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Executive Summary

The unabated high cost of prescription medicines in America has prompted a public outcry for solutions from state and federal policymakers as well as health care leaders. Meanwhile, FDA-approved generic medicines continue to generate competition for more expensive brand drugs and reduce costs for America's patients for 35 years running. Generic drugs are a core component to lowering drug spending, and the use of generic medicines saved $293 billion in 2018 alone.[1] This means greater affordability and access to care for millions of patients, as well as lower spending for government and private sector payers. As voters cite drug costs as one of their top issues for the 2020 campaign, it is critically important to ensure generic drugs are accessible to patients.[2]

New generic competitors are particularly important as brand drug prices increase, sometimes reaching $1 million or more. First generics – those drugs approved by the Food and Drug Administration (FDA) as the first competitor to a brand – benefit patients through new competition and lower prices. But although the FDA has been approving generic drug applications at a record-setting pace, access to these savings – particularly from first generics – continues to be under threat.

Data developed for and featured in this white paper highlight the challenges facing new generic competition, revealing that fewer than half of the first generics approved by FDA since 2016 are commercially available to patients.

Moreover, of those that are commercially available, AAM found that only about half were included on formularies of Medicare Part D plans. Once they are added to formularies, first generics are routinely placed on expensive brand drug tiers with higher patient copays, rather than on generic tiers with lower cost-sharing. As a result, seniors do not benefit from lower prices and lower out-of-pocket costs, and taxpayers continue to pay for high-priced brand drugs.

This is a result of two design features of the Medicare Part D program, including the availability of brand drug rebates on high-priced brand drugs. Policymakers can solve this issue by updating the Part D program to ensure that first generics are covered at launch with lower cost-sharing, including through a dedicated tier for specialty generic and biosimilar medicines. These changes could save seniors more than $4 billion yearly and save money for taxpayers.

1 AAM. (May 2019). 2019 Generic Drug and Biosimilars Access and Savings in the U.S. Retrieved from: https://accessiblemeds.org/resources/blog/2019-generic-drug-and-biosimilars-access-savings-us-report

2 Harvard T.H. Chan School of Public Health. (December 2018). "Americans' Priorities for the New Congress in 2019". Retrieved from https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2018/12/Politico-Harvard-Poll-Dec-2018-Priorities-for-New-Congress-in-2019.pdf

Introduction

Brand Drugs Drive Medicare Spending – First Generics Offer Competition

The need for new generic medicines to compete with more costly brand drugs has never been more acute. As Medicare spending continues to rise, brand drug prices have more than tripled over the past 10 years.[3] During that same period, generic drug prices have fallen by 75%[4] In fact, 15 of the 20 drugs with the highest spending in Medicare Part D in 2017 are brand drugs with no generic competition.[5] Many of these are specialty drugs, which today account for nearly half of all spending on medicines despite being only 2% of all prescriptions.[6]

"First generics" – defined by FDA as "the first approval by FDA which permits a manufacturer to market a generic drug product in the United States" – are considered by FDA to be a public health priority bringing new competition and savings.[7] "Authorized-generics" are not considered by FDA to be "first generics" and are not included in this analysis.

Moreover, at a time when generic medicines are experiencing unprecedented rates of price deflation – for more than 36 of the past 38 months – first generics represent the lifeblood of a sustainable generic drug industry.[8] Sales generated by first generics subsidize losses on older commodity generic medicines, allowing for continued provision of products that are critical to patient health but that may have unsustainably low prices.

Accordingly, first generics represent savings for consumers and sustainability for manufacturers. In fact, health consulting firm IQVIA projects that over the next five years, the "value" of brand drugs on track to lose patent protection exceeds $100 billion in annual sales, thereby opening new avenues for patients to save through generic competition.[9] It is essential to maximize the price competition that first generics bring to the marketplace for patients.

Policymakers recognized the importance of first generics by creating incentives for patent challenges and early generic entry in the Hatch Waxman Act, as well as a shortened priority review timeframe at

3 MedPAC. (June 2019). "Health Care Spending and the Medicare Program". Retrieved from: http://www.medpac.gov/docs/default-source/data-book/jun19_databook_entirereport_sec.pdf?sfvrsn=0

4 MedPAC. (June 2019). "Health Care Spending and the Medicare Program". Retrieved from: http://www.medpac.gov/docs/default-source/data-book/jun19_databook_entirereport_sec.pdf?sfvrsn=0

5 Medicare Part D Drug Spending Dashboard. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html

6 IQVIA Institute for Human Data Science. (May 2019). "Medicine Use and Spending in the U.S."

7 U.S. Food and Drug Administration. First Generic Drug Approvals. Retrieved from: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals.

8 Morgan Stanley. (August 30, 2019). Spec/Gx Trends in Pictures.

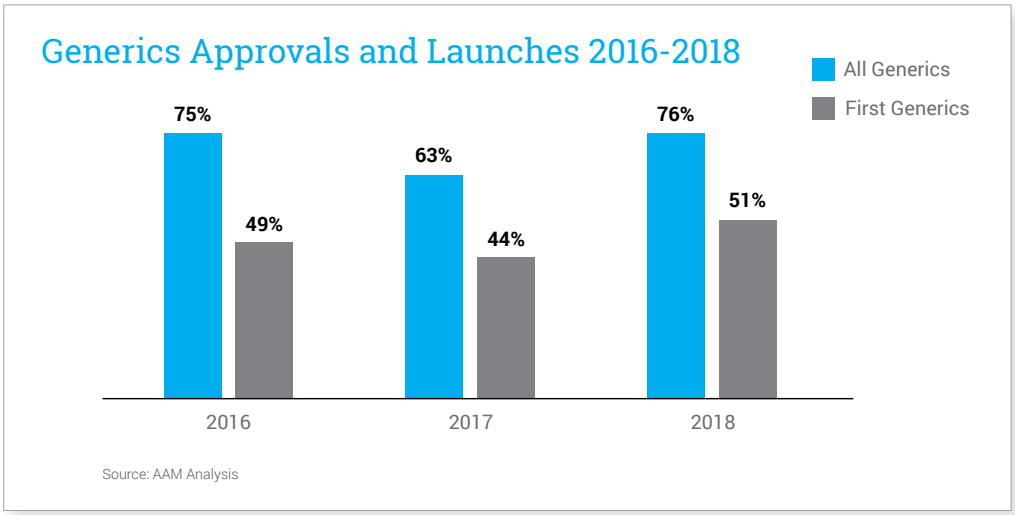
9 IQVIA Institute for Human Data Science. (May 2019). Medicine Use and Spending in the U.S.

FDA.[10,11] However, policymakers also assumed that health plans would ensure appropriate coverage of generics on generic tiers and thus drive generic uptake. While this assumption has historically been true, misguided CMS policies created loopholes over time that led to Part D plans preferring higher-cost products with high rebates at the expense of beneficiaries and the health care system.

Launch Rates for First Generics Are Alarming

At the same time FDA reports record numbers of generic approvals, there are also record numbers of approved generic applications not launching.[12] IQVIA reported that nearly 29% of generics approved between 2016-2018 did not launch.[13]

Figure 1



Unfortunately, this trend is even more pronounced among first generics.

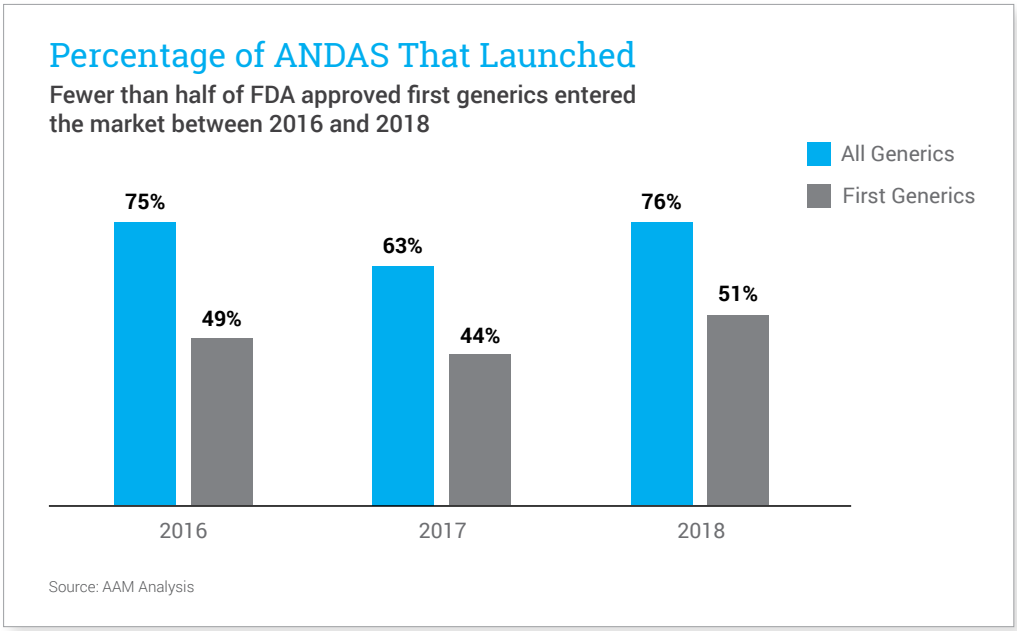
AAM reviewed FDA approvals of first generics since 2016. While the data showed a consistent increase in approvals, it also revealed that fewer than half of FDA-approved first generics entered the market between 2016 and 2018.

This trend shows no sign of abatement: As of May 2019, only 20% (5 of 25) of 2019 first generic approvals were commercially available.

12 FDA. (February 27 2019). 2018 Office of Generic Drugs Annual Report. Retrieved from: https://www.fda.gov/drugs/2018-office-generic-drugs-annual-report

13 IQVIA Institute for Human Data Science. (May 2019). Medicine Use and Spending in the U.S.

Figure 2



Those products that did launch did so at significant price savings for payers and customers. AAM found that between 2016 and 2018 first generics launched at an average list price discount of 18% compared to the brand. The savings were even greater when considering net price: First generics launched at a net price reduction of 33% less than the brand drug.[14] These savings increased further as generic prices declined rapidly.

However, defining competition through FDA approval numbers and generic price reductions alone fails to ensure competition.

Findings

Newly Launched Generics No Longer Covered on Formulary

Formulary coverage is critical to ensuring patient access to new medicines as they become available. While a patient may be able to obtain a medicine that is not on the plan's formulary, a formulary exclusion or block can serve as a significant barrier to patient use. To assess what barriers to market adoption, AAM examined whether Medicare Advantage and standalone Part D drug plans were adding first generics to formularies.

Historically, plan formularies would automatically cover a new generic medicine on a generic tier given the significant price discount provided through generic competition. However, this has not been the

14 WAC pricing information was retrieved on 06/25/19 and NSP pricing information was retrieved on 08/15/19 from IQVIA SMART. Brief from IQVIA on NSP Price: U.S. National Sales Perspectives (NSP)™ measures revenue within the U.S. pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices. The prices do not reflect off- invoice price concessions that reduce the net amount received by manufacturers.

case in recent years. In 2017, the Centers for Medicare and Medicaid Services (CMS) Part D formulary guidelines started to allow Part D plans to move generic drugs from a generic tier onto a higher tier, raising out-of-pocket costs of generic drugs, despite declining generic drug prices in the program.

Moreover, AAM's analysis found that while only half of first generics approved by the FDA entered the market, even fewer receive formulary coverage in Part D.[15] As the data in Figure 3 shows, it takes nearly three years before first generics are covered on 50% of Medicare Part D formularies. This "phase-in" period restricts patient access to lower-cost generics, denying patients savings in favor of unnecessarily high cost sharing for brand medications even though lower-cost alternatives are available.

Figure 3

Percentage of First Generics Covered on Medicare Part D Formularies, By Plan Year and Launch Year 2016-2019

	Medicare Part D Plan Year			
Launch Year	**2016**	**2017**	**2018**	**2019**
2016	22%	31%	63%	58%
2017		12%	25%	58%
2018			17%	27%

Source: Formulary data as of September in each plan. 2019 data is for the most recent months available. Analysis excluded coverage of 2019 launches that may be added to formulary through mid-year formulary updates permitted by CMS.

Overall, first generics are covered on formulary approximately 10 to 25% of the time in the first year of launch, 25 to 35% in the second year after launch and 55 to 65% in the third year after launch.[16]

> Even three years after launch, formularies exclude coverage of first generics approximately 40% of the time.

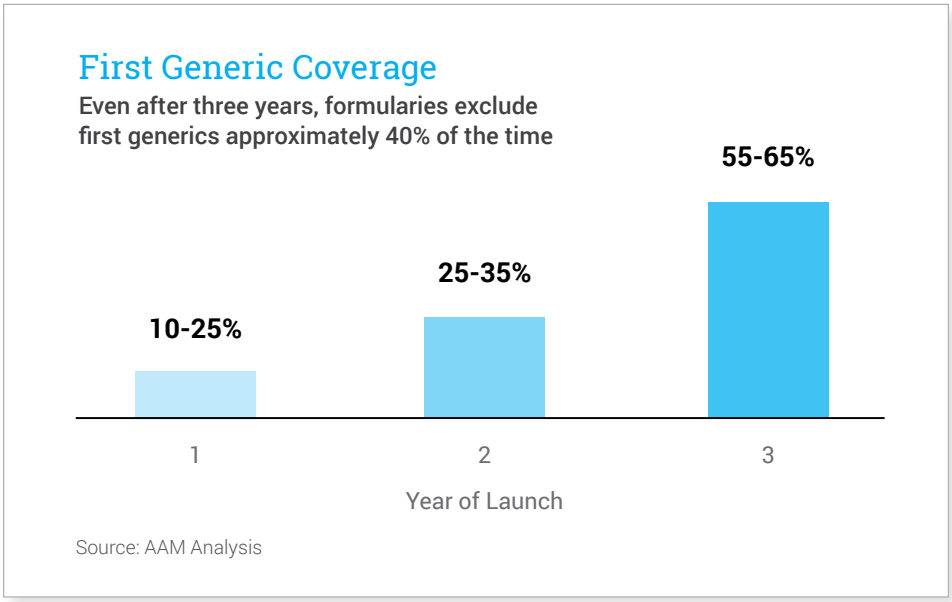
The three-year phase-in period is consistent across the years analyzed, demonstrating that first generics face an uphill battle in achieving formulary coverage in Medicare Part D.

15 In order to quantify the formulary coverage for, and subsequent patient access to, first generics in Medicare Part D, AAM analyzed all first generics that were marketed (i.e., available for purchase) from 2016 to 2019. AAM then determined the percentage of Part D formularies that included these products (at the molecule level) as covered drugs in the year of approval and subsequent years. Also, it is notable that none of these products is the subject of patent settlements.

16 Data is inclusive of first generics and subsequent generic entrants for the same molecule.

Surprisingly, formulary coverage did not appear to meaningfully increase as generic prices fell. Not only did the first generics reviewed in this analysis launch at a significant discount to the brand, but by the second year after launch, first generic net prices declined by 45% on average, yet plan coverage only improved by 9-13%. Plans are not proportionally responding to generic price decreases well after the first year of being on the market.

Figure 4



First Generics Are Being Placed on Brand Drug Tiers

These challenges extend beyond merely achieving formulary coverage. Proper tier placement is critical to beneficiary access and to attaining the full value of generics. Plans and pharmacy benefit managers (PBM) routinely encourage or discourage patient use of products based on formulary placement and have historically encouraged adoption of lower-cost generics through placement on generic tiers with lower copayments.

AAM found that once Part D plans decide to cover first generics on their formularies, they then consistently place those generics on non-generic tiers that have higher cost-sharing for seniors. In fact, first generics covered on Part D formularies are placed on brand tiers more than 50% of the time, putting them on the same or similar tier as their higher-priced brand counterparts. This means patients pay the same or more for a generic than for the higher-priced brand, which undermines the entire rationale for promoting generic competition.

> First generics that are covered on Part D formularies are placed on brand tiers **more than 50% of the time**, putting those products on the same tiers as their brand counterparts.

This trend appears to worsen as formulary coverage increases. As shown in Figure 5, the initial year of launch saw first generics placed on generics tiers the most frequently. But by the third year after launch, more formularies that covered the first generics did so on higher-cost, brand tiers. This occurred in spite of additional generic approvals and lower generic prices.

These findings echo a separate analysis recently published in the Journal of the American Medical Association (JAMA), which found 72% of Part D formularies had lower cost-sharing tiers and 30 percent of Part D formularies had fewer utilization controls on branded products with at least one generic alternative.[17]

Figure 5

Tier Placement of Covered First Generics 2016-2019

2016 Launches	Generic Tiers	Brand Tiers
2016	53%	47%
2017	43%	57%
2018	39%	61%
2019	42%	58%
2017 Launches		
2017	35%	65%
2018	34%	66%
2019	21%	79%
2018 Launches		
2018	42%	58%
2019	34%	66%

Source: AAM Analysis

AAM's data is also consistent with findings by Avalere Health that Part D plans are moving generics to higher tiers with greater patient out-of-pocket costs. As shown in Figure 6, plans have increasingly

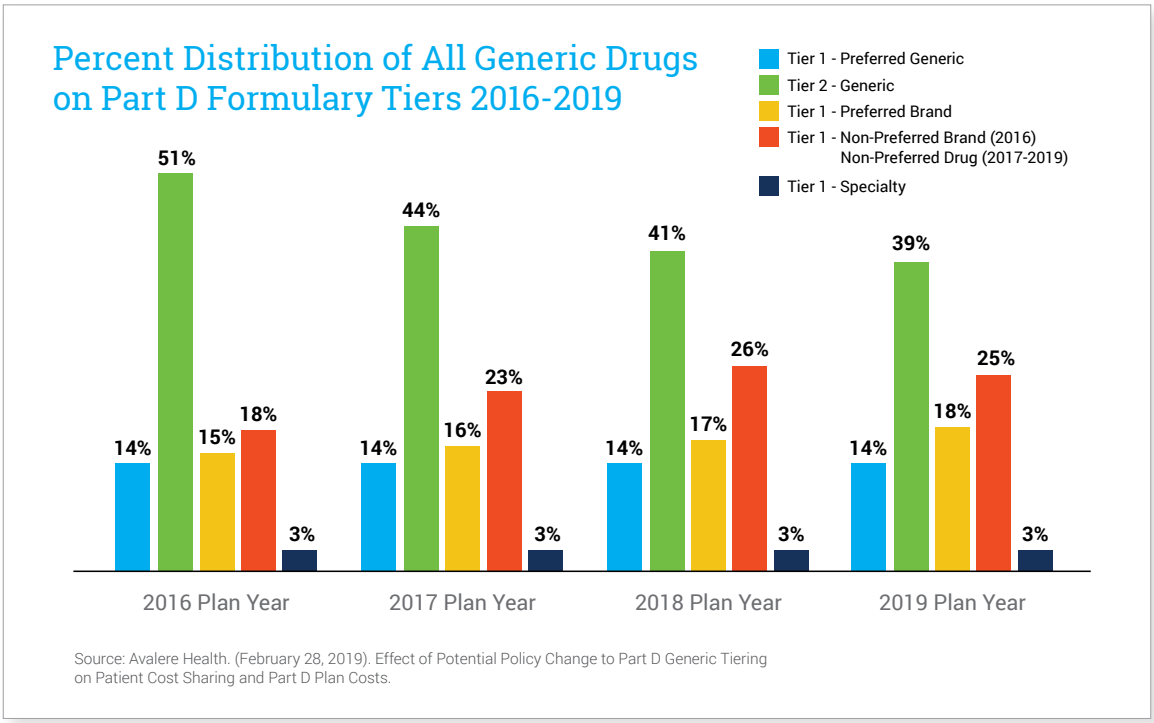
17 Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. JAMA Intern Med. Published online March 18, 2019. 179(6):832–833. doi:10.1001/jamainternmed.2018.7824

shifted generic drugs from tiers with lower copayments for patients to brand tiers with higher copayments and coinsurance.[18]

> **Patients could save more than $4 billion yearly if Part D plans simply covered generics on generic tiers.**

The practice of placing generics on higher-cost tiers has a particularly chilling effect on first generics that are intended to generate new savings, and it also drives higher patient spending. This acts as an additional barrier to generic competition and prevents beneficiaries from realizing the full value of generics. A previous analysis conducted by Avalere Health found that simply requiring generic drugs to be placed on generic tiers could have saved patients taking these medicines nearly $4.1 billion in 2019 alone.[19]

Figure 6



Source: Avalere Health. (February 28, 2019). Effect of Potential Policy Change to Part D Generic Tiering on Patient Cost Sharing and Part D Plan Costs.

18 Avalere Health. (February 28, 2019). Effect of Potential Policy Change to Part D Generic Tiering on Patient Cost Sharing and Part D Plan Costs. Retrieved from: https://avalere.com/insights/effect-of-potential-policy-change-to-part-d-generic-tiering-on-patient-cost-sharing-and-part-d-plan-costs

19 Avalere Health. (February 28, 2019). Effect of Potential Policy Change to Part D Generic Tiering on Patient Cost Sharing and Part D Plan Costs. Retrieved from: https://avalere.com/insights/effect-of-potential-policy-change-to-part-d-generic-tiering-on-patient-cost-sharing-and-part-d-plan-costs

Discussion

Reasons for Poor Coverage

Two structural features of Part D are largely accountable for these results: the availability of brand-drug rebates and the design of the Part D benefit.

The use of "rebate traps" by brand manufacturers occurs when a brand manufacturer threatens to revoke rebates it provides to the Part D plan for the brand product if the plan covers the lower-priced generic competitor. The brand manufacturer may go so far as to threaten its rebates for an entire basket of products if the plan utilizes a generic in place of the reference product.[20]

Even though the generic is entering the market at a significantly discounted price from the brand-name product, the rebate trap forces the health plan to either block the generic from the formulary or forego rebates for the brand-name product. At that point, the loss of significant rebate dollars may make it economically infeasible for a payer to cover a generic. This, in turn, leads a Part D plan to keep the first generic drug off its formulary, preventing patients from accessing the lower-priced product. And because patient out-of-pocket costs are based on list price, they are forced to pay more than necessary.

Figure 7

"Rebate Trap" Illustrated in Medicare Part D

Brand versus generic

Spending for a beneficiary who takes one prescription drug	**Brand** with list price of $12,000, 25% rebate	**Generic** with list price of $3,000, no rebate
Gross drug spending		
Beneficiary cost-sharing	$3,089	$1,050
Coverage gap discount	$2,069	$0
Covered benefits	$6,842	$1,950
Subtotal	**$12,000**	**$3,000**
Allocation of rebates and fees assuming 80% reinsurance		
Medicare reinsurance (at 80%)	$800	$0
Plan liability	$2,200	$0
Subtotal	**$3,000**	**$0**
Net effect		
Beneficiary cost-sharing	$3,089	$1,050
Medicare reinsurance after rebates	$2,529	$0
Plan liability after rebates and reinsurance	**$1,313**	**$1,950**

Source: MedPAC. (March 2017) Report to Congress: Medicare Payment Policy

20 Center for Biosimilars. (June 11, 2018). Walgreen, Kroger File Antitrust Suit Against J&J, Janssen Over Remicade. Retrieved from: https://bit.ly/2u76AKg.

Although the generic would cost less for patients and Medicare, the payer is financially incentivized to exclude the generic from its formulary due to the incentives created by the Medicare rebate sharing requirements.

Similarly, the current structure of the Medicare Part D coverage gap also can encourage payers to cover higher cost brands instead of their generic competition. In 2009, lawmakers created the Medicare Part D Coverage Gap Discount Program (CGDP). Through CGDP, brand drug manufacturers provide a 50% discount to beneficiaries in the coverage gap portion of the Part D benefit, but the discount is treated as beneficiary spending for purposes of calculating a beneficiary's true-out-of-pocket costs (TrOOP). In 2018, lawmakers increased the required discount to 70%.

MedPAC and other independent observers have noted that this benefit design can result in a beneficiary moving through the coverage gap and into the catastrophic phase of the benefit more quickly, thus reducing the Part D plan's financial liabilities and encouraging plans to prefer higher-cost drugs over lower-priced generics.[21,22]

Finally, CMS created a specialty tier intended for higher-priced brand products. Since then, new lower-priced generic and biosimilar competitors to specialty drugs are increasingly available. However, the benefit only allows a single specialty tier, limiting the ability to encourage use of specialty generics and biosimilars through different specialty tier cost sharing.

The flaws in Part D's benefit design, in combination with the perverse incentives of rebates traps, ultimately add to the obstacles facing generic competition. As a result, beneficiaries experience heightened financial responsibility because of less access to inexpensive generics.

Policymakers Can Ensure That Seniors and Medicare Benefit from Generic Price Competition

To ensure that patients have timely, affordable access to lower-priced first generics, policymakers should update the Part D program through three key steps to ensure that seniors receive the full benefit of lower-cost generics and biosimilars. These policies will meaningfully and immediately reduce out-of-pocket costs for Part D patients. They will also generate savings for the Medicare program through increased utilization of lower-priced drugs. They include:

1. Ensuring Medicare Part D plans cover new generic drugs at launch, particularly first generics;
2. Providing for placement of all generic products on tiers designated as generic and separate from higher-priced brand drugs; and
3. Creating a separate specialty tier to allow for differentiation among specialty brands versus generics and biosimilars.

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21 MedPAC. (June 2016). Report to the Congress: Medicare and the Health Care Delivery System. Retrieved from: http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf

22 In July 2019 the Senate Finance Committee included a provision to change the current Part D benefit design in the draft Prescription Drug Pricing Reduction Act (PDPRA). This provision eliminates the coverage gap and may help reduce plans' perverse incentives to favor high-cost brand products.

These policies would support greater patient access to lower-cost generics, ensuring that America's robust generics market can be sustained, and patients continue to realize substantial savings.

In 2018, about $12 billion was spent on brand-name products with new generics that had coverage rates below 25%. Accordingly, beneficiaries have already missed out on substantial out-of-pocket savings. As noted, previously a recent Avalere report analyzed Medicare claims data and determined that seniors would save $4.1 billion in 2019 alone ($16 billion from 2016-2019) if generic drugs were placed on generic tiers.[23] Moreover, seniors and Medicare would save through more rapid generic competition created by ensuring formulary placement for first-generic competitors. These policy solutions can be implemented quickly and would yield immediate savings for Medicare and beneficiaries.

Conclusion

First generics are a bellwether for patient and health care system savings and for sustainability of the industry that provides competition to expensive brand-name drugs, delivering 90% of America's prescription drugs at 22% of the cost. However, first generics face significant challenges to market sustainability – not least as a direct result of Medicare Part D formulary obstacles that undermine patient adoption. This trend harms future generic competition and deprives patients access to lower-priced generic medicines, forcing them to continue to pay for higher-cost brand drugs. Policymakers should act to ensure that America's patients, as well as the overall health care system, continue to attain the full value of lower-priced generic competition.

Methodology

The analysis relied on the FDA first generic approvals for each year of the analysis.[24] AAM confirmed that approved first generics were marketed in any given year using IQVIA data of sales in the United States.[25] That created a list approved and marketed first generics from which to conduct the analysis for 2016-2019.

Using the Medicare Part D prescription drug plan formulary, pharmacy network and pricing information files for each year, AAM calculated the percentage of Part D plan and formulary unique combinations that covered the first generics in any given year. Of those covered, AAM then determined the tier placement of those products when covered on Medicare Part D formularies.

Both stand-alone Medicare Advantage (MA) prescription drug plans (PDP) and MA managed care prescription drug plans (MA-PD) were included in the analysis.

23 Avalere Health. (February 28, 2019). Effect of Potential Policy Change to Part D Generic Tiering on Patient Cost Sharing and Part D Plan Costs. Retrieved from: https://avalere.com/insights/effect-of-potential-policy-change-to-part-d-generic-tiering-on-patient-cost-sharing-and-part-d-plan-costs

24 Approvals retrieved from FDA's public listing at https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals as of 05/23/19.

25 Marketing information retrieved from IQVIA on 06/20/19.

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