



Lina Khan, Chair

Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

May 23, 2022

Dear Chair Khan:

The Association for Accessible Medicines (“AAM”) and its Biosimilars Council (“the Council”) (collectively referred to henceforth as “AAM”) applaud the efforts of the Federal Trade Commission (“FTC”) to ensure consumers have access to fair and equitable pharmaceutical services.

AAM is the nation’s leading trade association for the developers, manufacturers and distributors of FDA-approved generic and biosimilar medicines. Today, generic and biosimilar medicines comprise 92% of prescriptions in the United States but only 16% of total drug spending.¹ Our core mission is to improve lives by advancing timely access to high-quality, affordable and safe generic and biosimilar medicines. In response to the FTC’s call for public comment “on the ways that large, vertically integrated pharmacy benefit managers (“PBMs”) are affecting drug affordability and access,” our submission highlights the negative impact that key PBM business practices have had on America’s patients and on the long-term sustainability of the nation’s competitive generic drug market.² AAM urges the FTC to investigate, under Section 6(b) of the FTC Act, the practices we discuss in this submission, in addition to studying the vertical consolidation occurring in the industry and to consider updating the agency’s vertical merger guidelines to address the anticompetitive aspects of PBM consolidations.

A distinct set of PBM business practices have resulted in higher prices and delayed access to generics and biosimilars for America’s patients. These business practices—placing generic drugs on non-generic formulary tiers and preferring high-cost drugs over lower priced alternatives—directly cause patient harm, increase patient costs for older, low-cost generics, delay patient

¹ IQVIA Institute for Human Data Science. (April 2022) The Use of Medicines in the U.S. 2022: USAGE AND SPENDING TRENDS AND OUTLOOK TO 2026. Available at: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf>

² Federal Trade Commission (February 24, 2022) FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers’ Practices. Available at: <https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices>

access to new generics and biosimilars, imperil billions in annual savings for taxpayers and the U.S. health care system, and undermine the long-term viability of generic drug competition. These anticompetitive results come directly from business practices that block patient access to lower cost drugs and increase patient out of pocket costs even as generic prices decline.

Left unchecked, such practices could compromise the sustainability of the competitive and essential generic drug market—and jeopardize the US biosimilar industry, which is still in its infancy— particularly as the PBM's market dominance positions them to exert greater influence on sites of care, pricing and patient access.

Background: The Consolidated PBM Market Adversely Impacts Patient Affordability and Access to Generic Drugs and Biosimilars

Because of their low cost and high value to patients and payers, generic medicines today account for the vast majority of all prescriptions dispensed in the U.S.; however, generics represent less than 3% of total U.S. health care spending.³ Overall, the health care system has saved nearly \$2.4 trillion in the last 10 years due to the availability of affordable generic drugs.⁴

Likewise, FDA-approved biosimilars are beginning to deliver on their promise to reduce costs. These medicines have scientifically comparable quality, safety and efficacy to their reference biologic and create competition in high-cost markets, resulting in lower costs and broader patient access. Biosimilars are projected to generate over \$133 billion in savings by 2025 and have been used in over 121 million days of patient therapy, successfully expanding otherwise unattainable patient therapy approaches.⁴

In fact, generic and biosimilars represent the only segment of health care in the U.S. that consistently reduces costs. The use of generic and biosimilar medicines generated more than \$338 billion in savings for the health care system in 2020.⁴ The value of generic and biosimilar medicines was recently highlighted by the Congressional Budget Office (“CBO”) in its report examining nationwide spending on prescription drugs. The report shows how generics place downward pressure on prices while expanding access for patients. For example, the Medicare Part D per enrollee use of prescription drugs increased from 48 prescriptions per year in 2009 to 54 in 2018, even as the average price for a generic prescription fell from \$22 to \$17.⁵

Generics achieve these savings through a robust and competitive market based solely on cost and the ability to supply—providing others in the supply chain, such as pharmacies, wholesalers

³ Centers for Medicaid and Medicare Services (March 2022) 2021-2030 Projections of National Health Expenditures. Available at: <https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2021-2030-projections-national-health-expenditures>

⁴ Association for Accessible Medicines, (October 2021). The U.S. Generic and Biosimilar Medicines Savings Report. Available at: <https://accessiblemeds.org/resources/blog/2021-savings-report>

⁵ Congressional Budget Office, (January 2022) Prescription Drugs: Spending, Use, and Prices. Available at: <https://www.cbo.gov/publication/57050>

and group purchasing organizations, greater ability to negotiate competitive acquisition costs and maximize their margins. In fact, the generic drug market is becoming less concentrated over time. In the US alone, there are 40 more companies in the market today than five years ago, and the share of the US market represented by the top 10 generic drug companies has declined from one-third to only a quarter in the past five years.⁶

However, this success story is threatened by excessive price deflation as detailed in our March 21 response to the FTC's January 18, 2022, Request for Information on Merger Enforcement. In fact, generic drugs have

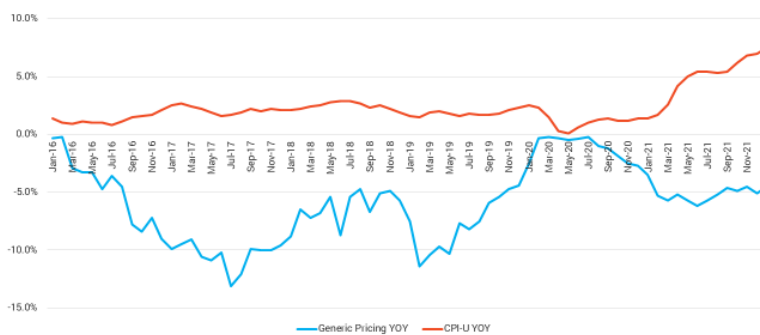
now experienced more than six years of consistent price deflation⁷ – a figure that is even more remarkable when compared to increases in overall inflation over the same time period.⁸ For context, since 2016, the generic share of

prescription volume has risen from 89% to 92% of all U.S. prescriptions, but generics have declined as a share of spending from 26% to 16%.⁹ Even with the recent economic shifts that have propelled the overall rate of inflation to unforeseen highs, prices for generic drugs continued to fall.

But these lower prices are often not reflected in lower patient out of pocket costs for generics. In fact, generics now represent a shocking 65% of patient out of pocket costs, despite being only 16% of total drug spending.¹ This stems from a distinct set of PBM business practices that have resulted in higher costs and delayed access to generics and biosimilars for many patients. In particular, two specific business practices— placing generic drugs on non-generic formulary tiers and preferring high-cost high-rebate drugs over lower list prices—are directly undermining the long-term viability of generic drug competition, to the detriment of patients.

Unlike the diverse makeup of the generic drug market, PBMs are highly consolidated, allowing them to leverage their market power over other supply chain actors through a variety of

PERCENT CHANGE FOR INFLATION (CPI-U) YEAR OVER YEAR OUTPACES GENERIC PRICING



Sources: Bureau of Labor Statistics. U.S. Department of Labor. February 11, 2022, Available at: <https://data.bls.gov/timeseries/CUUR0000SA0>; IQVIA, National Sales Perspective, February 2022

⁶ Long, D. (February 2022) Presentation at Association for Accessible Medicine Access!2022

⁷ IQVIA, (February 2022) National Sales Perspective

⁸ Bureau of Labor Statistics. U.S. Department of Labor, (February 11, 2022) Consumer Price Index. Available at: <https://data.bls.gov/timeseries/CUUR0000SA0>

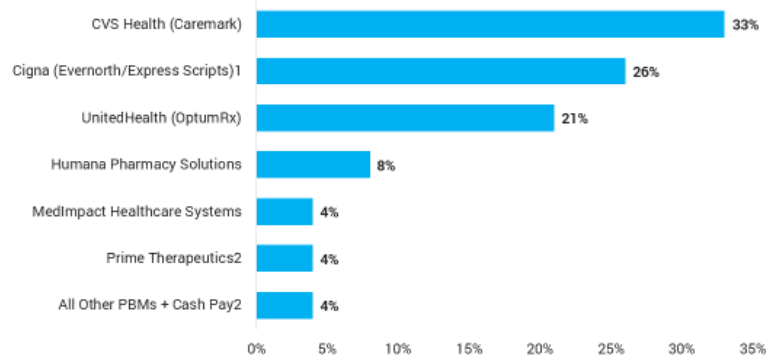
⁹ Association for Accessible Medicines, (2017) 2017 Report: U.S. Generic and Biosimilar Medicines Savings Report. Available at: <https://accessiblemeds.org/resources/reports/2017-generic-drug-access-and-savings-report>

mechanisms. PBMs negotiate the composition of formularies that many drug plan sponsors use and assist them in shaping the conditions under which patients may access medicines.

Initially, PBMs functioned primarily to support third party payers as a carve-out service focused on network administration and claims processing; however, the PBM industry has evolved through consolidation and has now amassed vast negotiating power. Indeed, the PBM industry has become highly concentrated, with 80% of all prescriptions processed by three major PBMs.¹⁰ Moreover, these PBMs are vertically integrated with large insurers and frequently with specialty pharmacies,

which further strengthens their negotiating leverage and raises risks that plan sponsors and their PBMs will not pass on savings from lower cost generics to patients, as they do not have a fiduciary obligation to either patients or even to plan sponsors and payers. AAM outlined our concerns with challenges posed by consolidation, integration, and the concentration of market power within the healthcare industry in our response to the FTC’s January 18, 2022, Request for Information on Merger Enforcement.¹¹

PBM MARKET SHARE, BY TOTAL EQUIVALENT PRESCRIPTION CLAIMS MANAGED, 2021



1. Includes a full year of Cigna claims, which fully transitioned to Express Scripts by the end of 2022, and the portion of Prime Therapeutics network claims volume for which Express Scripts handles pharmacy network contracting.
 2. Excludes Drug Channels Institute estimates of 2021 claims for which Express Scripts handles pharmacy network contracting.
 3. Figure includes some patient-paid prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.
 Source: Drug Channels Institute research and estimates. Total equivalent prescription claims includes claims at PBM’s network pharmacies plus prescriptions filled by a PBM’s mail and specialty pharmacies. Includes discount card claims. Includes claims for COVID-19 vaccines administered by retail pharmacies. 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.

PBM Practices Harm Patients and Lower-Cost Competition

We focus on two main PBM practices that have explicit and injurious consequences to patients: placing generic drugs on non-generic formulary tiers and preferring high-cost high-rebate drugs over lower list prices.

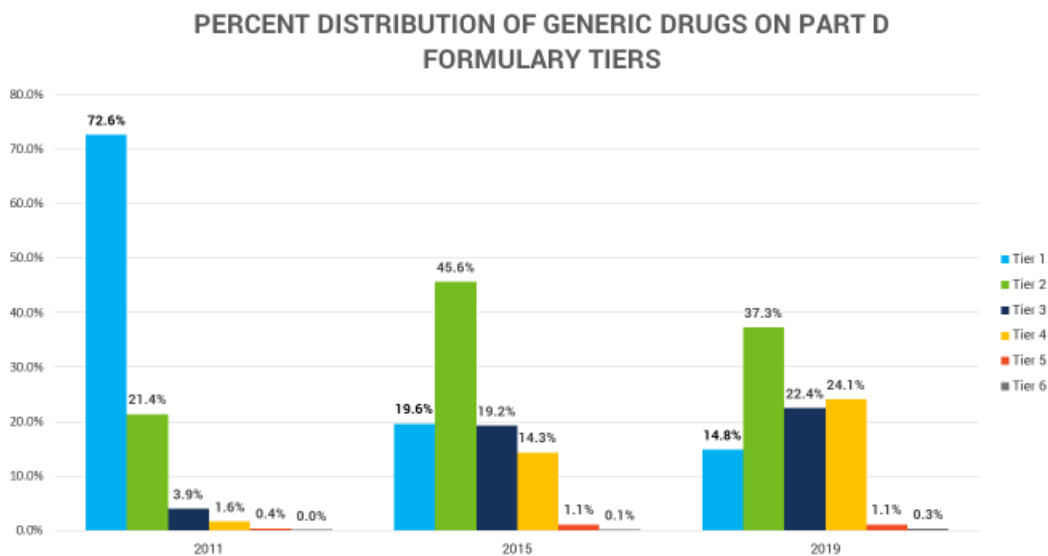
¹⁰ Drug Channels Institute (March 2022) The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers
¹¹ Association for Accessible Medicines (March 21, 2022) Request for Information on Merger Enforcement-Docket ID: FTC-2022-0003-0001, Available at: <https://www.regulations.gov/comment/FTC-2022-0003-0239>

A. PBM Influence on Health Plan Tiering Decisions Increases Costs to Patients

As generic drugs have declined in price, health plans have increasingly moved those same medicines to formulary tiers with higher patient out of pocket costs. This phenomenon of shifting generics to higher tiers has been well-documented by independent health care consulting firm Avalere Health.

Avalere first examined this issue by reviewing the formulary placement for generic drugs on Part D formularies in 2011 and 2015. They found that the number of generic drugs placed on the lowest tier, where patients pay less for their drugs, declined 53 percentage points between 2011 and 2015. This resulted in a 93% increase (\$6.2 billion) in total patient cost-sharing for these specific drugs.¹²

Avalere recently updated these results, again focusing on generic drugs that were on Part D formularies in 2011, 2015 and 2019, with similar results.

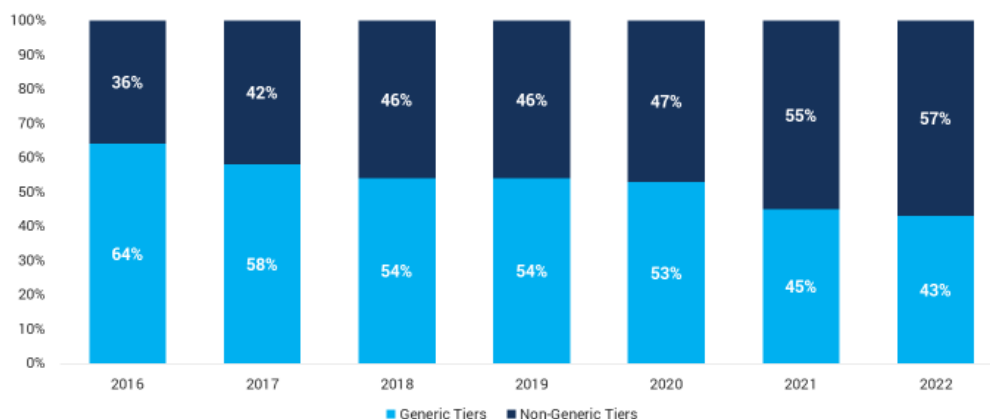


Further, Avalere calculated the total dollar amount attributed to patient's costs for this cohort of generic drugs. Due to the changes in generic tier placement, patient spending on these generic drugs more than doubled from \$8.5 billion in 2011 to \$20 billion in 2019.¹³ This 135% increase in out-of-pocket spending far exceeds increases in volume (21%) and came even as the actual price of the generics declined.

¹² Fix, A (February 2020) For the First Time, a Majority of Generic Drugs Are on Non-Generic Tiers in Part D. Available at: <https://avalere.com/insights/for-the-first-time-a-majority-of-generic-drugs-are-on-non-generic-tiers-in-part-d>

¹³ Analysis Forthcoming

DISTRIBUTION OF GENERIC DRUGS ON GENERIC AND NON-GENERIC TIERS, 2016-2022



Source: Fix, A., 57% of Generic Drugs Are Not on 2022 Part D Generic Tiers, January 24, 2022. Available at: <https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers>

This trend is not limited to a select few generics. An ongoing review of generic drug formulary placement in Medicare plans from 2016 – 2022 reveals a consistent trend whereby PBMs placed more generics on non-generic tiers with higher cost-sharing. In fact, this year represents the third year in a row where more generics were on non-generic tiers (57%) than on generic tiers (43%).¹⁴ And while this data comes from the Medicare market, anecdotal reports suggest that similar behavior occurs in the commercial market. These practices allow PBMs to generate additional revenue through higher copays for generic drugs – but result in patients unnecessarily paying more at the pharmacy counter.

In a separate study, Avalere found that nearly half of Part D beneficiaries were forced to pay the full cost for at least one generic as a result of generic tier placement decisions. For instance, because generics were placed on a non-preferred tier, over 87% of beneficiaries who were treated on generic cardiotoxic (for heart failure), paid the full cost for their medication (in addition to their monthly premiums), effectively nullifying the value of their Medicare Part D benefit.¹⁵ As a result, patients are harmed when utilizing generic drugs by being forced to pay full price for those same generic drugs in addition to the insurance premiums they have already paid.

It is important to note that these shifts in tier placement occur in the absence of generic drug price increases. Current contractual arrangements with PBMs suggest insurance plans are motivated to modify tier placement of generics because it allows them to generate more revenue on copays for inexpensive but widely used products. These analyses further emphasize the need

¹⁴ Fix, A., (January 2022) 57% of Generic Drugs Are Not on 2022 Part D Generic Tiers, Available at: <https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers>

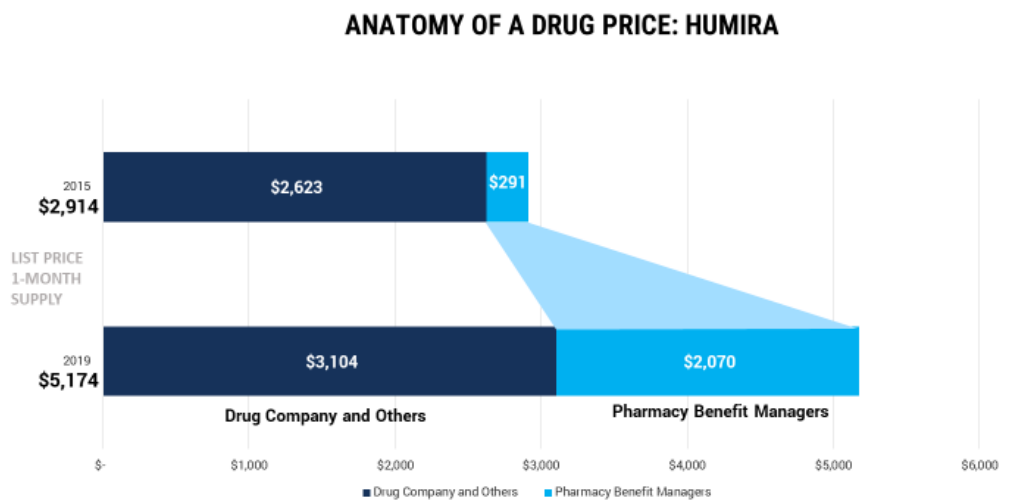
¹⁵ Fix, A., (July 2021) Some Part D Beneficiaries May Pay Full Price for Certain Generic Drugs, Available at: <https://avalere.com/insights/some-part-d-beneficiaries-may-pay-full-price-for-certain-generic-drugs>

to reject the self-rewarding nature of PBM practices that manipulate tier placement and ensure generic formulary placement and copays are truly reflective of low generic costs.

B. PBMs Block Access to New Generic Drugs and Biosimilars to Increase Revenues

Prescription drug rebates are generally paid by a brand pharmaceutical manufacturer to a PBM, which then shares a portion of that amount with the health insurer. Rebates are mostly used for high-cost, brand-name prescription drugs and biologics in competitive therapeutic classes. PBMs use rebates to incentivize health insurers to include certain products during their contractual negotiations and to receive preferred formulary status. However, these negotiations occur without transparency and contract terms are trade secrets that vary widely. PBM demands for increased rebate amounts drive manufacturers to raise list prices to maintain their profit margins, net of those higher rebates.¹⁶ In fact, drug rebates and list prices have been found by the USC Schaeffer Center for Health Policy and Economics to be positively correlated where, on average, a \$1 increase in rebates is associated with a \$1.17 increase in list price.¹⁷ Further, while a recent MedPAC analysis found that more expensive drugs are less likely to be highly rebated, these are also the drugs that will later adopt rebates as generic or biosimilar competition approaches.¹⁸ A drug that was once not rebated can move quickly into being heavily rebated. The high and rising list price that was set at the beginning of the drug’s life cycle now becomes a benefit to the PBM, which can exploit emerging or imminent marketplace competition to extract a deeper rebate for the brand drug or biologic. Because patient out of pocket costs are often based on product list prices, these practices directly result in greater costs to patients.

In this way, rebates can be used to block competition through pernicious “rebate traps”. Under these approaches, which may also be referred to as “bundled rebates”,



Sources: GoodRx (Humira List Prices). Other figures estimated based on Credit Suisse 2015 Global Pharma Report; Feb 26, 2019, Testimony to U. S. Senate Committee on Finance; and drug pricing experts.

¹⁶ Tomicki, S, Dieguez, G, Alston M. (May 2018) A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices, Available at: <https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing>

¹⁷ Van Nuys, K (February 2020) The Association Between Drug Rebates and List Prices, Available at: <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/>

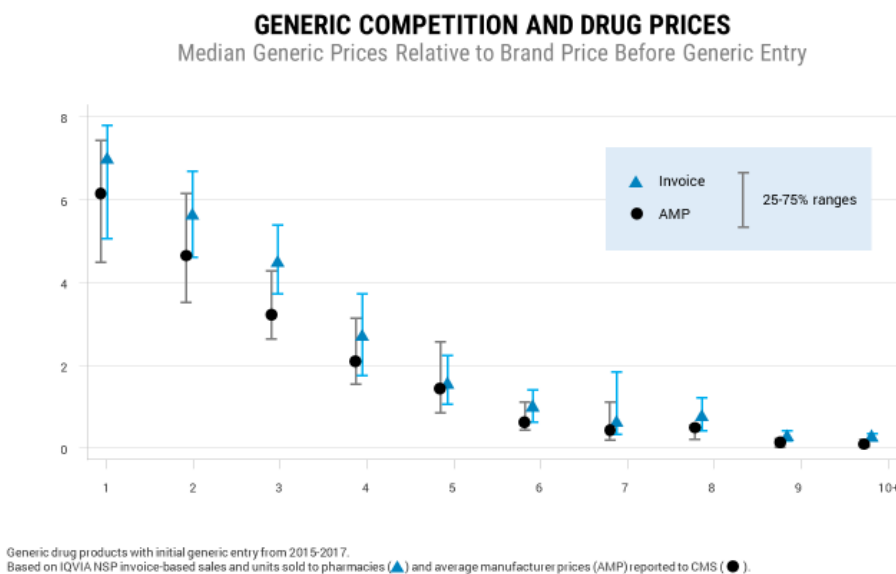
¹⁸ The Medicare Payment Advisory Council (April 2022) Initial findings from MedPAC’s analysis of Part D data on drug rebates and discounts, Available at: <https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf>

the manufacturer of an originator product may withdraw or threaten to withdraw some or all of the rebates on a basket of products (“bundling”) in the event that the contracted entity—typically the health plan—utilizes a biosimilar or generic rather than the reference product. Rebate traps mean that FDA-approved generics and biosimilars may not be placed on a formulary at all, making them completely unavailable to patients even though these medicines are available and less expensive than their brand-name drugs counterparts.

PBM Behavior Ignores and Undermines Potential Savings from New Competition

The failure of PBMs and plan sponsors to pursue the lower costs offered by first generics or new biosimilar competitors instead of expensive brand drugs and biologics is a stark example of the negative impact of PBM practices on drug affordability and accessibility. First generics - the first approval by FDA which permits a manufacturer to market a generic drug competitor product in the United States - are often disadvantaged in commercial and Part D plans through the significant delays experienced before PBMs finally add them to formularies. During this time, lack of formulary coverage restricts patient access to lower-cost generics, denying patients savings in favor of unnecessarily high-cost sharing for brand medications.

First generics are a critical tool for lowering patient costs. According to the FDA, first generic products with a single generic producer have an average manufacturer price (“AMP”) that is 39% lower than the brand prior to the launch of its first generic competitor (compared to a 31% reduction using invoice prices which indicate discounts facilitated by PBM practices). When the market reaches six or more competitors, generics show price reductions of more than 95% compared to brand prices.¹⁹ While rebates might offer PBMs and plan sponsors levers to generate revenue and reduce premiums, the traditional market structure of the generic industry has always offered sustainable savings that continuously



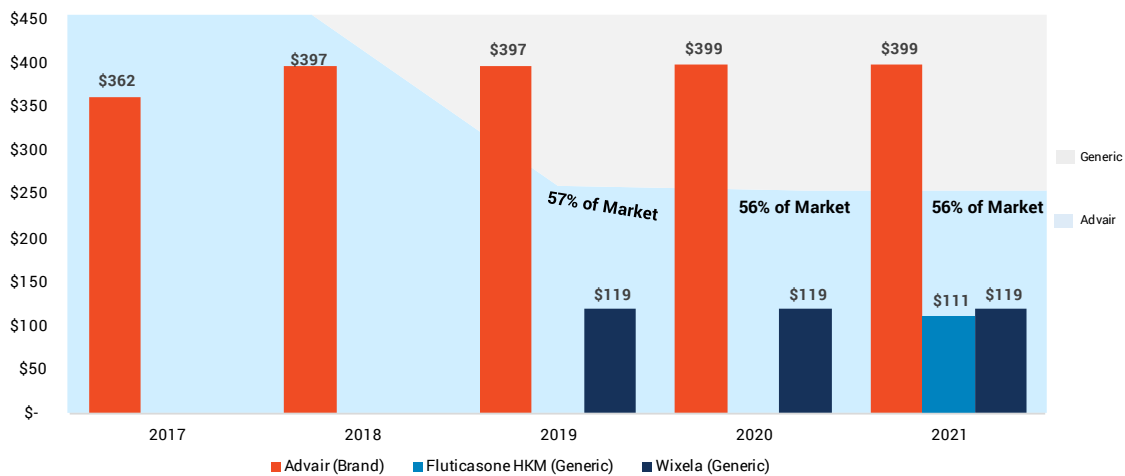
¹⁹ Association for Accessible Medicines, (July 2021) AAM Releases New Report: New Generics Are Less Available in Medicare Than Commercial Plans, Available at <https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf>

deliver essential medicines at affordable prices.

Rebate Opportunities Underlie Formulary Placement Delays and Exclusions

Despite the ability of generics and biosimilars to drive reductions in costs, preferential tier placement for brand drugs still limits the availability of low-cost prescription drug options. For example, the COPD drug Advair has had generic competition for three years now priced at a 70% discount to the Advair list price (a generic is available priced at a WAC of \$110 compared to \$399 for Advair), however Advair has managed to maintain over 50% of the market share. This illustrates the challenge that many generic products face due to PBM distortions favoring high list price/highly rebated products.⁷

ADVAIR PRICE/MARKET SHARE VS. GENERIC COMPETITION



Source: IQVIA, Monthly Module Views - Rx (NPA) - Rx View

The insulin market for patients with diabetes is another example. In July 2021, the FDA approved Semglee (insulin glargine-yfgn) as an interchangeable biological product, making it the first biosimilar to receive an interchangeable designation. Unfortunately, the market for this product reflects the perverse incentives by which PBMs prefer brands with a high list price and high rebate over generics or biosimilars with a lower list price. Reports indicate that interchangeable Semglee is available through two pricing options: a 5% price discount compared to the brand and an “unbranded” option available at a 65% discount. Not surprisingly, major PBMs appear to have chosen not to cover the lower priced option – and many continue to prefer the higher cost brands leaving patients with unnecessarily high out-of-pocket costs.

PBMs may dictate plans’ decisions on which medications are covered on their national formulary, including the ability to recommend which products are excluded. In 2021, 1,343 drugs were excluded by formularies as required by the three largest PBMs.¹⁰ Often, the excluded products are biosimilars with lower prices. Formulary exclusions often work against the financial

interests of patients, for example when the excluded medications have a lower list price than those that remain on formulary. PBMs often use their ability to design formularies (including to prioritize brand name products) as a tool to negotiate higher rebates. As a result, lower cost, high value generic and biosimilar medicines are frequently not accessible to patients. While it may be appropriate for PBMs to work to negotiate lower prices through the use of a formulary, the preference for highly rebated products and/or products with high WAC-based specialty pharmacy fees often imposes higher net costs on patients at the pharmacy and limits patient access to lower cost generics and biosimilars. As the number of drug exclusions have risen, these dynamics become more problematic for patients.

Even where new generic entrants are launched specifically to benefit patients and the health care system by introducing competition to high-priced drugs, PBMs remain incentivized to retain revenue through the rebate structure, and thus the savings that these generic entrants should bring to patients go partially or wholly unrealized. From 2016 to 2020, the FDA approved 368 first generic drug applications.²⁰ However, of the generic drugs launched in 2020, only 66% were placed on formulary by commercial plans and less than 21% by Part D plans. Avalere found it takes nearly three years before first generics are covered on more than half of Medicare Part D formularies. This delay in coverage restricts patient access to lower-cost generics, denying patients savings in favor of unnecessarily high-cost sharing for brand medications despite the availability of lower-cost alternatives.²¹

PERCENT OF FIRST GENERICS COVERED BY MEDICARE PART D AND COMMERCIAL PLANS

Launch Year	2016		2017		2018		2019		2020		2021	
	Medicare	Commercial	Medicare	Commercial	Medicare	Commercial	Medicare	Commercial	Medicare	Commercial	Medicare	Commercial
2016	22%	46%	31%	68%	63%	72%	58%	72%	60%	76%	59%	78%
2017			12%	58%	25%	73%	58%	73%	65%	76%	65%	76%
2018					17%	39%	27%	49%	51%	59%	51%	60%
2019							31%	44%	59%	60%	62%	61%
2020									21%	55%	21%	66%

Source: Association for Accessible Medicines, AAM Releases New Report: New Generics Are Less Available in Medicare Than Commercial Plans, July 19, 2021. Available at <https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf>

Some of the structural and incentive-based motivations for disparate coverage of generics at launch are due to the bundled, multi-year brand manufacturer rebates now central to the PBM

²⁰ Conrad, R. (December 2019) Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. Available at: <https://www.fda.gov/media/133509/download>

²¹ Association for Accessible Medicines. (February 2020) Medicare and Commercial Plans Fail to Get New Generics to Patients., Available at: <https://accessiblemeds.org/resources/reports/white-paper-medicare-and-commercial-plans-fail-get-new-generics-patients>

and plan business model. Brand manufacturers can leverage rebates through multi-year formulary contracts and bundle several of their brand products into a joint rebate agreement, thus incentivizing PBMs to delay the formulary placement of generics and biosimilars. This aggressive use of brand rebates impedes patient access to new generics at launch and results in higher patient costs.

The current business model for brand manufacturers often means that payers risk losing rebates unless the payers effectively exclude generics or biosimilars from the market. While generics or biosimilars enter the market at a significant discount from the brand-name product, incentives embedded in brand-negotiated rebates force the health plan to choose: either block generic or biosimilar use or pay the full price for the brand-name product. It then becomes economically unfeasible for the payer to cover a biosimilar due to the loss of anticipated rebate dollars from the brand-name company. The uncertainty of generic or biosimilar uptake—coupled with the certainty of the brand-name, removing its rebate—financially incentivizes PBMs to require the exclusion of the generic or biosimilar and continued use of the brand product, despite the generic or biosimilar option costing patients and payers less. These tactics prevent the use of safe, effective, and less-costly generic and biosimilar medicines by blocking the ability for patients and payers to access affordable medications. And they reduce the incentive to take on the expense to challenge a patent when first generics or biosimilars are not available to patients.

Rebates Distort the Advantages of Step Therapy

Brand drug rebate agreements with PBMs can also delay or prevent a plan's ability to "cover" a generic or biosimilar under a step therapy, or fail-first, requirement. Originally intended to control the costs posed by high-dollar therapies, this utilization management technique now delays coverage of more expensive drugs by requiring patients to attempt a course of therapeutic alternatives such as a generic or biosimilar medicine first. But in recent years, some PBMs prevent the inclusion of a biosimilar as a therapeutic alternative before the patient is eligible for its reference biologic, or even require a patient to fail first on the reference biologic before becoming eligible for the biosimilar.¹⁰

Sources of Revenue for PBMs Extend Beyond Rebates and Cause Misrepresentation of Generic and Biosimilar Pricing

The current PBM business model is not solely based on revenue from rebates and recently has expanded to extract additional proceeds from fees and fulfillment. High consolidation ensures that most patients are covered by health plans whose formularies are designed by PBMs. And these formularies, by design, incent patients to retrieve their prescriptions at the PBMs' wholly-owned specialty care or other pharmacy sites. Furthermore, the use of vertically integrated specialty pharmacies introduces yet another incentive for PBMs to prefer higher list price drugs, as many specialty pharmacy fees and services charged to manufacturers are calculated based on a percentage of the inflated Wholesale Acquisition Cost (WAC) of these products. This means

that PBMs, especially if they are vertically integrated with a specialty pharmacy, may prefer drugs with higher list prices due to the WAC-based fees collected through specialty pharmacies.

In fact, between 2017 and 2019, PBM gross profit from retained administrative fees paid by manufacturers increased 51%, from \$3.8 billion (15% of gross profit) to \$5.7 billion (20% of gross profit).²² Recent reports of a decline in PBM rebate revenues is almost entirely offset by the growth in administrative fees alone. This level of integration between the already highly concentrated PBM industry on the one hand, and plan sponsors and pharmacies on the other, raises significant risks regarding increasing costs for patients and employer purchasers going forward, as the large PBMs exert substantial control over drug pricing, patient access, and the sites where patients receive their pharmaceutical care.

The Consolidated PBM Market Adversely Impacts Biosimilar and Generic Competition

Despite generics and biosimilars' track record of lower costs and mass utilization by the American public, the long-term sustainability of these industries is fragile in many respects. Generic manufacturers face challenges related to the aggressive and discriminatory PBM practices, intense cost pressure from increased competition, and reduced leverage in negotiations with a highly consolidated PBM monopsony. Biosimilar manufacturers face challenges related to PBM preferences for higher cost, heavily rebated products, distortions in the marketplace due to PBM horizontal and vertical integration, as well as the challenges associated with investing in expensive development in new products. Early symptoms of potential market failure may present as persistent drug shortages and an emerging trend of manufacturer business decisions to not launch newly approved generics or biosimilars because of negative market dynamics.

Rebate Challenges Discourage Investment in and Threaten Viability of the US Biosimilars and Complex Generics Market

Brand specialty and biologic medicines account for roughly 2% - 3% of all prescriptions, but greater than 55% of all spending in the U.S.¹ And as noted, the promise of biosimilars is clear – lower costs and greater patient access.

Unfortunately, a myriad of roadblocks have prevented biosimilars from maximizing their full potential, and while these products are still new in the United States, their use saved patients and taxpayers more than \$8 billion in 2020.⁴ The U.S. Department of Health and Human Services Office of the Inspector General (OIG) published a report that notes how the Medicare program,

²² PBM Accountability Project. (2021) Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers. Available at: https://www.pbmaccountability.org/files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true

could have saved \$84 million to \$143 million, or 18- 31% of the program's gross spending on biosimilars products. And despite slower-than-expected adoption, Medicare beneficiaries still lost out on between \$1.8 million and \$3.1 million in savings, which is 12% to 22% of seniors' spending on these products. Full realization of biosimilars' promise is threatened by a lack of adoption. In comments regarding the OIG report, the HHS Inspector General recently noted how a major factor in slow adoption has been a failure of the PBM-recommended formulary design, noting that many Part D plans have not covered biosimilars and those that covered biosimilars did not use their tools to encourage their use.²³

These barriers to adoption loom large as biosimilar manufacturers weigh possible investments of \$150 million to \$300 million on each new biosimilar development and will likely discourage downstream development of lower cost biosimilars. Biosimilars have gained market share in several key product classes to date, however the future of the industry will depend on a level playing field in the marketplace that enables fair competition and ensures patients are able to access lower cost, high quality biosimilars.

The same challenge applies to many new generics, as the generic industry rapidly evolves to include the development of more complex generics with development costs far greater than traditional products. These products, which include a drug-device combination products or ocular suspensions, are more challenging and costly to develop, and yet the need for generic versions is critical need.

Finally, the development of new biosimilars and generics and the short-term economic returns to manufacturers of first generics, is also critical to the long-term production of older, more commoditized generics. Many of these medicines that patients need are sold at a loss by generic manufacturers as part of business calculations made feasible only by rapid adoption of new generics and biosimilars. In the absence of rapid adoption of new competitors due to PBM formulary constraints, it may become increasingly challenging for generic manufacturers to continue the production of older products.

PBM Markups Lead to Increased Regulatory Burden and Costs for Generic and Biosimilar Manufacturers

The public rightfully is concerned about the ever-increasing prices of prescription drugs. However, unlike brand drugs where the manufacturer stands to profit the most, generic medicines are often exploited by PBMs that simultaneously seize significant profits at the

²³ U.S. Department of Health and Human Services Office of Inspector General (March 2022) Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use. Available at: <https://oig.hhs.gov/oei/reports/OEI-05-20-0480.asp#:~:text=Biosimilars%20have%20the%20potential%20to%20significantly%20reduce%20costs.Part%20D%20formularies%20could%20limit%20this%20wider%20utilization.>

expense of patients and generic and biosimilar manufacturers. Given the proven track record of savings from generic and biosimilar competition, consumers conflate the price generic manufacturers set for their products with their out-of-pocket costs because of the markups facilitated by PBMs.

The impact of this misperception—that generic and biosimilar medicines contribute significantly to high costs—has resulted in policymakers enacting burdensome and ineffective regulatory requirements for their manufacturers at the state and Federal level. At least 13 states have passed laws requiring manufacturers to report their prices.²⁴ However, even though several states have found that brand name drugs are primary driver of drug costs, these mandates represent yet another cost and barrier to efficient generic drug production.

PBM Consolidation Thwarts Emergence of True Market Disruptors

With the top three PBMs controlling a dominant share of the market, there is limited opportunity for disruption from new entrants with alternative business models. Additionally, even new entrants are subjected to the ubiquity of these large players by requiring them to rely on the purchasing power of the overgrown and integrated PBMs.

Despite enrollment in a prescription drug plan or selection of a low-cost generics or biosimilars, many patients still must seek cost saving alternatives outside of their insurance plans. Even when patients chose to procure their medications outside of the PBM-third party payer system, they often are still met with systems underwritten by anti-competitive practices.

For example, recent years have seen the proliferation of drug discount programs. However, many of these programs simply build off the existing PBM infrastructure, leveraging PBM pricing and adjudicating cash or non-insurance based claims via a PBM. Further, that PBM also collects a per-prescription fee from the pharmacy for each transaction and then shares a portion of this fee with the discount card vendor.

AAM believes that the high market concentration in the current PBM industry creates additional opportunities for PBMs to redirect value to other aspects of the drug supply chain, harming both patients and generic manufacturers.

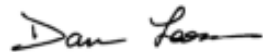
Conclusion

AAM and its Biosimilars Council appreciate the Federal Trade Commission's efforts to ensure the role of PBMs in the pharmaceutical supply chain supports the needs of U.S. consumers. In our

²⁴ National Academy for State Health Policy (January 2022) Drug Price Transparency Laws Position States to Impact Drug Prices, Available at: <https://www.nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/>

view, today's PBM practices too often deprive patients of lower cost generic and biosimilar options and can, in fact, increase patient costs. Moreover, these practices compromise the long-term sustainability of generic and biosimilars industry that delivers relied-upon savings to patients and the healthcare system. Accordingly, AAM urges the FTC to investigate, under Section 6(b) of the FTC Act, the practices we discuss in this submission, in addition to studying the vertical consolidation in the PBM industry and updating the agency's vertical merger guidelines to address the anticompetitive aspects of PBM consolidations. AAM looks forward to continuing to work with the FTC to expand patient access to more affordable generic and biosimilar medicines.

Respectfully,

A handwritten signature in black ink that reads "Dan Leonard". The signature is written in a cursive, flowing style.

Dan Leonard, President and Chief Executive Officer
Association for Accessible Medicines
