Biosimilars
FORUM

May 24, 2022

Federal Trade Commission

600 Pennsylvania Ave., N.W.

Washington, D.C. 20580

RE: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Commissioners Khan, Phillips, Slaughter, Wilson, and Bedoya,

The Biosimilars Forum is grateful for the FTC request for comments on the Business Practices of Pharmacy Benefit Managers and their impact on Consumers, especially in the area of access to lower cost biosimilars.

The Forum is the non-profit trade association representing the companies with the most significant U.S. biosimilars development portfolios, including Biogen, Boehringer Ingelheim, Coherus BioSciences, Fresenius Kabi, Organon Inc., Pfizer Inc., Samsung Bioepis, Sandoz, Teva, and Viatris. Our comments today represent the views of our members, all of whom manufacture or market biosimilar products in the US as well as other parts of the world.

Biosimilars have the potential to provide significant health care savings in the U.S. Without robust competition, innovator biologics will continue to represent approximately 40 percent of total prescription drug spending while they represent only 4 percent of the medicines prescribed to patients.[1] While U.S patients have the greatest access to innovative biologic medicines in the world, this has also resulted in the U.S. having the highest expenditures for these important medicines, biosimilars have successfully provided competition to lower the cost of biologic medicines in other highly regulated countries, their timely licensure, launch, and market access in the U.S is vital to ensuring patient access to lower-cost treatments in the U.S.

Pharmacy Benefit Managers ("PBMs") played a key role in the passage of the Biologic Price Competition and Innovation Act ("BPCIA"), as strong advocates for lowering drug costs through competition from biosimilars. Yet today, as more biosimilars are coming to the marketplace in the U.S., the actions of the PBMs in promoting access and competition from biosimilars shows

[1] Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions with Increased Biosimilar Use (March 2022) https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf

that PBMs are instead raising barriers to and restricting access to the lower cost biosimilars they advocated for in BPCIA. [2] These actions have a negative impact on patients and the future sustainability of the biosimilars industry.

PBMs manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, and large employers, and act as middlemen in the distribution of prescription drugs developing lists of covered medications, negotiating rebates from drug manufacturers, and contracting with pharmacies for reimbursement.[3] PBMs initially lowered prices by aggregating health plan customers to form large networks, allowing them to negotiate discounts with drug manufacturers while simultaneously building and maintaining networks of dispensing pharmacies. However, the business of PBMs has grown beyond the original concept with PBMs increasingly employing a host of practices that result in higher prices for payers/consumers and eliminate opportunities to reduce overall costs, including maximum allowable cost lists, direct and indirect remuneration fees, anticompetitive rebating practices, and differential pricing. In addition, PBMs couple their administrative and negotiating services with pharmaceutical distribution services, creating two choke points in the distribution chain.[4] Not only do these practices harm consumers in the short term, but the long-term effects threaten to undermine the economic viability of biosimilars.

Nature of the Problem

Rebates:

PBMs are not required by federal law to disclose rebates received from drug makers or spread pricing, the difference between the payment the PBM receives from the state or managed care organization and the reimbursement amount it pays to the pharmacy.[5] The State of Louisiana has filed a complaint against OptumRX and United Healthcare, to recover billions of dollars in inflated prescription drug prices charged by the Optum/United Healthcare to the Louisiana Medicaid Program.[6] Within the complaint, Louisiana notes that "due to the secrecy of all PBM contracts, spread pricing and other PBM pricing schemes are difficult to detect and rebate

[2] Pharmacy Benefit Expose, Community Oncology Association, (February 2022) https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

[3] Prescription Pricing for the People Act, https://www.grassley.senate.gov/imo/media/doc/prescription_pricing_for_the_people_act_-_one_pager.pdf.

[4] Robin Feldman, *Drugs, Money, and Secret Handshakes* ("In addition to rebates, drug companies offer payments to PBMs in the form of administrative fees or data-managing fees. Increasingly, drug companies are offering creative fees for 'services,' such as providing research and information to the drug company. These fees have the advantage of being invisible to the insurers in certain circumstances. Even when a drug company pays for services from a PBM, if the value of the service is substantially less than the payment made, the transaction is simply an indirect price concession. Once again, raising list prices can leave room for the drug company to offer these goodies without reducing the drug company's net income from sales of the drug. And, of course, many people will be forced to pay the higher list prices. As a transfer of money from the drug company to the PBM, these payments reduce the drug company's net income from sales of the drug and increase the PBM revenue related to a specific drug. In this manner, the drug company shares some of its monopoly rent with the PBM. Together, the rebates and other transfers of value can be called "persuasion payments.")

[5] See How the FTC Protected the Market Power of Pharmacy Benefit Managers (February 19, 2021), https://promarket.org/2021/02/19/ftc-market-power-pharmacy-benefit-managers/;

[6] State of Louisiana VS OptumRX, (April 2022) http://freepdfhosting.com/be3e3e8988.pdf, Sec. 40

amounts are confidential…..however, they ultimately drive up total drug costs and prices.[7] Louisiana went on further to say "establishing spread pricing through frequent and continued regular business practices is in violation of LSA-R.S 22:1867 and R.S. 40:2870.[8]

Rebates arise in the context of contracts between manufacturers and providers or third-party payers, including commercial health plans, Medicare Part D programs, and PBMs. Many payers use PBMs to design their formularies (or list of covered drugs) for pharmacy benefits under their plan. A drug may be "preferred" or "on formulary" and there may be "tiers" to the covered medications. PBMs require pharmaceutical companies to provide rebates to get particular drugs on formulary or in a higher tier on the formulary. In practice, this results in PBMs keeping higher priced drugs on formulary even where lower cost alternatives are available.[9] Such rebates increase drug costs and disincentivize companies from developing new medicines or investing in biosimilars, harming competition.[10]

- The practice of excluding medications from the formularies by the three largest PBMs – Caremark, Express Scripts, and Optum Rx – has continued to grow. Formulary exclusions have emerged as a powerful tactic for PBMs to gain additional negotiating leverage against drug manufacturers, as they lead to deeper rebates to avoid exclusion.[11] These mega-PBMs have enormous leverage over the drug companies, who are forced to satisfy their demands for increased rebate payments or risk being excluded from a high proportion of the market as only three PBMs serve approximately 80% of the market.[12]

- Rebates and list prices are positively correlated roughly dollar-for-dollar.[13] Because market dynamics drive PBMs to favor drugs that offer higher rebates over lower cost alternatives, the result is to cause higher list prices, which do not align with actual net contract prices for the PBM. Uninsured and underinsured patients are directly impacted by higher list prices due to their co-pays and deductibles being based on the drug's list prices. Increasing scrutiny on the rebating system could lower drug costs by lowering list prices or changing formulary decisions to favor lower cost alternatives for these patients, who are often the most disadvantaged of all. [14]

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[7] State of Louisiana VS OptumRX, (April 2022) http://freepdfhosting.com/be3e3e8988.pdf, Sec 40

[8] State of Louisiana VS OptumRX, http://freepdfhosting.com/be3e3e8988.pdf, April 2022. Sec. 75

[9] See Federal Trade Commission Report on Rebate Walls, https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf

[10] See Federal Trade Commission Report on Rebate Walls, https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf

[11] Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions (January 18, 2022), https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html

[12] The Association Between Drug Rebates and List (February 11, 2020), Priceshttps://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

[13] The Association Between Drug Rebates and List (February 11, 2020), Priceshttps://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

[14] New Evidence Shows Prescription Drug Rebates Play a Role in Increasing List Prices (February 11, 2020), https://healthpolicy.usc.edu/article/new-evidence-shows-prescription-drug-rebates-play-a-role-in-increasing-list-prices/

Because of the current anti-competitive conditions, the use of rebates as a negotiation tool, discourages access to lower list price biosimilars. Patients have waited decades for biosimilar competition for the blockbuster drug Humira. Nine competitors are poised to launch in 2023. Because of these rebating dynamics, it is possible that the patient has no, or very little, out of pocket relief, even with 10 competitors on the market. However, PBMs stand to make significant revenue from the drug through rebates.

As noted in the Senate Finance Committee's Staff report, certain contracting and business practices of PBMs may create incentives for them to prefer drugs with high rebates and, in turn, discourage manufacturers from competing with lower list prices.[15] These practices do not support lower list price biosimilars and are not aligned with the affordability of patients.

For example, in an attempt to avoid payers switching to a competitor's product, Sanofi and Novo Nordisk increased their rebate bids to respond to Eli Lilly. The investigation found that rebate offers made by Sanofi and Novo Nordisk to CVS Caremark have increased exponentially between 2013 and 2019 For example, in July 2013, Sanofi offered rebates between 2% and 4% for preferred placement on CVS Caremark's client's commercial formulary. By 2018, Sanofi rebates were as high as 56% for preferred formulary placement.[16]

Similarly, rebates to Express Scripts and OptumRx increased dramatically for long-acting insulins. In 2019, Sanofi offered OptumRx rebates up to 79.75% for Lantus for preferred formulary placement on their client's commercial formulary, compared to just 42% in 2015.[17]

The Forum has also become aware of practices in national payer coverage of biosimilars that will drive immediate and potential future restrictions on physician choice of biosimilars. In the past, physicians have voiced their concern over payer restricted products and disapproval of manufacturers pursuing payer exclusive product arrangements. In the biosimilar space, some of our members have responded and have consistently declined to compete for 1 of 1 or exclusive offers as part of our support for physician choice.

For example, we have been recently informed that one member's oncology biosimilars, among other products, were removed from coverage from a commercial medical benefit plan effective January 1, 2022, when they chose not to compete for exclusive or 1 of 1 medical coverage, which is what the payer accepted from another competitor brand, likely based on higher rebate rates offered for exclusive coverage[18].

PBMs are managing provider-administered biosimilars on their pharmacy benefit formularies and do not favor lower cost biosimilars which is concerning to biosimilar developers and should be to stakeholders who are looking for ways to lower drug costs. For example, in the case of the

[15] Senate Finance Committee Staff, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Washington, District of Columbia, 2021

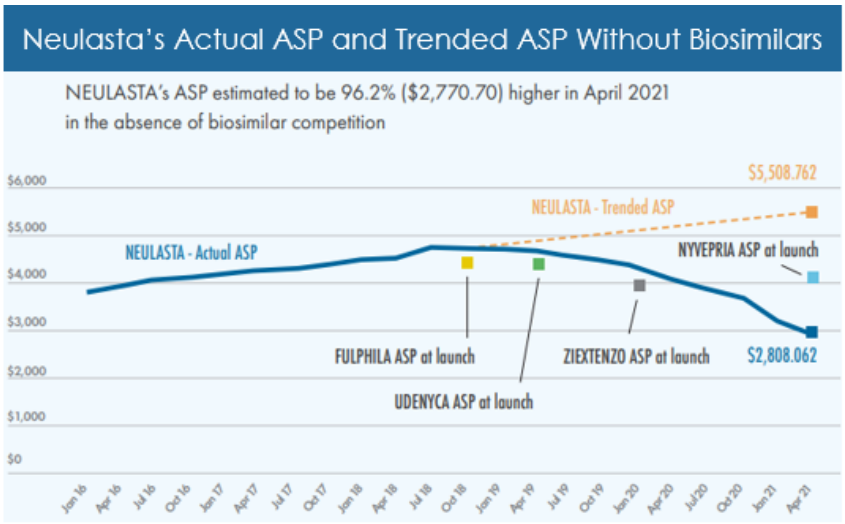
[16] Senate Finance Committee Staff, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, Washington, District of Columbia, 2021. page 67.

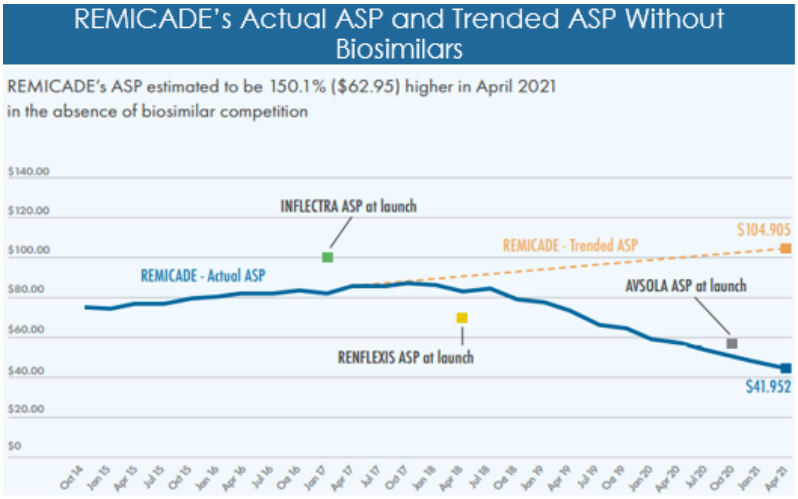
[17] Senate Finance Committee Staff, Examining the Factors Driving the Rising Cost of a Century Old Drug, page 67

[18] BSF Member company interview, J. Reed May 2022

infliximab biosimilars, one PBM prefers the one biosimilar, and excludes the reference biologic and two of other biosimilars, while another PBM prefers two biosimilars, yet excludes the reference biologic and another biosimilar, and yet another PBM excludes all the biosimilars and prefers the reference biologic.[19]

Excluding lower list price biosimilars and limiting robust competition in the marketplace is concerning to biosimilar developers. The Forum has published reports demonstrating that direct competition from multiple biosimilars and the reference product can produce the greatest level of savings and lowering of the average sales price of all the products, both biosimilars and the reference biologic on a sustainable basis:





Payer restrictions, enforced with higher rebates to payers in exchange for payer exclusives, will likely negate many provider and GPO contracts that were intended to safeguard physician choice. Moreover, manufacturers that win exclusive contracts with payers will have no incentive

to offer discounts to GPOs and providers. More long-reaching implications to payer restricted products lead to additional concerns including more national and regional payers restricting physician choice through product exclusion on all biosimilar manufacturers, may have to pursue exclusives; and payers may move to alternative dispensing practices as a norm, limiting physician choice, market competition and again, creating a negative impact on the development of biosimilars in the future.

This practice must stop in order to protect & preserve provider choice and ensure parity positions for products.

Horizontal Consequences & Vertical Consolidation:

Vertical consolidation and integration between health insurers, providers, pharmacy benefit managers, and other sectors of the healthcare market has transformed the PBM industry and exacerbated the harmful conduct.

In addition, horizontal concentration and the resulting increase in market power of PBMs limits the choice of insurers and pharmacies and reduces competition within the PBM industry, keeping brand (and subsequently generic and biosimilars) prices high through rebates and spread pricing.

- Per one expert's study, "for every $100 in spending by an insured consumer on a drug sold in a retail pharmacy only $58 reaches the manufacturer and the remaining $42 is kept by intermediaries or "middlemen". [20]

Evidence confirms that horizontal and vertical market consolidation has allowed these companies to expand their use of harmful conduct. The rebate-for-exclusion practice has become prevalent particularly and has foreclosed biosimilars by shielding incumbent drugs with high costs from competition and the resulting diminished biosimilar –entry has a huge impact on consumers. As a result of large rebates, including multi-product bundles, extracted from brand manufacturers, biosimilars are not being regularly added to PBM formulary tiers.[21] In many instances the PBM extracts large rebates from brand manufacturers that either explicitly exclude biosimilar products or prefer brand drug products in such a way as to result in de facto exclusivity. This practice can have a costly and direct impact on patients.

Vertical consolidation and conglomeration have allowed PBMs to expand into new practices and find new ways to abuse their position. For instance, PBMs have recently introduced purchasing organizations, rebate aggregators, or contracting entities known as "group purchasing

[20] Neeraj Sood, Potential effects of the proposed CVS acquisition of Aetna on competition and consumer welfare (June 14, 2018). Dr. Sood was a presenter at the FTC's pharmaceutical workshop entitled "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain" https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf beginning at slide 74.

[21] Employers Face Barriers with Adopting Biosimilars, Formularywatch.com, March 2022, https://www.formularywatch.com/view/employers-face-barriers-with-adopting-biosimilars

organizations."[22] The groups' missions are expressly to further use scale and leverage to aggressively negotiate lower costs for consumers; however, with the PBMs already representing 75% of covered lives it is difficult to imagine additional savings on behalf of consumers. More likely, the addition of yet another middleman allows for the vertically integrated companies to hide discounts and fees collected from drug makers, making the system even less transparent and accountable to patients.

Buying groups can force drug manufacturers to accept prices below a competitive level because such groups exercise "monopsony" power (upstream market power). In these upstream buying markets, lower prices result in anticompetitive effects in the form of restricted output as manufacturers (particularly generic manufacturers) exit the market, decide not to launch approved products in a particular market, or reduce research and development activity. The lack of incentives to produce such drugs has resulted in drug shortages. This practice will also impact biosimilar development in the future and impeded the emergence of a sustainable specialty market.

Joint negotiating entities, sometimes referred to as "rebate aggregators,"[23] are a recent phenomenon in the pharmaceutical ecosystem. Through separate entities (often housed internationally) PBMs concentrate negotiating power vis-à-vis biosimilar manufacturers, creating a bottleneck for access to commercial lives. These include the following:

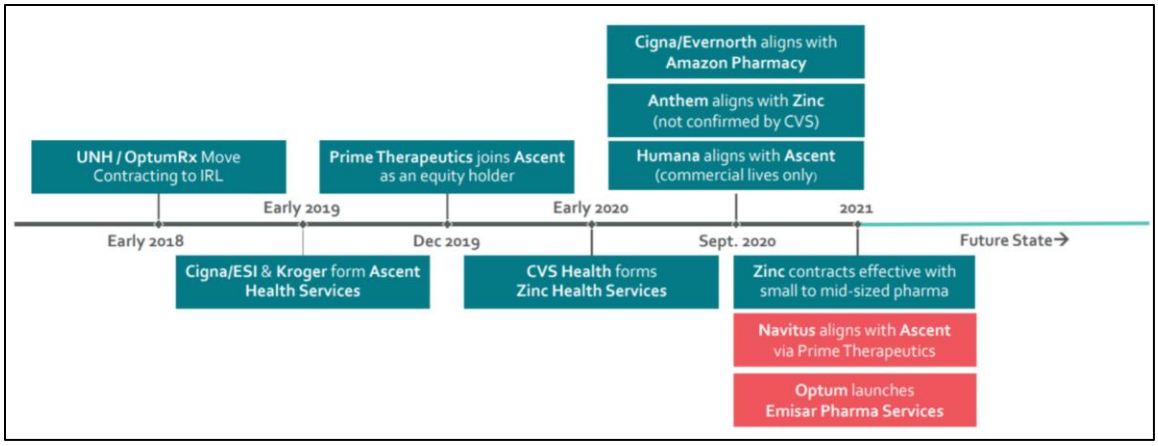
- Ascent (Express Scripts + Prime Therapeutics + Kroger + Humana)
- Zinc Health (CVS/Caremark + Anthem)[24]
- Emisar Pharma Services (OptumRx)[25]

[22] Already concerned with drug costs, large employers, family pharmacists worry about more middlemen, Ohio Capital Journal (September 2, 2021) https://ohiocapitaljournal.com/2021/09/02/already-concerned-with-drug-costs-large-employers-pharmacists-worry-about-another-layer-of-middlemen/

[23] The state of Arkansas recently alleged that several PBMs "used their controlled rebate aggregator entities in furtherance of" an alleged conspiracy regarding insulin products. See Complaint, State of Arkansas ex rel. Leslie Rutledge v. Eli Lilly et al, No. 60-cv-22-2976 (Pulaski Cnty. Cir. Ct. May 11, 2020).

[24] Drug Channels News Roundup, August 2021: OptumRx's New GPO, Pharmacy DIR Fees, State Biosimilar Laws, UM Views, and a Newspaper Delivers, Drug Channels (August 25, 2021) https://www.drugchannels.net/2021/08/drug-channels-news-roundup-august-2021.html

[25] Marty Schladen, Already Concerned with Drug Costs, Large Employers, Family Pharmacists Worry about More Middlemen, OHIO CAPITAL JOURNAL (Sept. 2, 2021) available at https://ohiocapitaljournal.com/2021/09/02/already-concerned-with-drug-costs-large-employers-pharmacists-worry-about-another-layer-of-middlemen/ ("Cigna/Express Scripts launched its "group purchasing organization," Ascent, in Switzerland in 2019. Last year, CVS launched Zinc domestically and in July, news broke that Optum was launching Emisar Pharmacy Solutions in Ireland. The companies have been called purchasing organizations, rebate aggregators or contracting entities. As those names suggest, they'll negotiate rebates and contract with drugmakers on behalf of their affiliated PBMs.")



PBMs' market concentration and power has enabled practices that have resulted in decreased competition and higher prices through blocking market access. PBMs have a clear financial incentive to drive up the price of pharmaceutical products because they receive rebates from drug manufacturers in exchange for preferential formulary placement, market share targets, or de facto exclusivity.[26] The formulary placement fees and other rebates give PBMs positive incentives to distort prices and increase their own profits.[27] The higher the list price, the more price concessions a PBM can collect and retain.[28] The rebate-for-exclusion practice has become prevalent particularly in excluding or diminishing the impact of entry by biosimilars, again, with the result of shielding incumbent drugs with high costs from competition from biosimilars, ultimately with a huge negative impact on consumers. .

In addition, PBMs increasingly employ a host of practices that result in higher prices for downstream payers/consumers and eliminate opportunities to reduce overall costs, including maximum allowable cost lists, direct and indirect remuneration fees, anticompetitive rebating practices, and differential pricing. In addition, PBMs couple their administrative and negotiating services with pharmaceutical distribution services, creating two choke points in the distribution chain.[29]

[26] ." Elizabeth Seeley and Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead*, THE COMMONWEALTH FUND, (Mar. 26, 2019).

[27] US Drug Prices Distorted to Favor Pharmacy Benefit Managers, Drug Topics (March 22, 2022), https://www.drugtopics.com/view/us-drug-prices-distorted-to-favor-pharmacy-benefit-managers.

[28] US Drug Prices Distorted to Favor Pharmacy Benefit Managers, Drug Topics (March 22, 2022), https://www.drugtopics.com/view/us-drug-prices-distorted-to-favor-pharmacy-benefit-managers.

[29] Robin Feldman, *Drugs, Money, and Secret Handshakes* ("In addition to rebates, drug companies offer payments to PBMs in the form of administrative fees or data-managing fees. Increasingly, drug companies are offering creative fees for 'services,' such as providing research and information to the drug company. These fees have the advantage of being invisible to the insurers in certain circumstances. Even when a drug company pays for services from a PBM, if the value of the service is substantially less than the payment made, the transaction is simply an indirect price concession. Once again, raising list prices can leave room for the drug company to offer these goodies without reducing the drug company's net income from sales of the drug. And, of course, many people

DIR Fees, Service Fees, Data Fees, and Administrative Fees:

There are additional fees that PBMs charge from other participants in the supply chain. Direct and Indirect Remuneration (DIR) is an accounting system that Part D plans use to report to CMS all prescription drug price concessions that take place after the point of sale. Service fees, data fees, and administrative fees are some (but not all) of the additional fees that PBMs extract, often from manufacturers, which do not count as rebates. "Over time, payors have secured contract provisions guaranteeing them all or some portion of the "rebates" paid by the Manufacturers to the PBMs. But—critically— "rebates" are only a portion of the total secret Manufacturer Payments."[30]

"PBMs have begun renaming the Manufacturer Payments in order to keep a larger portion of this money. Payments once known as "rebates" are now called administrative fees, volume discounts, service fees, inflation fees, or other industry jargon terms designed to obfuscate and distract from the substantial sums being secretly exchanged."[31]

White Bagging:

White Bagging is the practice of shipping pharmaceuticals, typically specialty pharmaceuticals, directly to clinics or medical centers. PBMs enforce white bagging practices, and often combine white bagging with PBM-affiliated specialty pharmacies, eschewing traditional distribution channels and often compromising safety protocols at clinics and medical centers.[32]

Co-Pay Accumulators Adjustments:

A few years ago, plan sponsors and PBMs began adopting benefit designs that exclude the value of a manufacturer's payments from the patient's annual deductible and out-of-pocket maximum obligations. With Copay accumulator adjustments the value of a manufacturer's copayment support payments is excluded from the patient's annual deductible and out-of-pocket maximum obligations. The manufacturer funds prescriptions until the maximum value of the deductible is reached. A patient's out-of-pocket spending will then count toward their annual deductible and out-of-pocket maximum. Accumulators therefore reduce the plan's cost by shifting more of a prescription's expenses to patients and manufacturers, because the plan effectively captures the value of two deductibles.[33] Shifting these costs back to patients undermines a co-pay program, patient compliance with their medication regimes and patient access to biosimilars.

Employer Experiences with Access to Biosimilars

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will be forced to pay the higher list prices. As a transfer of money from the drug company to the PBM, these payments reduce the drug company's net income from sales of the drug and increase the PBM revenue related to a specific drug. In this manner, the drug company shares some of its monopoly rent with the PBM. Together, the rebates and other transfers of value can be called "persuasion payments.")

[30] Arkansas vs Eli Lilly filed May 11, 2022, case paragraphs 378-379.

[31] Arkansas vs. Elie Lilly filed May 11, 2022, case paragraphs 378-379.

[32] Drug Channels, White Bagging Update: PBMs' Specialty Pharmacies Keep Gaining on Buy-and-Bill Oncology Channels, (October 12, 2021), available at https://www.drugchannels.net/2021/10/white-bagging-update-pbms-specialty.html.

[33] Drug Channels, Four Reasons Why PBMs Gain As Maximizers Overtake Copay Accumulators (rerun), (April, 22, 2022), available at https://www.drugchannels.net/2022/04/four-reasons-why-pbms-gain-as.html.

In addition to the PBM practices experienced by Forum members that are limiting patient access to lower cost biosimilars, employers in the U.S. have also voiced their concerns regarding their access to lower cost biosimilars through PBM management of their employer purchased pharmacy and health benefit plans.

In their paper published this year, the National Alliance of Healthcare Purchasers Coalition ("The Alliance") found that lack of transparency and misaligned incentives in the US drug market have contributed to purchasers' lack of engagement and reduced adoption of biosimilars.[34]

The Alliance reported that many employers across their discussions agreed their consultants, PBMs, and insurance companies "sold" them on a standardized formulary, telling them they would have to pay for customization if biosimilars and biologics were added.[35]

In addition, there was significant conversation about drug pricing and how rebates and credits are used. Some employers said their PBMs, and payers have told them biosimilars are more expensive and less safe than their branded counterpart and an unnecessary addition to the formulary. One of the most common concerns employers expressed was that they have been told they could lose their rebates if they switched patients from branded products to biosimilars and would therefore pay more.[36] While the PBM is actively encouraging the employer to seek rebates from the branded product as a cost lowering strategy, the Alliance reminded their members that the difference in cost should, in many cases, offset the loss of rebates. In the long term, this would create better price transparency and a lower out-of-pocket cost to the patient, since rebates are not passed on to individual patients at the point of sale.[37] This is the strategy the Forum had hoped the PBMs would embrace when they advocated for BPCIA and a robust, competitive biosimilars market in the U.S.

The Alliance was also told by their employers, that some have been told biosimilars are not always available in inventory and patients would encounter delays or lack of stock at the pharmacy or infusion center. When in fact, the reason a biosimilar or biologic may not be available is that some PBMs are restricting access or not including them on the formulary, not because the supply chain or dispensing pharmacy lacks inventory.[38]

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13 Improving Drug Management, Employer Strategies on Biosimilars, (February 2, 2022) available at: Public Resources - National Alliance of Healthcare Purchaser Coalitions (nationalalliancehealth.org)

[35] Improving Drug Management, Employer Strategies on Biosimilars, (February 2, 2022) available at: Public Resources - National Alliance of Healthcare Purchaser Coalitions (nationalalliancehealth.org)

[36] Improving Drug Management, Employer Strategies on Biosimilars, (February 2, 2022) available at: Public Resources - National Alliance of Healthcare Purchaser Coalitions (nationalalliancehealth.org)

[37] Improving Drug Management, Employer Strategies on Biosimilars, (February 2, 2022) available at: Public Resources - National Alliance of Healthcare Purchaser Coalitions (nationalalliancehealth.org)

[38] Improving Drug Management, Employer Strategies on Biosimilars, (February 2, 2022) available at: Public Resources - National Alliance of Healthcare Purchaser Coalitions (nationalalliancehealth.org)

The Alliance recommended to their employers the following key priorities when dealing with PBMs in their discussions around biosimilars, which demonstrate the PBMs lack of support for access to biosimilars and long-term sustainability of the biosimilars marketplace:

1. **Collecting objective information on biosimilars and the value of uptake** — During the roundtable sessions, employers reported receiving conflicting information (e.g., biosimilars will be more expensive than the reference products if employers cover them) from health plans, PBMs, benefits consultants, providers, and pharmacists. This caused confusion, misinformation, and a lack of biosimilar uptake. Employers want to better understand the rules/regulations, as well as the pipeline and related legislation.

   Understanding the availability and interchangeability of biosimilars for biologics — Employers seek credible information about the 100% interchangeability of biosimilars with their reference products because they have been told patients could suffer side effects or have a worse response therapeutically. That an interchangeability designation by FDA only impacts dispensing (subject to state law) for a limited number of Part D biologics, and not prescribing for the vast majority of biologics is usually omitted from the discussion. Employers want up-to-date lists of biologics and biosimilars (including the availability of interchangeability) and regular updates as new biosimilar drugs are approved. The FDA has been helpful here.

With the launch of seven adalimumab (Humira™) biosimilars in 2023, the Forum is genuinely concerned about the PBM misinformation and lack of patient access to biosimilars as reported by the members of the Alliance.

Suggested Actions for the FTC and Policymakers More Broadly

PBM behavior towards biosimilars can be addressed or curtailed through increased immediate action by the antitrust agencies.

- Antitrust agencies should investigate and litigate against harmful conduct.
  - Investigate (and enjoin) the unlawful exercise of market power through rebates, exclusive contracting, monopsony pricing or other exclusionary conduct, by joint purchasing and joint negotiating entities, whether they are formal joint ventures or loose agreements between competing purchasers.
  - Bring a complaint under Section 5 of FTC Act ("unfair methods of competition" – broader than Sherman Antitrust Act) to challenge unfair methods of competition that have largely eluded private civil plaintiffs due to artificially strict standing or direct purchaser requirements.
  - Bring product-specific lawsuits that include allegations that PBMs conspired to block access to and reduce uptake in biosimilars.

- Utilize the FTC's rulemaking power to promulgate guidelines limiting PBM's use of the anticompetitive practices detailed above.

- Antitrust agencies should scrutinize transactions that do not meet the HSR thresholds for mandatory reporting in order needs revamping to capture transactions or arrangements not currently subject to agency review.

  - PBM joint ventures currently are not subject to HSR review, such as Emisar, Ascent Health, or Zinc.

    - Agencies should recognize that buying groups can exercise dangerous monopsony power even if an individual buying group possesses less than 35% of the relevant purchases and even though overall output may not immediately be reduced in the generic pharmaceutical market when monopsony power pushes prices below competitive levels such buying groups still pose significant long-term threats to competition and public health.[1]

    - Buying groups are already forcing input prices below competitive levels resulting in competitors abandoning certain products and smaller competitors being driven out of the market.[1] The anticompetitive effect of artificially lower prices is restricted output. The buying groups have increasingly utilized restrictive contract terms to reduce prices and margins, including MFN clauses, price reductions, administrative fees, service penalties, uniform pricing, extended price protections and restrictions, and extended payment. These penalties and provisions leave a generic manufacturer with the false choice of absorbing high penalties or abandoning the market.

- Antitrust agencies should conduct studies to deepen knowledge on the ways in which PBMs serve as the gatekeepers for prescription drugs for millions of Americans, and how their dominance and opacity has resulted in limited choice/competition and higher pricing for patients.

  - Studies should seek to determine whether PBMs charge certain payers a higher price than reimbursement rates for competing pharmacies while reimbursing pharmacies in which the PBMs have an ownership interest at the rate charged to payers; steer patients to pharmacies in which the PBM has an ownership stake; audit or review proprietary data of pharmacies not owned by the pharmacy benefit manager and use such data for competitive advantage; and use formulary designs to depress the market share of low-cost, lower rebate prescription drugs.[39]

  - Studies should seek to understand the impact of buying group consolidation.

[39] Prescription Pricing for the People Act, https://www.grassley.senate.gov/imo/media/doc/prescription_pricing_for_the_people_act_-_one_pager.pdf.

- Legislative committees should hold hearings regarding anticompetitive PBM business practices including pharmaceutical rebates and spread pricing. Legislators should contemplate banning pharmaceutical rebates, such that list prices are actual prices and PBMs would have to compete for business based on ability to promote strong therapeutic outcomes and customer service, rather than rebate arrangements.[40]

Conclusion:

The Biosimilars Forum is grateful for the opportunity to provide the Federal Trade Commission with our experiences to date on how PBMs are impacting access to lower cost biosimilars in the U.S. PBMs control patient access to many biosimilars and limiting this access limits competition and thus lower costs as well as has the potential to negatively impact the future development of biosimilars in the U.S.

With the advent of more biosimilars coming to the marketplace in the coming years, across multiple new therapeutic categories, such as endocrinology and ophthalmology, and especially with the seven adalimumab biosimilars launching in 2023, PBMs have control over the future of biosimilars in the U.S. Their immediate impact on those biosimilars already approved and currently in development is important, but manufacturers choices for their future investments are being curtailed pending their confidence in the emergence of a sustainable and fair competitive specialty market in the US.

The Biosimilars Forum recommends that the FTC review any PBM practices that are not supporting robust biosimilar access and competition. We also ask our PBM stakeholders to rejoin us in our fight to make biosimilars a success in the U.S, just as we did to achieve passage of BPCIA 12 years ago.

Respectfully submitted,

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The Biosimilars Forum

[40] Industry Voices—Why it's time for PBM rebates to come to an end, https://www.fiercehealthcare.com/payer/industry-voices-why-it-s-time-for-pbm-rebates-to-come-to-end