February 2, 2024

The Honorable Jamie Comer
Chairman
House Committee on Oversight and Accountability
2157 Rayburn Building
Washington, DC 20515

The Honorable Jamie Raskin
Ranking Member
House Committee on Oversight and Accountability
2157 Rayburn Building
Washington, DC 20515

Dear Chairman Comer and Ranking Member Raskin:

The Association for Accessible Medicines (AAM) and its Biosimilars Council is the nation's leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved/licensed generic and biosimilar medicines. The Biosimilars Council, a division of AAM, works to increase patient access to lifesaving, high-value biosimilar medicines.

Because of their low cost and high value to patients and payers, generic and biosimilar medicines today account for greater than 90% of all prescriptions dispensed in the US, but only 17.5% of prescription drug spending. In fact, generic medicines are less than 2% of total U.S. health care spending. The U.S. health care system has saved nearly $2.9 trillion in the last 10 years due to the availability of affordable generic medicines. In 2022, competition from generic medicines resulted in more than $408 billion in savings to the health care system, including more than $130 billion in savings for the Medicare program.[1]

AAM supports H.R. 6283, the Delinking Revenue from Unfair Gouging Act" or the "DRUG Act," which would prohibit pharmacy benefit managers (PBMs) from linking administrative and other fees charged to pharmaceutical manufacturers to the list price of a prescription drug. The price of a drug has no bearing on the value of these ancillary services, and the perpetuation of this dynamic in both Medicare and the commercial market creates a perverse incentive for PBMs to prefer more expensive prescription drugs over less expensive biosimilar or generic alternatives. Instead, PBMs should only be permitted to set fees (apart from rebates) for *bona fide* services, and such fees should be at a flat

[1] Association for Accessible Medicines. (September 2023) The US Generic and Biosimilar Medicines Savings Report (Link)

rate that is not connected in any way to the list price of a prescription drug or any other metric related to the drug's price (e.g., the value of rebates offered by the manufacturer).

Administrative Fees Have Been Linked to Higher List Prices

These fees were one factor cited in the Senate Finance Committee's report[2] on insulin prices as a driver of increased list prices for insulin products. PBMs charge pharmaceutical manufacturers administrative fees each time a claim is processed for one of the manufacturer's products. The fees, which can run as high as 5 percent of the drug's wholesale acquisition cost (WAC), are paid in addition to any rebate negotiated by the manufacturer for formulary placement. These fees generate revenue for PBMs and increase drug spending. During the Senate Finance Committee investigation, insulin manufacturers reported that the presence of these fees, and the revenue that they represented for PBMs, caused the manufacturers to fear retaliatory actions from PBMs if the manufacturers were to decrease their list prices.

PBMs note that these fees are used to reduce premiums, lower cost-sharing, and fund wellness programs for plan members. However, it is difficult to tell how exactly the fees are allocated.[2] The lack of transparency surrounding these fees, including the total amount received by the PBM and how the fees are used, compounds the necessity to sever the link between the fee and the list price of the drug. Moreover, because patients often face cost-sharing based on the list price of a prescription drug, the relationship between these fees and the drug's list price effectively increases costs for the patient.

Evidence Continues to Grow Showing PBMs Prefer Higher-Cost Drugs Over Lower-Cost Alternatives

Rebates – and the revenue they generate for PBMs and health plans – create a perverse incentive for PBMs to prefer higher-cost drugs over lower-cost alternatives, including small-molecule, traditional generic drugs and biosimilars. Medicare Part D sponsors are increasingly delaying coverage of generic drugs and placing generic drugs on higher cost-sharing tiers.[3] In the commercial market, when biosimilar versions of one of the top-ranked medicines by annual spending in the world became available in the United States, an early analysis of health plan coverage showed that 27% of commercial plans continued to prefer the higher-cost reference biological product over the biosimilar, while 73 % of commercial plans covered both the reference biological product and the biosimilar, but on the same cost-sharing tier.[4] Early experience indicates that plans that covered the biosimilar on the same cost-sharing tier as the reference product are seeing little patient migration to the biosimilar, likely due to relatively small differences in out-of-pocket costs for the patient.[5]

This continued PBM preference for higher-cost brand drugs and biological products has a direct result on patients, denying them access to lower-cost generic drugs and biosimilars, and forcing them to pay

[2] U.S. Senate Finance Committee Staff Report. (January 2021) Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug (Link).
[3] Avalere Health. New analysis of trends in Part D generic tiering, pricing, and patient spending. September 14, 2022. (Link).
[4] LaMountain F, Beinfeld M, Chambers J. First look at US commercial health payers' coverage of Amjevita shows Humira remaining on top – at least for now. Center for the Evaluation of Value and Risk in Health. September 12, 2023 (Link).
[5] Allen, Arthur. Save billions or stick with Humira? Drug brokers steer Americans to the costly choice. *Los Angeles Times*. September 18, 2023. (Link)

more. For instance, PBMs deny more than half of all written prescriptions for lower-priced biosimilar insulin.[6]

PBMs and health plans should welcome the price relief offered by generic and biosimilar competition. Depriving patients of access to lower-cost alternatives increases costs for patients, employers, and taxpayers.[7] PBMs and health plans should not be able to maximize rebate revenue generation from brand-name manufacturers at the expense of the patients they are supposed to serve.

In the absence of broader reform to the rebate system in both Medicare and the commercial market, Congress must address the separate issue of administrative fee revenue generation and its relationship with the list price of a drug. Requiring PBMs to set flat administrative fees that are not linked to a drug's list price, or any other metric tied to preferential coverage, will help to level the playing field and reduce pernicious incentives for PBMs and health plans to continue to prefer higher-cost products when lower-cost alternatives are available.

AAM appreciates the opportunity to provide comments on these issues. We thank you for your consideration and look forward to working with you to ensure that Americans have access to safe, effective, and lower-cost prescription medicines.

Sincerely,

Craig Burton

Craig Burton
Senior Vice President, Policy & Strategic Alliances, AAM
Executive Director, Biosimilars Council

[6] https://biosimilarscouncil.org/resource/pharmacy-benefit-managers-are-blocking-patient-access-to-biosimilar-insulin/

[7] On this note, AAM has consistently requested that the Centers for Medicare and Medicaid Services (CMS) update Part D program rules to require plan sponsors to cover generic drugs and biosimilars on lower cost-sharing tiers than the brand-name drug's or reference biological product's original formulary placement.