Testimony of Ashlie Van Meter, Senior Director, State Government Affairs at the Association for Accessible Medicines

Regarding SB 393, Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars

My name is Ashlie Van Meter. I am the Senior Director of State Government Affairs at the Association for Accessible Medicines (AAM); I submit this testimony on behalf of AAM, the Nation's leading trade association for generic and biosimilar manufacturers. AAM works to preserve patient access to generic and biosimilar medicines, ensure coverage and promote the use of biosimilars, lower patient costs by ensuring appropriate formulary placement for generics and biosimilars, and address the harmful impact rebates have on these important goals.

Improving Patient Access and Savings from Generic and Biosimilar Medicines Generics and biosimilars represent **90% of all prescriptions** filled in the U.S. but **only 13.1%** of prescription drug spending. In 2023, these medicines **generated $445 billion in savings in the U.S**., including **$206 billion in savings** for commercial health insurance plans and patients. On average, the use of generics and biosimilars saved more than **$8 billion per state in 2023**, with annual savings ranging from **$600 million to nearly $38 billion**.[1] **In 2023, generics and biosimilars saved the State of Maryland $1.3 billion**. Although generic drugs and biosimilars provide significant cost savings, patients may not receive the savings because of PBM practices that (1) delay coverage and (2) force patients to pay more than necessary. Policymakers should ensure rapid formulary coverage of new generics and biosimilars and ensure that patients receive the full value of lower-cost medicines.

Problem: Delays in formulary coverage block patient access to new, lower-cost generics and biosimilars.

According to the U.S. Government Accountability Office, rebates on high-priced brand drugs can be used to block patient access to lower-priced generic or biosimilar medicines. For instance, brand drug manufacturers may threaten to withdraw rebates on a product or group of products if the plan prefers a generic or biosimilar on its formulary. As a result, a first generic - the first approval by FDA of a new generic drug - can face significant, multi-year delays in achieving broad formulary coverage. In fact, it takes up to three years for new generics to achieve coverage on 50% of Part D formularies, despite generic prices up to 95% less than brand prices. Although an average of 50 percent or more of commercial plans typically cover first generics the year after launch, this coverage appears to plateau over time.[2]

PBM formulary decisions to delay coverage of new generics and biosimilars deny patients access to lower-cost generics and biosimilars and create incentives for brand drugs to maintain high prices. For example, PBMs and health plans are increasingly placing generic medicines on non-generic formulary tiers, forcing patients to pay more for affordable drugs. A staggering 60% of generics in Medicare are placed on higher tiers, and from 2011 to 2019, patient costs for these medicines rose by 135%—even as drug prices dropped. And, as we saw with the launch of lower-cost biosimilar versions of Humira®,

[1] Association for Accessible Medicines (September 2024) The US Generic and Biosimilar Medicines Savings Report, https://accessiblemeds.org/resources/blog/2024-savings-report

[2] Association for Accessible Medicines Contributors. (October 2022). Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down. https://accessiblemeds.org/resources/blog/patients-pay-more-when-generic-drugs-are-placed-non-generic-tiers

PBMs are increasingly slow to cover new generics and biosimilars, even when they offer price discounts of greater than 80%.[3]

PBMs Block Patient Access to Biosimilar Insulin

Although biosimilar insulin came to market at a 60% discount compared to the brand, Avalere Health recently found that PBM formulary controls significantly restrict access to biosimilar insulin in Medicare, with the five major payers offering better coverage for the brand while blocking or limiting coverage for the lower cost biosimilar. In fact, Medicare Advantage plans covered the lower-priced biosimilar only 3% of the time.[4]

PBMs Slow Adoption of Lower-Priced Biosimilar versions of Humira IQVIA data reveals commercial health plans and patients missed out on savings up to $6 billion as a result of rebate schemes by pharmacy benefit managers, highlighting PBMs' strategy to protect $2 billion in profits by suppressing adoption of lower-cost, biosimilar versions of Humira. IQVIA found that adalimumab biosimilars offer up to $6 billion in potential savings to the U.S. healthcare system; however, switching all U.S. patients would lead to an estimated 84% decrease in PBM profits. Because the majority of branded adalimumab is dispensed by large specialty pharmacies, a switch would also represent a potential loss of revenue for these businesses that frequently share corporate ownership with PBMs. IQVIA also found that, even when rebates are taken into account, lower wholesale acquisition cost (WAC) biosimilar options have lower net costs for employers and patients.[5]

Problem: Formulary placement forces patients to pay high prices for generics even as their prices fall.

Despite years of demonstrated savings and price deflation, PBMs continue to make coverage, formulary, and utilization management decisions that require patients to pay more for many generic drugs and biosimilars even as the prices of those medicines have fallen. It is critical that states address PBM tiering practices that increase patient costs for lower-cost medicines. Simple formulary reforms that place lower-cost generic drugs and biosimilars on existing generic and preferred product tiers can level the playing field by prioritizing coverage decisions and by nudging health plans and PBMs towards patient-centric choices. Even when PBMs cover generic and biosimilar medicines, formulary placement can cause confusion and generate unnecessarily high costs to patients. Generic drugs are increasingly moved to formulary tiers with higher patient out-of-pocket costs despite their lower prices. Although generic drug prices have fallen more than $6.4 billion in the past five years, they are often placed on formulary tiers with higher copays. Formulary placement has a direct impact on patient costs. Avalere found that patient spending on generic drugs in Medicare skyrocketed from $8.5 billion in 2011 to $20 billion in 2019. This 135% increase in out-of-pocket spending is directly attributable to higher patient copays and occurred as the average price of generics fell by more than one-third. Nearly two-thirds of Medicare patients were

[3] Biosimilars Council (July 2024) PBM Schemes to Control Biosimilar Humira Are Denying Patients Savings – New Analysis Shows PBM Strategies and Brand 'Product Hopping' Are Suppressing Uptake of Lower Cost Biosimilar Adalimumab, https://biosimilarscouncil.org/news/pbm-schemes-control-biosimilar-humira-denying-patients-savings

[4] Association for Accessible Medicines Contributors. (March 2024). PBMs Continue to Block Patient Access to Lower-Priced Biosimilar Insulin. https://biosimilarscouncil.org/resource/pbms-block-patient-access-lower-priced-biosimilar-insulin

[5] IQVIA, Adalimumab Biosimilar Tracking, prepared for Biosimilars Council: https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf

also forced to pay full cost for at least one generic in 2020 as more insured patients pay cash to save on their generics, a practice that creates risks for patient safety.[6]

Problem: While generics and biosimilars have created significant savings, more savings should be available to patients, especially in the area of lower-cost biosimilars.

An IQVIA study found that had all U.S. patients using Humira been switched to adalimumab biosimilars after they launched in 2023, commercial plans, employers, and patients could have realized additional savings of approximately $6 billion dollars. PBM rebates and fees tied to high brand list prices continue to maintain a stranglehold on coverage decisions, to the detriment of patients. Despite price discounts of greater than 80 percent, adoption of biosimilar versions of Humira has been disappointingly slow, achieving less than two percent market share in their first year on the market. Even when rebates are considered, biosimilar options have lower net costs for employers and patients. IQVIA found that adalimumab biosimilars offer up to $6 billion in potential commercial market savings; however, switching all U.S. patients would lead to an estimated 84 percent decrease in PBM profits. Savings from appropriately tiered generic and biosimilar medicines would limit the need for PBMs and health plans to increase premiums. The vast majority of biosimilar Humira adoption in 2023 was by PBMs that are not reliant on rebate revenue and that prioritize use of lower-priced medicines.

Solution: Passage of SB 393: Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars

With the passage of SB 393, generics will appropriately be placed on a formulary tier with lower out-of-pocket costs than the brand. This approach requires plan design to optimize the use of generic and biosimilar medicines by creating clarity and consistency in formulary construction. SB 393 will rightfully establish a level playing field between lower-cost medicines and high-cost products that rely on the payment of hidden rebates and fees to PBMs to secure favorable placement on health plan formularies. SB 393 ensures that a transparent model of plan and formulary design will be utilized in an effort to deliver the largest amount of savings to payers and patients without the reliance on questionable PBM rebate practices.

SB 393 would require commercial health insurers to increase (or provide) patient access to lower-cost generic and biosimilar medications when they are brought to market at a lower cost (WAC) than the brand. Additionally, SB 393 provides for a more favorable out-of-pocket cost for the patient with the correct placement of generic and biosimilar medicines. If multiple biosimilars are available, the plan must cover at least one. Requiring PBM's and health plans to cover new generics and at least one biosimilar at launch if the generic/biosimilar has a lower list price than the brand will increase patient access to life-saving medications and will create incentives for brand drugs to reduce their list price to compete with generics and biosimilars. Placing generics on a formulary tier with lower out-of-pocket costs than the brand requires plan design to optimize the use of generic and biosimilar medicines by creating clarity and consistency in formulary construction.

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[6] Association for Accessible Medicines Contributors. (October 2022). Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices for Generics Are Going Down. https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf

Without this legislation, generic drugs are being moved to formulary tiers with higher patient out-of-pocket costs in spite of their lower prices. Rapid formulary placement would remove current multi-year delays in achieving broad coverage caused by PBM controls favoring the higher-cost brand drugs with rebates over lower-cost generics and biosimilars. For these important reasons, AAM provides this testimony in support of SB 393, and respectfully requests it is favorably voted out of committee.