AAM's Study on Generic Tiering is Methodologically Flawed and Contrary to the Evidence

A September 2019 white paper from the Association for Accessible Medicines (AAM) examines formulary uptake of first generics onto the market between 2016 and 2018.[i] Importantly, AAM's use of an inappropriate data sample calls into question its conclusions about first generics and Part D formulary placement.

Part D plan sponsors and PBMs have consistently promoted generic substitution since the beginning of the program and have achieved a nearly 90% generic substitution rate.[ii]

Generics approved by the FDA but not launched are a significant problem. Of the first-entry generics approved in 2017 and 2018, 36% were not on the market in January 2019.[iii] The number of brand-generic manufacturer settlements reported to the Federal Trade Commission (FTC) has increased. In 2016, 96% of the brand-generic settlements that involved first-entrant generics included provisions limiting the sale of the generic.[iv] Pay-for-delay settlements between brand and generic manufacturers cause $3.5 billion in higher drug costs annually, according to the FTC.[v] As the number of delay settlements grow, these costs seem likely to grow.

Problems with the data sample make it difficult to draw conclusions or verify AAM claims.

- **AAM used proprietary, unpublished data to create the list of drugs used in the sample.** It is impossible to verify that drugs were not kept off formularies for good cause. For example, some drugs may be inappropriate for the Part D population. This would include drugs used mainly in children, drugs not covered by Medicare Part D, and drugs considered High-Risk Medications in the Elderly (HRM).
- **The paper does not show that the prices—often higher than existing therapies—of first-entry generics warranted placement on a low generic tier.**
- **Given that so many newly Food and Drug Administration- (FDA-) approved generics are kept from the market,** the study's timeframe may be too short to understand the trends in generic uptake.

Many new first generics during the study period were versions of expensive brand-name drugs, where the generic entered at a price too high for the generic tiers. For Imatinib mesylate (generic Gleevec), for example, two generics were approved in 2016 and launched on the same day at a price barely lower than the brand version, which qualifies them for the specialty and not generic tier.[vi]

Many new first generics that entered the market during that period launched at list prices only slightly below the brand list price, and much above the brand net cost. Teva received FDA approval and launched the first-entrant generic of abacavir/lamivudine (generic Epzicom) HIV combination pill in 2016 at a price just below the brand version's and considerably higher than the brand cost with price concessions.[vii] Despite the entry into the market of subsequent generics with lower list prices, Teva has not changed the price of its first generic since launch.

AAM advocates for the placement of all new generics – not just first generics – onto Part D formularies without exceptions for appropriateness or price. Coverage guarantees lead to higher launch prices and unchecked price increases, the opposite of what generics promise. This has played out with many generic drugs in the CMS protected classes. Automatic formulary placement would allow generic

manufacturers to price their new generics however they wanted and force beneficiaries, the federal government, and taxpayers to bear the costs.

The AAM paper does not consider subsequent generics. The sample of generics included in the paper covers the first generic launched but not subsequent generics. Including second and third generics in the analysis would likely show robust generic coverage and demonstrate Part D plans and PBMs leverage the available competition to negotiate to the lowest overall cost for a given drug.

The AAM paper does not consider CMS formulary rules: In the Part D program, the Centers for Medicare and Medicaid Services (CMS) does not require plans to cover all drugs on their formularies. Accordingly, not every first generic would replace a brand drug if that brand drug is not on the formulary to begin with.[viii]

CMS has already considered and dismissed AAM's arguments about additional tiers and tier labeling. AAM proposes separate generic and brand tiers and creation of a new generic and biosimilar specialty tier. However, Part D plans are limited to five drug tiers (and a sixth, no-cost vaccine tier). There aren't enough levels to separately tier brands and generics, preferred and non-preferred, and specialty drugs. Further, CMS guidance already restricts Part D plans from placing a large number of generics on tiers that are labeled as "brand" tiers.[ix] Rather, CMS prefers that Part D plans exercise flexibility in their formulary designs, "…including the ability to mix brand and generic drugs within the Non-Preferred Drug tier."

Biosimilars are not interchangeable with the reference biologic, thus automatic placement on a tier with generics as proposed by AAM would not be appropriate.

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[i] Association for Accessible Medicines. Access Denied: Why New Generics Are Not Reaching America's Seniors. September 2019. https://accessiblemeds.org/resources/reports/white-paper-access-denied-first-generics

[ii] Medicare Payment Advisory Commission. Report to Congress, March 2019. Chapter 14: The Medicare prescription drug program (Part D): Status report. http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0

[iii] Kaiser Health News, "Trump Administration Salutes Parade Of Generic Drug Approvals, But Hundreds Aren't For Sale." February 2019. https://khn.org/news/trump-administration-salutes-parade-of-generic-drug-approvals-but-hundreds-arent-for-sale/

[iv] FTC. "Overview of Agreements Filed in FY 2016 A Report by the Bureau of Competition." May 2019. https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf

[v] FTC. "Pay for Delay." https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay

[vi] The first entrant generics from Teva and Apotex both launched at a list price of just 16% lower than the brand list price. Per 90-bottle, the generic products list price exceeded $7,000 for 90 100mg tablets, well above the CMS specialty-tier threshold in 2016 of $600.

[vii] The list price per tablet was $37.20 at launch, while the brand Epzicom had a list price just 16% higher at $43.06 per tablet. At the generic launch, the net price for the brand Epzicom was estimated at $25.26.

[viii] In order to understand when new first generics replace or augment brand drugs on formularies, a more useful analysis would involve a plan-by-plan examination of Part D formularies.

[ix] "Similar to CY 2019, we intend to maintain a maximum threshold of 25% generic composition for the Non-Preferred Brand tier for CY 2020. We would like to remind Part D sponsors that they have the option to choose a tier model that incorporates a Non-Preferred Drug tier label if a larger proportion of generics will be included on that tier." Centers for Medicare and Medicaid Services "Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter." April 2019.