[m]anufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements all of which limit potential returns. Current contracting practices contribute to a 'race to the bottom' in pricing."



More recently, FDA Commissioner Califf has reinforced the key role that unsustainably low pricing plays in drug shortages, noting "we have got to fix the core economics if we're going to get this situation fixed."[44]

The increase in shortages is a direct result of the abuse of consolidated market power by Buying Groups and PBMs – a consolidation that has resulted in decisions to exit markets due to low margins; decisions not to launch (despite approval) due to low margins; large price declines on current products; and the scale-up to meet needs of a large buyer, followed by the need to drop prices to retain the volume in light of the created capacity. In addition, the requirement that manufacturers scale up to supply the entire business of each of the large customers to secure the contract (i.e., with each having a one-third share), creates a "musical chairs" environment with competitors bidding for the limited number of contracts. This phenomenon poses business challenges that directly limit a generic manufacturer's willingness and ability to scale up production, which must occur at least several months prior to when the product is needed. Even if a manufacturer is willing to scale up production, there is a significant delay in bringing the product to market due to, among other things, lack of Active Pharmaceutical Ingredient (API) available and manufacturing capacity. The Buying Groups in both the retail and hospital markets do not commit to production volumes but can ramp up or down their purchases at any time. Put simply, this means that a contract is binding on a manufacturer but can be dismissed at will by a Buying Group or other purchaser if they receive a "better offer". This uncertainty may lead manufacturers to exit the market rather than incurring unreimbursed costs.

[43] Drug Shortages: Root Causes and Potential Solutions (Feb. 21, 2020) (updated) ("FDA Shortage Report), fda.gov.
[44] Jewett, C. "Drug Shortages Near an All-Time High, Leading to Rationing". (May 17, 2023). New York Times, Available at: https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html.

III. Buying Group and PBM Consolidation each Contribute to Long-Term Sustainability Challenges and Pose a Risk for Increased Shortages

The increase in drug shortages of recent years is a symptom of the underlying fragility of the generic and biosimilar markets. This fragility is caused by unsustainably low prices and anticompetitive contract terms imposed by Buying Groups, slow adoption of lower-priced generics and biosimilars by PBMs that instead continue to prefer high-cost brand drugs with high rebates, and also by a range of federal and state policies that impose unfair penalties and unnecessary cost burdens on generic and biosimilar manufacturers. These challenges are laid out in white papers published by AAM that are attached to this comment letter.

And, as noted, the recent IQVIA Institute analysis not only highlighted the correlation between low prices and shortages, but also noted that, more than with past shortages, single-source generic markets are *less likely* to see a shortage compared to multi-source markets.

This last point highlights the role of Buying Groups in contributing to or preventing shortages and points the way to reforms that can reduce the likelihood of drug shortages. These include, most notably, limiting buyer consolidation, putting an end to abusive contract terms, and ensuring that contracts provide certainty for manufacturers through price and volume commitments.

IV. The Agencies Should Address Buyer Consolidation and Shortages

A. FDA/DOJ Should Issue New Guidelines

AAM suggests that FTC and the Department of Justice (DOJ) issue new guidelines on antitrust enforcement in health care. FTC previously issued guidelines in 1996 creating a "safe harbor" of 35% for GPOs.[45] DOJ revoked that policy in 2023, noting that the guidelines for group purchasers were "overly permissive" and that "the healthcare landscape has changed significantly."[46] Given this changed landscape, AAM suggests that FTC and DOJ issue new guidelines focused on two key issues. New guidelines are not a bar to filing actions now, if FTC/DOJ deems that appropriate, but will help clarify the landscape going forward.

First, AAM suggests that the guidelines characterize a specified market share not as a "safe harbor," but rather as a rebuttable presumption that once a market share is exceeded, monopsony power is present. To clarify, in the prior guidelines, a buyer market

[45] *Statements of Antitrust Enforcement Policy in Health Care* at 54-55, *available at* https://www.ftc.gov/system/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf

[46] Office of Public Affairs | Justice Department Withdraws Outdated Enforcement Policy Statements | United States Department of Justice.

share under 35% constituted a safe harbor, meaning monopsony power was not present. The new guidelines should both adopt a more accurate threshold considering current market conditions and reverse the presumption. That is, a market share above the new threshold should be presumed to establish monopsony power. AAM additionally suggests that the market share percentage be 20%, rather than the previous 35%, where no more than three Buying Groups control 70% of the market.

Second, AAM suggests that FTC and DOJ specifically note in the guidelines that onerous contractual terms—such as failure-to-supply or most-favored nations provisions—are additional evidence that monopsony power is being maintained in an anticompetitive manner.

B. 6(b) Study

FTC should also initiate a comprehensive 6(b) study of the large Buying Groups aimed at understanding and eventually preventing generic drug shortages, incenting more generic production, and disincentivizing reliance on offshore production. Specifically, the FTC should study the following:

- The effects of Buying Group consolidation and vertical integrations in the supply chain on the generic drug market;
- The effects of Buying Group purchasing and contracting practices on generic drug shortages;
- The onerous contract provisions contained in the contracts between Buying Groups, including wholesalers, and generic drug suppliers;
- The frequency and effects of Buying Groups' usage of sole-source or exclusive contracts;
- The frequency and effects of multi/dual source arrangements and whether this leads to unpredictable demand outlooks;
- The extent to which administrative fees and charges, particularly percentage-based fees that are linked to drug prices rather than the cost of providing the services, may contribute to instability in the generic drug market, violate the letter or spirit of the Anti-Kickback statute, or both;
- Whether elimination of the Anti-Kickback statute's safe harbor provision could alleviate some of these problems;
- Whether Buying Groups are engaging in tying, abusing their monopsony purchasing power to sell services to drug manufacturers (e.g., "administrative" or "data" services), at prices above fair market value or that manufacturers would not

otherwise purchase or would purchase elsewhere, by making the Buying Group's willingness to purchase drug products from the manufacturer contingent on the drug manufacturer's agreement to purchase services from the Buying Group;

- Whether elimination of safe harbors for joint purchasing arrangements could lead to more stability in the market and reduce shortages; and

- The full net discounts achieved by the Buying Groups whether such discounts are passed on to consumers.

AAM also suggests that FTC should seek relevant documents and records to address these topics, including, *inter alia*:

- All contracts between Buying Groups and generic/biosimilar manufacturers;

- Documents sufficient to show the percentage of contracts containing MFNs and FTS penalties;

- Documents sufficient to show the number of times that MFNs or FTS penalties have been triggered with respect to a drug/biologic on FDA's shortage list;

- Documents sufficient to show per-product fees for oral solids, general parenteral, ophthalmology, dermatology, sterile injectables, buy-and-bill biosimilars, and medical/pharmacy benefit biosimilars;

- Documents sufficient to show compliance with the Anti-Kickback statute with respect to the purchase of generic drugs and biosimilars; and

- Records sufficient to show the extent to which price reductions are passed on to consumers.

C. The Agencies Should Take Additional Steps

The Agencies should also consider implementing or seeking the following statutory initiatives:

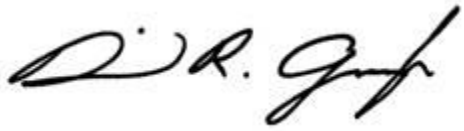
- AAM suggests that the Anti-Kickback Statute safe harbor provisions be revised to exclude anticompetitive fees and charges imposed by Buying Groups.

Conclusion

In light of myriad competitive threats to the generic pharmaceutical market identified herein and elsewhere, AAM urges the Agencies to make a key focus of their efforts the issue of competitive threats in this industry.

AAM stands ready to assist the Agencies by providing additional information. Thank you in advance for your consideration.

Respectfully submitted,



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