



March 21, 2022

Re: Request for Information on Merger Enforcement
Docket ID: FTC-2022-0003-0001

Dear Sir or Madam:

The Association for Accessible Medicines (“AAM”) is pleased to provide comments to the Federal Trade Commission and Antitrust Division of the Department of Justice (“the Agencies”) in response to the Agencies’ January 18, 2022, Request for Information on how the Agencies can modernize enforcement of the antitrust laws regarding mergers.

AAM wishes to address the anticompetitive challenges caused by merger and/or consolidation in the healthcare industry in two main areas: (i) monopsony power in drug buying groups’ purchasing of generic drugs, and (ii) consolidation, integration, and concentration of market power by Pharmacy Benefit Managers (“PBMs”) and their vertically integrated affiliates.

First, AAM believes that pharmaceutical buying group monopsony power should receive greater attention as the Agencies explore revisions to the merger guidelines and otherwise modernize policy and enforcement initiatives. Thus, in response to the Agencies’ question number 9 relating to “monopsony power,” AAM submits that the high concentration of buying power in the generic purchasing market is causing and will continue to cause anticompetitive harm to patients and consumers in the form of terminated or abandoned products and drug shortages. Therefore, AAM suggests that the Agencies consider revisions to the merger or healthcare guidelines and a renewed enforcement focus to recognize these concerns. For example, such guidelines and policies should recognize: (i) that buying groups can exercise dangerous monopsony power even if an *individual* buying group possesses less than 35% of the relevant purchases; (ii) that overall output may not immediately be reduced in the generic pharmaceutical market when monopsony power pushes prices below competitive levels but still poses significant long-term threats to competition and public health. The Agencies should consider specifically studying the impact of buying group consolidation.

Second, AAM submits that the high concentration in the PBM market is deserving of attention. Mergers and consolidation in this area have led to high levels of market power and integration that threaten healthy competition. AAM submits that in the past the Agencies have focused more on horizontal consolidation, but that the vertical consolidation occurring with respect to PBMs and insurers/payers is a significant competitive threat. Accordingly, AAM believes the Agencies should update the vertical merger guidelines to address the anticompetitive aspects of PBM consolidations. Since the Agencies’ January 18, 2022, Request for Information focuses on merger

enforcement and related topics, AAM will limit its comments here to the issues of vertical merger and consolidation in the PBM market. However, the competitive concerns relating to the PBM and drug reimbursement network are far broader. AAM will address those broader topics by submitting comments in response to the FTC's subsequent February 22, 2022, Request for Information on the Impact of PBMs, and will not repeat that discussion here.

Background

AAM is a nonprofit, voluntary association representing the leading manufacturers and distributors of finished generic pharmaceutical products and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry.

AAM's core mission is to improve the lives of patients by advancing timely access to safe, effective, and affordable prescription medicines. AAM is the sole association representing America's generic and biosimilar pharmaceutical sector. Our members' medicines are used in more than three billion prescriptions every year. Generic medicines account for 90 percent of all prescriptions dispensed in the U.S., but only 18 percent of expenditures on prescription drugs, saving patients and payers nearly \$5 billion every week. AAM, "The U.S. Generic & Biosimilar Medicines Savings Report," October 2021, <https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>. America's patients and the U.S. health care system have saved nearly \$2.4 trillion in the last 10 years due to the availability of safe and affordable generics.

However, the sustainability of a competitive generic market, the availability of alternative generic treatments, and the continuing supply of FDA-approved generic medicines for patients, uninterrupted by shortages, is in jeopardy. Although generic drug developers have dramatically lowered costs for patients, that competition is now threatened by excessive consolidation in the market -- in the hands of pharmaceutical buying groups ("Buying Groups") as well as pharmacy benefit managers ("PBMs") and associated payers. Consolidation in and among such intermediaries has adversely affected generic competition.

Issue #1 -- Consolidation and Monopsony Power of Pharmaceutical Buying Groups

The first area deserving additional scrutiny is the consolidation of competing buyers into three powerful Buying Groups who exercise monopsony power with respect to the purchase of generic drugs. The Request for Information specifically requested comment on monopsony power in question number 9.

Buying Groups are joint ventures, each consolidating major wholesale and retail purchasers into a single entity for purposes of buying generic products from manufacturers. These Buying Groups have substantially consolidated purchasing power in the generic pharmaceutical market. Three major customers (WBAD, Red Oak, and

ClarusOne) now account for over 90% of the generic purchases. (Fein, A., “The Big Three Generic Drug Mega-Buyers Drove Double-Digit Deflation in 2018,” Drug Channels Institute, July 9, 2019, available at <https://www.forbes.com/sites/roomykhana/2020/07/06/unsustainable-low-prices-causing-generic-drug-market-failure-leading-to-supply-chain-disruptions-and-shortages/?sh=182f2d8574d4>.)

Red Oak Sourcing	34%
Walgreens Boots Alliance (WBAD)	37%
ClarusOne/McKesson	21%
Top 3 Buying Group Control	92%

This consolidation has led to unsustainable generic drug prices and margins on some products, which has led to volatile supply and risks of drug shortages. These entities have been able to extract below-competitive prices and onerous contract terms, such as MFNs, service level penalties, and extended price protection. Buyer consolidation has contributed to substantial generic price deflation and exit by manufacturers on numerous products. Moreover, the savings achieved by purchasing consortia are not all passed on to patient end users.

The increasing consolidation in the supply chain is a key threat to sustainable generic markets. Compared to the fragmented and highly competitive generic market, consolidation in the wholesale market and contractual arrangements between pharmacy chains and wholesalers have left generic manufacturers with only a small number of purchasers. The result is a market where three purchasers account for more than 90 percent of all wholesale revenue. (*Id.*)

These purchasing consortia have been moving more and more toward single-source contracts for generic drugs. As a result, it is often possible that no more than three generic manufacturers are able to market any given product. This dynamic puts reliable access to affordable generic medicines at risk for the patients who need them. The FDA has found that generic prices using both AMP and invoice prices show price reductions of more than 95% compared to brand prices when there are six or more competitors. (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>.) Notwithstanding the economic principle that more suppliers of a good or service tend to create lower prices for consumers, the imbalance between 200 generic competitors and a handful of purchasers is not sustainable—and indeed, has lessened competition in this very important space.

The existing Horizontal Merger Guidelines devote only a brief section to the issue of monopsony power generally. (See DOJ & FTC Horizontal Merger Guidelines, No. 12, Aug. 19, 2010.) The Agencies recognized that buyers may acquire market power (or “monopsony power”) just as may occur in mergers of competing sellers. Guideline 12 states:

To evaluate whether a merger is likely to enhance market power on the buying side of the market, the Agencies employ essentially the framework described above for evaluating whether a merger is likely to enhance market power on the selling side of the market. In defining relevant markets, the Agencies focus on the alternatives available to sellers in the face of a decrease in the price paid by a hypothetical monopsonist.

Market power on the buying side of the market is not a significant concern if suppliers have numerous attractive outlets for their goods or services. However, when that is not the case, the Agencies may conclude that the merger of competing buyers is likely to lessen competition in a manner harmful to sellers.

(Guidelines at 32-33 (emphasis added).) Here, generic drug companies do not have “numerous attractive outlets” outside of the Buying Groups.

The Agencies’ Request for Information raised the issue of “monopsony power” in question 9, focusing largely on labor markets. AAM submits that monopsony power by drug Buying Groups raises similar concerns. The Agencies specifically ask: “How should the guidelines’ analysis of monopsony power differ from its analysis of monopoly power?” and “Are there specific monopsony situations that the guidelines should address explicitly?” AAM submits that the Agencies’ existing approach to monopsony power has been too narrow, and in fact narrower than its analysis of monopoly power. In addition, AAM submits that the drug supply chain dominated by buying groups is a monopsony situation that the Agencies should address specifically.

The first major concern with group purchasing is that the buying group may amass so much power that it can force input prices below a competitive level. That phenomenon has been previously recognized in other markets. 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). It is now starting to occur here. (See, e.g., “Unsustainable Low Prices Causing Generic Drug Market Failure Leading to Supply Chain Disruptions and Shortages,” *Forbes*, July 6, 2020, <https://www.forbes.com/sites/roomykhani/2020/07/06/unsustainable-low-prices-causing-generic-drug-market-failure-leading-to-supply-chain-disruptions-and-shortages/?sh=182f2d8574d4>.) This includes scarcities “in a wide range of drugs used in cardiovascular, anti-infective, and cancer treatments” as well as shortages in “old generic drugs, intravenous (“IV”) saline solutions, anesthetics, and antacids.” (*Id.*) 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.

The other major concern is that a buying group will reduce competition among its members in output markets. This concern can arise if collectively purchased products account for too large a percentage of members’ input costs, because knowledge of other members’ input costs through the group purchasing program may facilitate price fixing or other forms of collusion among members. See, e.g., DOJ/FTC Health Care Guidelines Statement 7A.

Buyers may violate the antitrust laws (just as sellers may) because “monopsony power is the mirror image of monopoly power.” *Improving Health Care: A Dose of Competition* at 13 (2004). As Judge Posner 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.” *Vogel v. American Soc. of Appraisers*, 744 F.2d 598, 601 (7th Cir. 1984). As the Supreme Court has recognized, there is a “close theoretical connection between monopoly and monopsony” and that this “suggests that similar legal standards should apply.” *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 127 S. Ct. 1069, 1076 (2007).

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. See, e.g., *Telecor Communications v. Southwestern Bell*, 305 F.3d 1124, 1134-36 (10th Cir. 2002). The anticompetitive effect of “lower prices” in the long run is that output will be restricted. So, for example, some generic products have been discontinued and shortages have already resulted. *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”). Eventually, analysts have recognized that “mid-tier and smaller manufacturers likely will be acquired or forced out of business.” (See *Blueshift Report*, “Generic Drug Joint Purchasing Will Squeeze Manufacturers,” May 7, 2014.) Output may be reduced by sellers being forced to consolidate, smaller sellers going out of business, or manufacturers leaving the market. *Id.*

In the generic drug marketplace currently, it is clear that the three large buyer groups exercise monopsony power. 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: Most Favored Nation clauses; price reductions; administrative fees; service penalties; uniform pricing; extended price protections and restrictions; and extended payment. As an initial matter, such terms can directly harm competition. 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 substitutes when a failure-to-supply situation occurs. These penalties leave the generic manufacturer with the choice of absorbing high penalties or abandoning the market, reducing competition.

Moreover, these tactics have the following long-term impacts on generic manufacturers: 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 margins have resulted in decisions to exit the market (or not launch). Of note, at least 65 generic drugs were approved by the FDA in 2020; however, by December of that year, only twenty-five were launched and available commercially for patient use due to the lack of business viability.

One reason the consolidation of Buying Groups may have avoided scrutiny in the past is that the Buying Groups are generally not merged, completely-integrated entities, but are instead joint ventures between purchasers. AAM notes that the Agencies asked how they could “modernize enforcement of the antitrust laws regarding mergers,” and specifically noted that their use of the term included not only formal mergers but also “acquisitions, joint ventures, and other structural realignments.” (Jan. 18, 2022 RFI at 1.)

Joint ventures have typically been analyzed by the Agencies pursuant to the Antitrust Guidelines for Collaborations among Competitors (“Collaboration Guidelines”). As these guidelines state: “in some cases, competitor collaborations have competitive effects identical to those that would arise if the participants merged in whole or in part.” (*Id.* at 5.)

With respect to buying collaborations specifically, the Collaboration Guidelines recognize that “such agreements can create or increase market power (which, in the case of buyers, is called “monopsony power”) or facilitate its exercise by increasing the ability or incentive to drive the price of the purchased product, and thereby depress output, below what likely would prevail in the absence of the relevant agreement. Buying collaborations also may facilitate collusion by standardizing participants’ costs or by enhancing the ability to project or monitor a participant’s output level through knowledge of its input purchases.” (*Id.* at 14.)

The Collaboration Guidelines say that the Agencies should analyze a joint venture under the Horizontal Merger Guidelines when the joint venture participants compete in the same market, and the venture involves integration of economic activity in the relevant market, eliminates competition among its participants in the relevant market, and lasts a long time period. (Collaboration Guidelines § 1.3 & n.10 (April 2000).) Joint ventures such as the pharmacy buying groups should be scrutinized more carefully and under less stringent rules. For practical purposes, with respect to the relevant activity of such groups, the parties are eliminating competition in the market for the purchase of pharmaceutical products, particularly generic products.

In sum, the Buying Groups are not merged entities, but rather collaborations or joint ventures formed to be able to exert pressure on pricing, particularly with regard to generic drugs. The fact that they are formed by joint venture instead of by merger is not dispositive. The Buying Groups have been successful in driving prices to less than competitive levels. While lowering costs for themselves, these large purchasers have not been passing these prices on to consumers. While lower drug prices are typically the Agencies’ goal, here the supply savings are not reaching the patient. Instead, the buyer consolidation is causing supply side competitive damage with no real demand side benefit (in terms of lower prices for patients at the pharmacy counter)

An unfortunate yet foreseeable consequence of fewer generic manufacturers is a significantly increased risk of drug shortages. “Prices are so low that some generics are deciding to exit, stop producing and marketing certain drugs that are no longer profitable.” (Barlow, A., “Fair Competition Is Needed to Keep Generic Prescription Drugs Affordable,” Antitrust Lawyer Blog, May 30, 2018.) “If prices are pushed down too low,

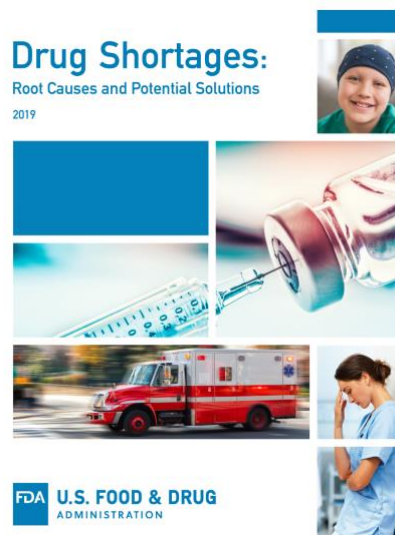
generics may be forced to stop producing certain drugs and launching other drugs that are critical to patients and consumers.” (Id). Evidence suggests that generic drugs are particularly susceptible to drug shortages, potentially related to existing market incentives as well as low reimbursement. (Stromberg, C. (May 2014), Drug Shortages, Pricing, and Regulatory Activity, National Bureau of Economics Working Paper, <http://www.nber.org/chapters/c13102.pdf>.)

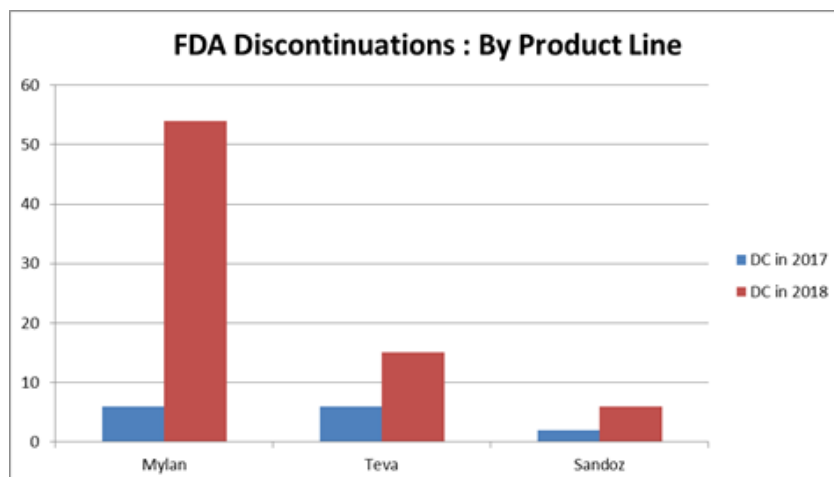
Such shortages have a serious effect on patient care. Responding to a series of drug shortages in 2011, Dr. Scott Gottlieb testified before Congress that many such shortages were a direct result of low reimbursement for older, low margin products and that “many hospitals are being forced to ration key medicines and patients to sit on waiting lists for vital drugs.” Gottlieb, Scott. “Drug Shortages: Why they happen and what they mean,” Testimony before the Senate Finance Committee. December 2011, <https://www.finance.senate.gov/imo/media/doc/Gottlieb%20Testimony1.pdf>. RBC Capital Markets found that the number of abbreviated new drug applications (ANDAs) that have been withdrawn spiked in 2018, going from 21 withdrawals in 2017 to 71 withdrawals per month in the first half of 2018.

In June 2018, a bipartisan Congressional group asked the FDA to convene a task force on drug shortages. The task force was coordinated by the FDA with participation by CMS, DoD, FTC, and HHS. In October 2019, the FDA released the report.

FDA concluded that a primary “root cause” of drug shortages was the “lack of incentives to produce less profitable drugs.” (FDA Shortage Report at 23.) 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.” (Id. at 6.) It 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.” (Id.)

Examination of available data from IQVIA shows that this consolidation has had significant deleterious effects, including: decisions to exit markets due to low margins; decisions not to launch (despite approval) due to low margins; large price declines on current products; harmonization of prices; 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. The FDA Shortage Report, for example, showed that product discontinuations sharply increased during the period studied. One of the largest generic companies, Mylan, for example, saw its product discontinuations increase over ten-fold from 2017 to 2018 (from under 10 to over 50):





The current contracting environment will result in fewer generic competitors for two reasons. *First*, a substantial reduction in margins, below competitive levels, will inevitably lead to manufacturers (1) to exit existing products, (2) to decide not to market approved products, and/or (3) to reduce future research and development activity. *Second*, the requirement that manufacturers scale up to supply the entire business of each of the large customers (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 in terms of a generic manufacturer’s willingness and ability to scale up production. The three large guying groups do not commit to production volumes, but can ramp up or down their purchases at any time. This uncertainty may lead manufacturers to exit the market rather than incurring unreimbursed costs.

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 costs and reducing output, all of which can lead to producers exiting the market, or reducing production of unprofitable drugs. This consolidation of buying power also incentivizes production to low-cost firms and regions where quality control issues may pose safety and shortage issues. Finally, such consolidation also poses a danger of stabilizing and elevating downstream costs to end users and end payers in the market. In short, as the FDA has observed, the ever-increasing market power of Buying Groups may lead to medicine shortages. Ultimately this will be reflected in public health cost and higher prices for consumers.

Issue #2 -- PBM/Payer Consolidation

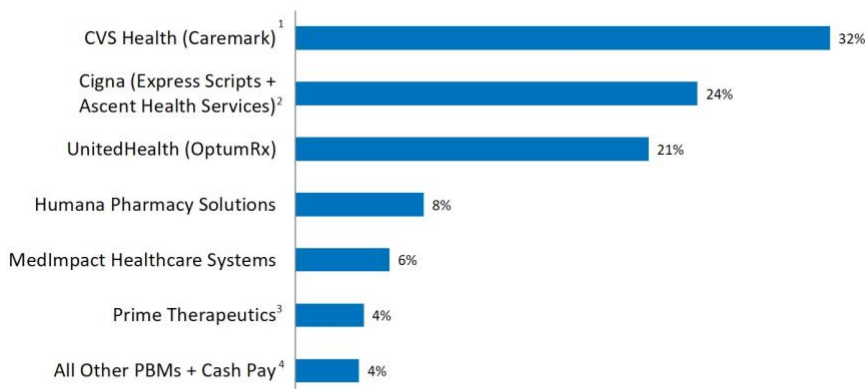
The other area where mergers and other consolidation is threatening competition is in the area of PBM and payer consolidations. The horizontal and vertical combination of health insurance plans with pharmacy benefit managers with retail and mail order pharmacies has resulted in substantial harm to competition.

PBMs handle pharmacy services for insurance plans. They negotiate with pharmaceutical companies for rebates in exchange for, among other things, preferred formulary placement. They also manage pharmacy prescription reimbursement through contracts with pharmacies participating in the health plan's network.

Just three PBMs -- CVS Health, Express Scripts, and OptumRx -- control nearly 80 percent of the market. They exert this control over both the commercial as well as the Medicare Part D (Advantage) 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 drugstore chain. PBMs are able to control competition in a number of ways, detailed below. PBMs are also not required by federal law to disclose rebates they receive from drug makers or the difference between what they are paid by insurers to fill a prescription and how much they pay the pharmacy that fills it.

PBM Market Share, by Total Equivalent Prescription Claims Managed, 2020



1. Excludes Drug Channels Institute estimates of double-counted network claims for mail choice claims filled at CVS retail pharmacies.
2. Includes Cigna claims, which fully transitioned to Express Scripts by the end of 2020. Includes Ascent Health Services, which includes Kroger Prescription Plans and a partial year of Prime Therapeutics.
3. Excludes Drug Channels Institute estimates of 2020 claims for which Ascent Health Services handled rebate negotiations and pharmacy network contracting.
4. Figure includes some cash pay prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.
Source: *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, Exhibit 92. Total equivalent prescription claims includes claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.



In addition, 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. "PBMs haven't only consolidated horizontally, they've also done so vertically," he said. "As of today, every major PBM owns or is owned by a major health insurer. Furthermore, every major PBM owns or is owned by a specialty mail-order or retail pharmacy or all three. This means that when PBMs negotiate with a pharmacy or a health insurer, they are either negotiating with themselves or one of their direct competitors." (Rep. Comer Statement, House Committee on Oversight, Nov. 17, 2021.)

PBM consolidation threatens competition in numerous ways. The PBMs have dramatically expanded their formulary exclusion lists to limit access to therapies for patients. (Fein, A. (2021). *The 2021-2022 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*. Drug Channels Institute.) This has allowed them to extract sizable rebates from brand manufacturers for brand medicines on formulary, limiting generic manufacturers' ability to gain market share when a generic launch occurs.

Consolidation of PBMs has caused -- and will continue to lead to -- increases in patient's prices at the pharmacy, both through the implementation of various fees and rebates and by controlling access to networks, which limits options for patients. As PBMs have become increasingly involved in supporting formulary design, the development of standardized, stagnant formularies and the availability of non-pharmacy price concessions (such as rebates) often disincentivize the inclusion of newly approved generic drugs on their formularies, because rebates benefit the PBM and/or plan sponsor without benefiting the consumer. Further, when generics *are* covered, the cost of the product is often times less than the assigned copay 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. These practices have also led to increased PBM profits rather than reduced drug prices, as demonstrated by the proposed OIG and CMS rules requiring those discounts be given to patients at the point of sale rather than the PBMs.

In this area, “[w]here a payor is also a provider they can manipulate the relationship to raise health care costs.” (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.) The vertical consolidation in this area has resulted in an oligopoly of integrated healthcare companies controlling the pharmacy supply chain. (Greaney, T., “Navigating the Backwater: Vertical Mergers in Healthcare,” CPI Antitrust Chronicle at 3 (May 2019).)

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.” (Greaney, T., *The New Health Care Merger Wave*, 46 J. Law. Medicine & Ethics 918, 921 (2018).)

The 2020 Draft Guidelines contain some improvements but mostly restate conventional analytical frameworks that have failed to protect healthcare consumers. In revising and interpreting the guidelines, the Agencies should focus on the anticompetitive harm to healthcare quality, access, service, and price in vertical merger enforcement. Such increased scrutiny is required in this sector, where the three largest PBMs and the four largest commercial health insurers account for more than 80% of their respective markets. (Dafny, L., “Health Insurance Industry Consolidation,” 114 Cong. 5 (2015),

available at <http://www.judiciary.senate.gov/imo/media/doc/09-22-15%20Dafny%20Testimony%20Updated.pdf>.)

Moreover, to date, the Agencies have focused most of their attention in this space on horizontal anticompetitive effects. In this sector, it is critically important that the Agencies focus on the PBMs' vertical combinations, which has led, among other things, to increased prices. (See Post, B. et al., Vertical Integration of Hospitals and Physicians, 75 Medical Care Research & Rev. 399, 418 (2018) ("the literature we reviewed finds that vertical integration generates higher prices, higher spending and ambiguous changes in quality").

The new draft 2020 Vertical Merger Guidelines recognized some of the distinct considerations of the impact of vertical mergers that substantially lessen competition. An update to the guidelines is necessary in light of the many large mergers between PBMs and health insurers and other healthcare vertical mergers that can harm the drug supply chain, consumer choice, prices, and access to health care products and services.

Conclusion

In light of the myriad of 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.

As previously stated, the consolidation and vertical integration of PBMs, payers, and insurers poses many competitive threats beyond those addressed here and that may be addressed in the Agencies' vertical merger guidelines and policy. AAM refers the Agencies to its separately submitted response to the FTC's February 24, 2022, Request for Information specifically directed to the PBM market for further comments.

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

Respectfully submitted,

Dan Leonard
President and CEO



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