June 6, 2019

Richard E. Neal, Chairman
House Ways and Means Committee
Washington, D.C. 20510

Kevin Brady, Ranking Member
House Ways and Means Committee
Washington, D.C. 20510

Frank Pallone, Chairman
House Energy and Commerce Committee
Washington, D.C. 20510

Greg Walden, Ranking Member
House Energy and Commerce Committee
Washington, D.C. 20510

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady and Ranking Member Walden:

On behalf of the Association for Accessible Medicines (AAM) and its member companies, we applaud your work to modernize the Medicare Part D prescription drug program. America's seniors rely on Medicare for access to life-saving prescription medicines, and FDA-approved generic drugs such as those manufactured by our members are critical to providing affordable drugs within the program. Generics now represent 90 percent of all prescriptions dispensed in the United States but account for only 22 percent of all prescription drug spending.[1] In the last ten years alone, generic drugs have saved patients and the U.S. health care system nearly $2 trillion – including $293 billion in 2018 just in Medicare.[2]

Indeed, patients pay less than $6 for a generic prescription compared to more than $40 for a brand.[3] And because patients are 2 to 3 times more likely to abandon a brand prescription, generic medicines contribute to improved health outcomes through medication adherence.[4]

Since the enactment of Part D sixteen years ago, there have been important changes in medicine and the prescription drug marketplace. These changes include the advent of new FDA-approved biosimilar medicines that are poised to continue to make lifesaving therapies more accessible to patients. Nowhere is the need for lower-priced alternatives, and the challenges facing them, more real than among high-priced brand-name specialty medicines, including biologic and complex non-biologic medicines.

Specialty medicines as a group are now responsible for more than 49 percent of all spending on medicines.[5] For instance, brand-name biologics, many of which are specialty medicines, are the most rapidly growing segment of increasing prescription drug costs in the United States, which

[1] AAM, "Generic Drug Access & Savings Report," May 2019.
[2] *Ibid*.
[3] *Ibid*.
[4] *Ibid*.
[5] IQVIA Institute for Human Data Science: "Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023." (May 2019).

reached $125.5 billion in 2018.[6] And while only 2.2 percent of America's patients use biologics today, they already account for about 26 percent of prescription drug spending in the United States.[7]

By the year 2025, more than 70 percent of drug approvals are expected to be biological products.[8] Experts estimate that FDA-approved biosimilars could save $54 billion over the next 10 years. That means that 1.2 million U.S. patients could have greater access to lifesaving cures.[9] Women, lower income and elderly patients will particularly benefit from access to biosimilar medicines.[10]

Another key change impacting Medicare program has been the growth of brand-name pharmaceutical rebates and their role in health plan formulary design. Too often, these rebates create perverse incentives for anti-competitive exclusion of lower priced biosimilar and generic medicines from formularies, resulting in higher out-of-pocket costs for seniors.

As you modernize Medicare, we recommend the following steps to ensure that the program's policies and incentives are aligned to reduce out-of-pocket costs for seniors through greater generic and biosimilar adoption.

1. Ensure automatic plan coverage and preferred formulary placement of lower-priced generics and biosimilars in Part D,
2. Encourage provider adoption of biosimilars in Part B, and
3. Improve patient utilization of generics and biosimilars in Part B and D.

Ensure Automatic Plan Coverage and Preferred Formulary Placement of Generics and Biosimilars to Lower Patient Spend in Medicare Part D

We strongly encourage the Committees to ensure that Part D plans are actively encouraging the use of lower-cost generic and biosimilar medicines by directing CMS to:

- require plans to automatically include lower-priced generic and biosimilar medicines on generic formulary tiers immediately after launch;
- ensure that plans place generics and biosimilars on separate tiers with lower cost-sharing than brand drugs; and
- provide for plans to establish a more favorable generic and biosimilar specialty tier.

These steps are critical to address recent Medicare Part D plan formulary design trends that undermine generic and biosimilar adoption.

[6] IQVIA Institute for Human Data Science: "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022." (April 2018).
[7] *Ibid*.
[8] U.S. Pharmacist, "Biosimilars: Current Approvals and Pipeline Agents," October 2016.
[9] The Biosimilars Council, "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," August 2017.
[10] *Ibid*.

Plans are Putting Generics on Brand Formulary Tiers

Historically, plans have used CMS flexibility in formulary design to encourage the use of lower-cost generic drugs. However, recent data from Part D indicates that generic drugs are increasingly being placed on higher tiers with higher cost-sharing, sometimes in a disadvantaged position compared to the higher cost brand.

In a study released last year, health care consulting firm Avalere Health found that the percentage of generic drugs placed on tier 1 – the lowest cost-sharing available for patients – had declined precipitously, from 71 percent in 2011 to only 19 percent in 2015.[11] By 2015, almost half (46 percent) of all generic drugs were placed on tier 2 and the remaining 35 percent of generic drugs were placed on tier 3 or higher.[12] This occurred equally among both high and low-cost generics even though prices for generic drugs have remained flat or fallen.[13]

More recently, Avalere examined Medicare data from 2016 – 2018. Their analysis shows that in 2016, plans covered generic drugs on the generic tier (Tier 2) 51 percent of the time – by 2019, that number had declined to only 39 percent of the time. This was accompanied by continued growth in the placement of generics on Tiers 3 and 4. In 2019, 43 percent of all generics were placed on either Tier 3 (Preferred Brand) or Tier 4 (Non-Preferred Drug) with higher cost-sharing levels.[14]

These practices are particularly harmful to vulnerable Medicare beneficiaries. In 2019, "the 2 generic tiers had a weighted average cost sharing of $2 and $7, respectively. Branded tiers had substantially higher cost sharing, with the non-preferred drug tier averaging 39 percent coinsurance."[15] From 2011 to 2015, this tactic has led to a 97 percent increase – $6.2 billion – in additional out-of-pocket spending by Medicare beneficiaries, even though prices for those drugs were largely unchanged or declined.[16]

As a result, Medicare beneficiaries are now forced to spend more for drugs that cost only a fraction of the price of their brand counterparts and are prevented from realizing the full value of low-cost generic medicines.

Exclusionary Brand Rebate Contracts are Blocking Patient Access to Newly Launched Generics and Biosimilars

Earlier this year, CMS noted its expectation "that Part D sponsors prioritize formulary placement for generics and biosimilars through favorable tier placement relative to branded products".[17] Unfortunately, generic and biosimilar medicines face increasing challenges to being included a

[11] Avalere Health: "Generic Drugs in Medicare Part D: Trends in Tier Structure and Placement." May 22, 2018). Available at: https://bit.ly/2kx8cIP.
[12] *Ibid*.
[13] *Ibid.*
[14] Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG.
[15] *Ibid.*
[16] *Ibid*.
[17] CMS "Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Call Letter".

formulary in the first place – often the result of anti-competitive brand drug rebate traps, which are conditioned on complete formulary exclusion of a lower-cost generic or biosimilar medicine. This practice blocks patient access to lower-cost generic or biosimilar products and imposes additional costs on the U.S. health care system. The most pernicious form of this "rebate trap" is "bundled" rebates.

As we have seen, the manufacturer of an originator product may even withdraw the rebates on a basket of products ("bundling") in the event that the contracted entity utilizes a biosimilar or generic in place of the reference product.[18] If brand-name manufacturers can eliminate the financial viability of manufacturing less-expensive competitor products, there will be no incentive for future investment, effectively ensuring long-term market protection far beyond congressional intent. This is why both Secretary Azar and former-FDA Commissioner Gottlieb have criticized the use of "rebate traps." For instance, Gottlieb noted:

> *"Manufacturers are using several schemes to hamstring biosimilar competition… restrictive contracting, rebating, and distribution agreements deter coverage and reimbursement…the net result is a lopsided playing field that disincentives biosimilar developers from making the sizable investment in bringing such products to market. I am concerned this will lead to reduced competition in the long-run and unsustainable costs."*[19]

In addition, for biosimilars, there have been examples of health plans requiring patients to "fail first" on a reference product before they can access the biosimilar. This is even though FDA's licensure of a biosimilar means that the agency has deemed that there is no meaningful clinical difference between the biosimilar and the reference product. As a scientific matter, it would be clinically irresponsible for a provider to prescribe a patient a biosimilar once they have failed on the reference product, given that the biosimilar has the same active ingredient and mode of action as the reference product. Thus, access to a lower priced biosimilar is effectively blocked.

This type of rebate-driven utilization management furthers no medical or policy goal and only serves to further deter market entry of lower priced generic and biosimilar competition. Ensuring lower cost-sharing and preferred formulary placement for biosimilars and generics could help expand patient access to needed medicines.

The Standard Part D Benefit Design Does Not Account for Newer, Specialty Generics and Biosimilars

These challenges are compounded by the lack of a dedicated specialty tier with lower cost-sharing for new biosimilars and generics that exceed the specialty cost threshold. The ability for plans to impose a lower coinsurance rate on generic and biosimilar products through the establishment of a generic specialty tier, as well lower cost-sharing for those biosimilars that do not meet the specialty threshold on lower cost-sharing generic tiers, would help to mitigate high

[18] *Pfizer Inc., v. Johnson & Johnson and Janssen Biotech*. United States District Court Eastern District of Pennsylvania, Aug. 2017, www.bigmoleculewatch.com/wp-content/uploads/sites/2/2017/09/https-ecf-paed-uscourts-gov-doc1-153116591664.pdf.
[19] CNBC Interview of FDA Commissioner Gottlieb, March 28, 2018. Available at: https://cnb.cx/2pNVVlh.

costs for patients and drive utilization toward lower-cost alternatives.

Today, there are more are more than 60 generics used in Part D that meet the CMS specialty threshold.[20] As manufacturers invest in bringing generic and biosimilar competition to high-priced specialty drugs and biologics facing patent and exclusivity expiration, these numbers will only increase. Therefore, it is essential to create a market that encourages investments in developing generic or biosimilar alternatives to high priced brand specialty drugs. This will be critical to ensuring a sustainable market and increased patient access to new specialty generics, biosimilars, and interchangeable biologics.

Currently, generics exceeding the specialty tier threshold are eligible for specialty tier placement. However, beneficiaries are disadvantaged by the presence of only a single specialty tier limits the ability of health plans to encourage the use of lower cost generics or biosimilars through preferred formulary placement.

The Committee Should Ensure Automatic Generic and Biosimilar Formulary Placement

To address these challenges, the Committee should direct CMS to:

- require Part D plans to automatically include lower-priced generic and biosimilar medicines on generic formulary tiers immediately after launch;
- ensure that Part D plans place generics and biosimilars on separate tiers with lower cost-sharing than brand drugs; and
- provide for Part D plans to establish a more favorable generic and biosimilar specialty tier.

This would support greater patient access to lower priced generics and biosimilars, lowering out-of-pocket costs for America's patients and avoiding beneficiary confusion. It would also prevent health plans from using commoditized generics to manipulate the drug benefit program's formulary structure by placing generic drugs on higher tiers and disincentivizing their use relative to brands.

Such a shift would promote savings for the Medicare Part D program as more patients use lower-cost generics and promote a robust biosimilar and specialty generic market.

Ensuring Generic Formulary Placement Will Save Patients More than $4 Billion Annually

These changes are important to reducing patient out-of-pocket spending as well as preparing the program for the future. Ensuring placement of generic drugs on generic tiers alone would have saved beneficiaries $15.6 billion over the past three years - and $4.1 billion in out-of-pocket savings in 2019 alone.[21]

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[20] Analysis of Medicare Part D 2018 negotiated drug pricing files. Negotiated price was averaged across all plans offering each generic to arrive at an average negotiated price for the generic chemical entity.
[21] Avalere Health: Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs." February 28, 2018. Available at: https://bit.ly/2IDOdqG.

This can be done without increasing costs or upsetting the ability of plans to meet actuarial equivalence tests in the Part D bid pricing tool. Generic drugs only account for 16 percent of total prescription drug spending in Medicare Part D, and Avalere estimated that this policy change would result in a 4.5 percent increase in Part D plan prescription drug liabilities.[22] By comparison, the policy change would produce more than $4 billion in annual out-of-pocket savings for beneficiaries.[23]

Moreover, the HHS Assistant Secretary for Planning and Evaluation (ASPE) found that beneficiaries and taxpayers could have saved almost $3 billion in 2017 if all Medicare beneficiaries had taken advantage of generic substitution opportunities instead of filling prescriptions with brand-name drugs.[24]

Finally, ensuring that new generics and biosimilars are placed on formulary immediately upon launch, as well as providing for a dedicated generic and biosimilar specialty tier, would result in out-of-pocket savings for seniors as well as lower spending for the program. This would help Medicare realize the full value of biosimilar competition, conservatively estimated at producing savings of $54 billion over the next ten years.[25]

Ensuring Generic & Biosimilar Formulary Placement Would Support Robust Competition

Importantly, these policies still allow Part D plans to utilize their negotiating power to achieve lower prices and set their formularies within existing Medicare requirements.

Moreover, CMS gives plans a range of tools to manage costs as a means to keep premiums flat while still covering high priced brand drugs. Recently, CMS has taken important steps to give plans further flexibility[26], and plans should be aggressively working to manage high brand drug prices. While plan sponsors and CMS must meet and enforce program requirements, beneficiaries who take generic drugs should not be held financially responsible for pricing decisions made by brand manufacturers. Additionally, Part D plans should not have the ability to "mask" brand drug price increases by moving low-cost generic products to higher cost-sharing tiers.

Encouraging Provider Adoption of Biosimilars in Medicare Part B

Modernizing Medicare also requires examining opportunities to lower drug spending in Medicare Part B. Biologics constitute the majority of Part B drug costs, and significant savings can be achieved if appropriate systemic levers are in place to maximize the potential of biosimilar medicines. Therefore, it is important to ensure appropriate incentives for biosimilar utilization in

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[22] *Ibid*.
[23] *Ibid*.
[24] U.S. Department of Health and Human Services Office of the Assistance Secretary for Planning and Education. Data Point: Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D (July 23, 2018). Available at: https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf. Accessed: February 13, 2019.
[25] Mulcahy, Andrew, et al. "Biosimilar Drugs May Reduce U.S. Health Spending by $54 Billion." *RAND Corporation*, 22 Oct. 2017, www.rand.org/pubs/perspectives/PE264.html.
[26] CMS "Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)".

Part B.

CMS has taken significant steps to encourage the development of a robust biosimilars market such as providing individual codes for biosimilars and making all biosimilars eligible for transitional pass-through status. These policies are designed to support the emerging biosimilars market and provide manufacturers an opportunity to familiarize prescribers with biosimilars.

However, Medicare Part B statutory payment rules pay providers who administer biosimilars at the biosimilar's average sales price (ASP) plus 6% of the reference biologic's ASP. While this ensures that providers are not penalized when they prescribe a lower cost biosimilar, it also means that there is little incentive to prescribing a lower priced biosimilar over a higher price brand-name biologic. Changes that increase physician payment for lower priced biosimilars relative to the brand-name would help increase biosimilar utilization in Medicare Part B.

To align both Medicare Part B program savings and biosimilar market development, the draft legislation should include a provision for providers in Medicare Part B to share in the savings generated from using lower-cost biosimilar products (compared to the brand-name biologic), as both an incentive towards biosimilar utilization and a way to drive Medicare Part B program savings.

A biosimilar shared savings program in Medicare Part B would create a financial incentive for providers to administer biosimilars and guarantees additional savings to Medicare. Under this program, providers would share in the savings generated by the difference in ASP for the biosimilar, compared to the ASP of its brand-name biologic, when the biosimilar's ASP is lower than the reference ASP. Unlike other proposals, Medicare Part B would be largely guaranteed to see savings from this proposal, as the shared savings payments to providers are only available when the biosimilar ASP is less than the brand-name biologic ASP.

Modeled after other successful shared savings programs in Medicare and eliminating biosimilar Part B cost sharing, this proposal would follow a similar path towards incenting providers towards administration of lower cost, higher value therapies. At the same time, providers administering reference biologics are not penalized for that utilization, which still provides them the flexibility to continue their current prescribing practices without being financially penalized.

Improving Patient Utilization of Generics and Biosimilars in Medicare Parts B and D

Congress Should Eliminate Biosimilars Cost Sharing

Congress should also eliminate cost sharing for biosimilars in Medicare Part B. Today, patients pay less for Medicare Part B biosimilars compared to reference biologics because that biosimilars ASP are, on average, 18% lower than their respective reference biologics ASP. However, the difference in cost sharing is rarely substantial enough, nor does the patient fully understand the availability of a biosimilar, for that cost sharing difference to drive patients to request a biosimilar. While some Part B beneficiaries are already able to reduce their 20 percent cost sharing via supplemental coverage, eliminating cost sharing should encourage physicians to use biosimilars for their patients. Additionally, as patients are made aware of this provision,

patient demand for biosimilars should dramatically increase their utilization. This, in turn, will benefit not only patients, but will also generate meaningful savings for the Medicare program and taxpayers.

Congress Should Increase Generic Drug Adoption Among Low-Income Medicare Beneficiaries

Likewise, within Part D, there are opportunities to generate additional savings for patients and the program through greater patient adoption of generics.

MedPAC has estimated that "nearly 70 percent of Medicare's total spending for Part D plans was on behalf of the 30 percent of Part D enrollees who receive the LIS."[27] Compared with other Part D beneficiaries, Low-Income Subsidy (LIS) enrollees not only fill more prescriptions but fill more expensive prescriptions.

While it is true that LIS beneficiaries tend to have greater health needs requiring more prescriptions, LIS beneficiaries typically utilize more expensive brand-name drugs even when lower-cost options such as biosimilars and generics are available. This seems to occur, at least in part, because Medicare Part D plans have limited ability to modify cost sharing for LIS enrollees. This is evidenced by the significant differences in generic dispensing rates between the LIS population versus all Medicare Part D beneficiaries. MedPAC analysis of Medicare Part D Prescription Drug Event data revealed for the antipsychotic therapeutic drug class that only 58 percent of total LIS enrollees utilized generics versus 78 percent of all Medicare Part D enrollees using an antipsychotic.[28] This difference in generic utilization appears across multiple therapeutic classes when generic equivalents are available and represents a missed opportunity for patients and the federal government.

MedPAC has recommended changes to Medicare Part D cost-sharing policies for LIS enrollees to improve generic utilization. Specifically, MedPAC recommended that Congress:

- "modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;
- direct the Secretary to reduce or eliminate cost-sharing for generic drugs, preferred multisource drugs, and biosimilars; and
- direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every two years."

We encourage Congress to modify the Medicare Part D LIS copayment structure to achieve this goal that has been endorsed by a range of nonpartisan experts, including MedPAC, the Bipartisan Policy Center and Simpson-Bowles Moment of Truth Project as well as included in budget proposals from the current and previous Administration. Not only would addressing this issue could reduce Medicare spending, but it would also benefit Medicare beneficiaries through

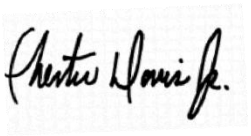
[27] MedPAC. June 2016 Report to the Congress. Available at: https://bit.ly/2tXyQzP.
[28] MedPAC. June 2016 Report to the Congress. Available at: https://bit.ly/2tXyQzP.

lower cost-sharing expenses.

Conclusion

Again, we commend you for your work to improve the Medicare program. Generic and biosimilar medicines are critical to ensuring continued affordable patient access. We look forward to working with you in this effort.

Sincerely,



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