



June 6, 2019

The Honorable Richard Neal  
Chairman  
Committee on Ways and Means  
1102 Longworth House Office Building  
United States House of Representatives  
Washington, DC 20515

The Honorable Kevin Brady  
Ranking Member  
Committee on Ways and Means  
1102 Longworth House Office Building  
United States House of Representatives  
Washington, DC 20515

The Honorable Frank Pallone  
Chairman  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
United States House of Representatives  
Washington, DC 20515

The Honorable Greg Walden  
Ranking Member  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
United States House of Representatives  
Washington, DC 20515

Re: Joint committee request for legislative proposals to improve and reform Medicare Part D Program

Dear Chairmen Neal and Pallone and Ranking Members Brady and Walden:

Mylan appreciates the opportunity to provide comments in response to the Committees' request for ideas to improve and reform the Medicare Part D program. We applaud the Committees' interest in seeking ideas to better align Part D program incentives and improve the structure and benefits for Medicare beneficiaries and taxpayers, including promotion of lower-cost generic alternatives.

Mylan is one of the largest providers of prescription generic medicine in the U.S. and has one of industry's largest generic portfolios and now biosimilar portfolios. Mylan's generic medicines saved the U.S. \$50 billion in the last two years based on IQVIA's annual savings reports for 2016 and 2017. Nearly \$15 billion of those savings were to the Medicare program. Mylan's generics saved Medicare Part D \$6.4B in 2017 based on IQVIA 2017 prescription sales data and AAM 2017 generic savings data.

As Congress considers opportunities to modernize the Part D program and ensure that incentives are appropriately aligned to benefit seniors, we urge the Committees to explore legislative solutions that advance patient access to lower-cost generics and biosimilars. Unfortunately, recent formulary design changes and the increasing use of rebates by brands after generic (and biosimilar) launch is increasingly leading to generics either not being added to Part D formularies after launch, despite lower generic pricing, or generics are being placed on non-generic tiers with higher out-of-pocket costs for seniors. In the case of specialty medicines – the highest cost drugs in the US - Part D plans have not created dedicated formulary tiers for specialty generics and biosimilars causing seniors to pay the same cost sharing as the higher cost brand.

As a result of these practices, Part D seniors suffer serious financial consequences:

- **Nearly half of all new first generics approved since 2016 were not covered on Part D formulary tiers at launch** based on a review of all of the first generic launches in the U.S. since 2016.<sup>1</sup> When the first generic was finally added to formulary—which could be up to two years after launch—the generic often was not added to a generic tier, but instead placed on a brand tier. This has deprived seniors of billions of savings that could have been achieved through the use of lower cost generics.
- **Two recent studies from Avalere found that Part D seniors paid \$22 billion in extra out-of-pocket costs from 2015-2019** because their lower cost generic drugs were placed on brand drug tiers with higher out of pocket costs for seniors.
- **Specialty generics have alarmingly low generic utilization for the costliest drugs.** Of the Top 30 specialty medicines by spend in 2018, **only two Part D drugs have specialty generic competition. In both cases, the generic market share has not exceeded 36%** (much lower than the historic generic average of 90%).

Without Congressional action to address these structural issues that no longer favor lower cost generics and biosimilars in Medicare Part D, seniors will continue to face unnecessary and increasing out-of-pocket costs within Part D and the savings associated with access to lower-cost generics and biosimilars will be greatly diminished. Mylan urges the Committees to enact the following changes to the Medicare Part D program to reverse these practices:

1. Require lower-cost generics and biosimilars be included on Part D plan formularies immediately upon launch;
2. Ensure generic drugs are included on generic-only formulary tiers so that patients are not charged the higher brand cost sharing rate; and
3. Create a dedicated specialty tier for specialty generics and biosimilars with meaningfully less cost-sharing than the specialty tier for branded specialty drugs.

Additionally, Mylan appreciates the Committees efforts to lower patients' out-of-pocket costs by eliminating cost-sharing once beneficiaries reach the catastrophic phase of the Part D program. To ensure the draft bill does not have the unintended impact of exacerbating the incentive for seniors to receive higher-cost brand drugs over generics and biosimilars that provide meaningful cost savings for patients and the Medicare program, Mylan recommends the Committees adopt the three formulary design solutions identified above and also incorporate a provision in the draft bill to ensure that patients who use generic drugs in the coverage gap are credited with the same true out-of-pocket (TrOOP) spending as they would receive if they used the branded drug equivalent. This important policy will eliminate the perverse economic incentives for patients to use higher cost brand drugs over less expensive generics and biosimilars in order to reach the catastrophic phase at a faster rate. We believe these measures are important to include to ensure the goals of the draft bill are achieved.

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<sup>1</sup> First generic approvals from FDA for 2016-2019 accessed from FDA website (<https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/andgenericdrugapprovals/default.htm>; launches determined utilizing press releases and IQVIA sales data from 2016-2019; Formulary placement determined from AARP, SilverScript, and Aetna plan formularies available through Q1Medicare.com: <https://q1medicare.com/PartD-BrowseMedicarePartDPlanFormulary.php>. Accessed 04/03/2019. Humana plan formularies available at: <https://www.humana.com/pharmacy/prescription-coverages/medicare-drug-list>. All Humana formularies. Accessed 04/03/2019. WellCare Classic formulary available through FormularyNavigator.com: <https://client.formularynavigator.com/Search.aspx?siteCode=3119159574>. Accessed 04/03/2019. Kaiser Permanente formulary available at: [https://medicare.kaiserpermanente.org/medicare/pdfs/plans\\_current/comprehensive\\_formulary.pdf](https://medicare.kaiserpermanente.org/medicare/pdfs/plans_current/comprehensive_formulary.pdf). Accessed 04/03/2019.

Expanded comments on these key policy proposals to improve Part D and the proposed out-of-pocket cap legislation are attached below and focused in two sections:

- I. Ideas to improve Medicare Part D program for seniors and taxpayers; and
- II. Feedback on draft legislation to cap out-of-pocket costs and lower the government's share during the catastrophic phase.

Mylan appreciates the opportunity to comment on the joint Ways and Means and Energy and Commerce Committees' efforts to address the Medicare Part D program. We look forward to working with both Committees on pursuing policies that will reduce drug prices and facilitate greater patient access to lower cost generics and biosimilars. Should you have any questions, please do not hesitate to contact David Marin, Head of Government Affairs, either via phone, 202-212-9566, or email, [David.Marin@mylan.com](mailto:David.Marin@mylan.com).

Sincerely,

David Marin  
Head of Government Affairs



Marcie McClintic Coates, JD, MBA  
Head of Global Policy



## **I. Ideas to Improve Medicare Part D Program and Encourage Use of Lower Cost Generics and Biosimilars**

### **A. Concerning trends in Medicare Part D**

Generic competition is a market-based American solution that has shown incredible savings of \$1.79 trillion over the last decade according to IQVIA. For prescriptions picked up at the pharmacy counter, the U.S. has historically had the highest generic utilization rates in the world – generics make up nearly 90% of prescriptions but represent only 23% of prescription spend.<sup>2</sup> On average, the patient copay for a generic drug is just \$6.06 versus \$40.30 for brands.<sup>3</sup>

The savings offered by generics are in large part due to the structural favoring throughout the health care system of lower cost generics, including in plan benefit design to help encourage utilization of FDA approved generics that will, in turn, enhance patient access and lower costs. This cost-saving, foundational element of health care is important across all aspects of the U.S. system, including pharmacy benefits in Part D and across Medicare Advantage.

Alarming, this success is quickly eroding, including in Part D, due to dramatic changes in formulary practices that have traditionally favored lower cost FDA approved generics over branded medicines. As demonstrated further below, generics and biosimilars are now experiencing significant challenges in gaining and sustaining market share in Medicare, despite their higher value as cost-competitive alternatives.<sup>6</sup>

Historically, once companies launched lower cost FDA approved generics, these products would go on formulary on a lower cost generic tier soon after launch and patients would immediately garner the benefits of generic competition through lower out-of-pocket costs. Unfortunately, this is no longer the case as a result of formulary trends that are not even adding generics to formularies or instead placing lower cost generic drugs onto brand drug tiers (now confusingly labeled as just “drug” tiers) with much higher patient cost sharing. These practices are further expanded with the increasing use of rebates as a means for brands to receive more favorable formulary treatment over generics and biosimilars. Ending practices that discourage the use of generics and biosimilars are vitally important to ensure lower out-of-pocket costs for Part D beneficiaries, more competition through a vibrant generics and biosimilars market, and the future solvency of Medicare. As described further below, these issues are only exacerbated for specialty generics and biosimilars which currently lack any structural way in Part D to encourage use of these lower cost options without a dedicated, more favorable tier for specialty generics and biosimilars.

These practices are undermining what has long been, far and away, the most effective mechanism for controlling drug prices in the United States: generic competition. They also threaten the promise of biosimilars to bring down high prices for branded biologics.

Research shows these trends have serious financial impact for seniors:

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<sup>2</sup> Association for Accessible Medicines, 2018 Generic Drug Access & Savings in the U.S., 2018, available online at: [https://accessiblemeds.org/sites/default/files/2018\\_aam\\_generic\\_drug\\_access\\_and\\_savings\\_report.pdf](https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf)

<sup>3</sup> Ibid.

- **Nearly half of all new first generics approved since 2016 were not covered on Part D formulary tiers at launch** based on a review of all of the first generic launches in the U.S. since 2016.<sup>4</sup> When the first generic was finally added to formulary—which could be up to two years after launch—the generic often was not added to a generic tier, but instead placed on brand tiers.
- **Part D Seniors paid \$22 billion in extra out-of-pocket costs** as a result of their lower cost generic drugs being placed on brand drug tiers according to recent analyses by Avalere.
- **Specialty generics have alarmingly low generic utilization for the costliest drugs.** Of the Top 30 specialty medicines by spend in 2018, **only two Part D drugs have specialty generic competition. In both cases, the generic market share has not exceeded 36%.**

Consequently, to achieve the goal of lower patient costs and encourage use of lower cost generics and biosimilars, we encourage you to adopt legislation which incorporates three critical measures for seniors, including:

1. **Automatic coverage of lower cost generic and biosimilar medications on Part D plan formularies immediately after launch;**
2. **Placement of generics on generic-only formulary tiers with meaningful differences in cost-sharing levels versus the brand; and**
3. **Creation of a dedicated specialty tier for specialty generics and biosimilars with meaningfully less patient cost-sharing than the specialty tier for branded specialty drugs.**

#### 1. **Automatic coverage of lower cost generic and biosimilar medications on Part D plan formularies immediately after launch**

Generics and biosimilars are increasingly experiencing significant challenges in gaining and sustaining market share, particularly in Part D despite their higher value as a result of concerning formulary trends and brand rebates that are now continuing after the launch of generic or biosimilar competition. As noted above, historically, under Part D, generic medicines have been added to more preferred formularies immediately upon FDA approval and placed on favored tiers to encourage maximum generic utilization, as well as offer the most savings for payors along with the lowest out-of-pocket costs for patients. Unfortunately, lower-cost generics are increasingly not being covered on formularies or are covered now on higher cost-sharing previously brand only tiers.

A look at first generic launches over the last couple of years against some of the highest spend brand medicines demonstrate this trend. **A review of all of the first generic launches since 2016 shows that nearly 50% of the time, the top 10 Part D plans DID NOT EVEN ADD the generic to formulary at launch**

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<sup>4</sup> First generic approvals from FDA for 2016-2019 accessed from FDA website (<https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/andgenericdrugapprovals/default.htm>; launches determined utilizing press releases and IQVIA sales data from 2016-2019; Formulary placement determined from AARP, SilverScript, and Aetna plan formularies available through Q1Medicare.com: <https://q1medicare.com/PartD-BrowseMedicarePartDPlanFormulary.php>. Accessed 04/03/2019. Humana plan formularies available at: <https://www.humana.com/pharmacy/prescription-coverages/medicare-drug-list>. All Humana formularies. Accessed 04/03/2019. WellCare Classic formulary available through FormularyNavigator.com: <https://client.formularynavigator.com/Search.aspx?siteCode=3119159574>. Accessed 04/03/2019. Kaiser Permanente formulary available at: [https://medicare.kaiserpermanente.org/medicare/pdfs/plans\\_current/comprehensive\\_formulary.pdf](https://medicare.kaiserpermanente.org/medicare/pdfs/plans_current/comprehensive_formulary.pdf). Accessed 04/03/2019.

as provided in the chart below.<sup>5</sup> **When the generic was later added to formulary—which could be up to two years after launch—the generic was often added to a non-generic drug tier with higher patient out of pocket cost.**

Additionally, when looking at some of the highest spend Part D drugs which now have generic competition on the market, nearly 13.4 million (74%) of the 18.1 million beneficiaries in the top 10 Part D plans did not have any formulary coverage for the lower cost generic or the generic was placed on brand drug tier in 2018 as noted in the chart below. In 2016, Medicare spent almost \$4.5 billion on these three brand medications alone before generic entry.

2018 PART D FORMULARY COVERAGE FOR TOP 20 PART D HIGHEST SPEND MEDICINES WITH GENERIC COMPETITION <sup>9</sup>							
PART D TOP 10 PLANS	BENEFICIARY LIVES COVERED	COPAXONE® (PART D SPEND = \$1.4B)		ZETIA® (PART D SPEND = \$1.5B)		RENVELA® (PART D SPEND = \$1.5B)	
		BRAND WAC \$7,114	GENERIC WAC \$1,950 (2 generics)	BRAND WAC \$345	GENERIC WAC \$9 (11 generics)	BRAND WAC \$1,524	GENERIC WAC \$490 (11 generics)
AARP MedicareRx Preferred PDP	2,452,573	TIER 5	TIER 5	NOT COVERED	TIER 2	TIER 3	NOT COVERED
Humana Walmart Rx PDP	2,438,523	TIER 5	NOT COVERED	NOT COVERED	TIER 3	TIER 3	NOT COVERED
Humana Preferred RX PDP	1,646,478	TIER 5	NOT COVERED	NOT COVERED	TIER 3	TIER 3	NOT COVERED
AARP Medicare	1,383,990	TIER 5	TIER 5	NOT COVERED	TIER 2	TIER 3	NOT COVERED

<sup>5</sup> First generic approvals from FDA for 2016-2019 accessed from FDA website (<https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/andgenericdrugapprovals/default.htm>; launches determined utilizing press releases and IQVIA sales data from 2016-2019; Formulary placement determined from AARP, SilverScript, and Aetna plan formularies available through Q1Medicare.com: <https://q1medicare.com/PartD-BrowseMedicarePartDPlanFormulary.php>. Accessed 04/03/2019. Humana plan formularies available at: <https://www.humana.com/pharmacy/prescription-coverages/medicare-drug-list>. All Humana formularies. Accessed 04/03/2019. WellCare Classic formulary available through FormularyNavigator.com: <https://client.formularynavigator.com/Search.aspx?siteCode=3119159574>. Accessed 04/03/2019. Kaiser Permanente formulary available at: [https://medicare.kaiserpermanente.org/medicare/pdfs/plans\\_current/comprehensive\\_formulary.pdf](https://medicare.kaiserpermanente.org/medicare/pdfs/plans_current/comprehensive_formulary.pdf). Accessed 04/03/2019.

<b>Complete* MA</b>							
<b>HumanaChoice Medicare MA</b>	1,077,995	TIER 5	<b>NOT COVERED</b>	TIER 4	<b>TIER 3</b>	TIER 2	<b>NOT COVERED</b>
<b>WellCare PDP</b>	988,260	<i>NOT COVERED</i>	<b>TIER 5</b>	<i>NOT COVERED</i>	<b>TIER 4</b>	TIER 3	<b>NOT COVERED</b>
<b>Kaiser Permanente Senior Advantage MA</b>	870,704	TIER 5	<b>TIER 2</b>	TIER 4	<b>TIER 2</b>	TIER 3	<b>TIER 2</b>
<b>SilverScript Choice PDP</b>	4,586,237	TIER 5	<b>NOT COVERED</b>	<i>NOT COVERED</i>	<b>TIER 4</b>	TIER 2	<b>NOT COVERED</b>
<b>Humana Gold Plus* MA</b>	1,396,865	TIER 5	<b>NOT COVERED</b>	TIER 4	<b>TIER 3</b>	TIER 3	<b>NOT COVERED</b>
<b>Aetna Medicare Rx Saver PDP</b>	1,297,662	TIER 5	<b>NOT COVERED</b>	TIER 3	<b>TIER 4</b>	TIER 3	<b>TIER 3</b>

<https://client.formularynavigator.com/Search.aspx?siteCode=3119159574>. Last updated 12/2018. Accessed 2/28/2019. Kaiser Permanente formulary available at: [https://medicare.kaiserpermanente.org/medicare/pdfs/plans\\_current/comprehensive\\_formulary.pdf](https://medicare.kaiserpermanente.org/medicare/pdfs/plans_current/comprehensive_formulary.pdf). Last updated 11/01/2018. Accessed 2/28/2019. <sup>9</sup> *Ibid*.

In light of these troubling practices, we urge legislation to require that Part D seniors have access to lower cost generic and biosimilars through placement on Part D formularies upon launch. We believe this change will provide significant savings for patients and the government.

## 2. Placement of generics on generic-only formulary tiers with meaningful differences in cost-sharing levels versus the brand

When Part D plans are adding lower cost generics onto Part D formularies upon launch, recent studies have found that Part D plans have been increasingly placing lower cost generics onto brand tiers with higher cost sharing for patients instead of generic formulary tiers.<sup>6</sup>

The following chart is an example mailer that Part D patients receive to indicate a patient's cost sharing amount depending on the formulary placement of the prescription drug. Given the much lower patient out-of-pocket costs for medicines on the generic drug tier, this chart denotes the structural issues that patients face when they have to pay higher cost sharing as a result of their lower priced generic being

<sup>6</sup> Avalere "Generic Drugs in Medicare Part D, Trends in Tier Structure and Placement Study," May 22, 2018; Avalere "Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs," February 28, 2019, available at <https://avalere.com/wp-content/uploads/2019/02/20190228-White-Paper-Part-D-Generic-Tiering.pdf> (hereinafter, Avalere 2019 Study").

placed on a non-generic drug tier or in the case of specialty generics or biosimilars, patients have the same cost sharing as the brand without a dedicated specialty tier.

**THIS USED TO BE KNOWN AS: TIER 4 – NON-PREFERRED “BRAND”**  
before it was renamed in 2016

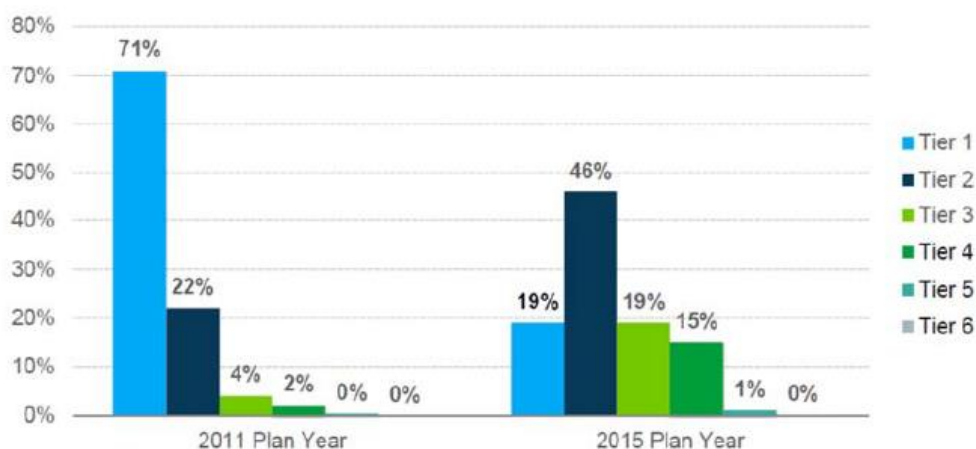
Drug Tier	Standard Retail Pharmacy Copay/Coinsurance <sup>2</sup>	Preferred Retail Pharmacy Copay/Coinsurance <sup>2</sup>
<b>Tier 1 – Preferred Generic</b> Lower-cost, commonly used generic drugs.	\$10	\$7
<b>Tier 2 – Generic</b> Many generic drugs.	\$14	\$10
<b>Tier 3 – Preferred Brand</b> Many common brand name drugs, called preferred brands, and some higher-cost generic drugs.	\$45	\$37
<b>Tier 4 – Non-Preferred Drug</b> Non-preferred generic and non-preferred brand name drugs.	50%	40%
<b>Tier 5 – Specialty Tier</b> Unique and/or very high-cost drugs.	33%	33%

CMS defines specialty drugs as those with a one month supply of at least \$670.

Currently, all specialty drugs – whether generic, biosimilar or brand – are all in one Specialty tier.

A May 2018 Avalere study found that the number of generic drugs placed in tier 1, representing the lowest cost-sharing available for patients, significantly decreased from 2011 to 2015.<sup>7</sup> Approximately 71 percent of generics were placed on tier 1 in 2011 and by 2015, only 19 percent of generics were placed on tier 1 (with 46 percent on tier 2 and the remaining 35 percent on tier 3 or higher). The numbers of generic medicines moved to branded drug tiers (tier 3 or higher) is astonishing given that generic drug prices overall have decreased approximately 15% each year for the last seven years.<sup>8</sup> The following chart from Avalere demonstrates these trends.

**Figure 1: Percent Distribution of Generic Drugs on Part D Formulary Tiers, 2011 to 2015**



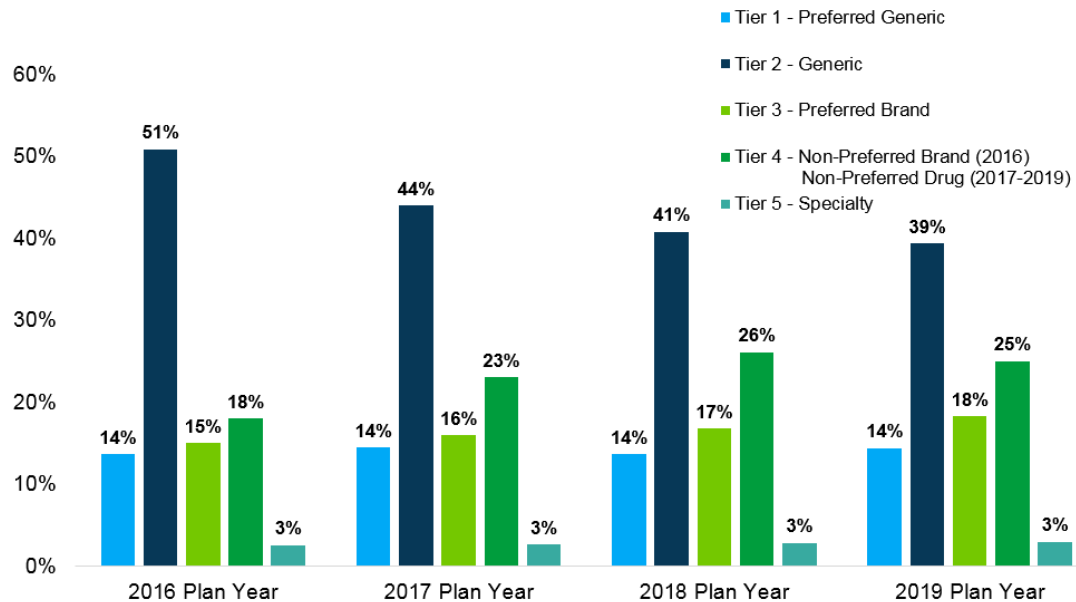
<sup>7</sup> Avalere, “Seniors Pay More for Generics in Medicare Prescription Drug Plans Despite Stable Prices,” May 22, 2018, available at [http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1526995040\\_Avalere\\_Part\\_D\\_Generic\\_Tiering\\_Analysis.pdf](http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1526995040_Avalere_Part_D_Generic_Tiering_Analysis.pdf) (hereinafter “Avalere 2018 Study”), at 1-2.

<sup>8</sup> See US Health and Human Services, Assistant Secretary for Planning and Evaluation. ASPE Issue Brief (Jan 27 2016): Understanding Recent Trends in Drug Prices, referencing Express Scripts Drug Trend Report and IQVIA



A follow-up study looked at Part D tiering trends for years 2016 through 2019.<sup>9</sup> As the chart below indicates, Medicare Part D plan sponsors placed generic drugs on the lowest tier (preferred generic) at a consistent rate of only 14% of the time over 2016-2019, and that placement of generics on the second-lowest tier (generic) fell from 51% in 2016 to 39% in 2019. By contrast, coverage of generics on tier 4 (non-preferred brand/non-preferred drug) rose from 18% in 2016 to 25% in 2019, with coverage on tier 3 (preferred brand) rising from 15% to 18%.

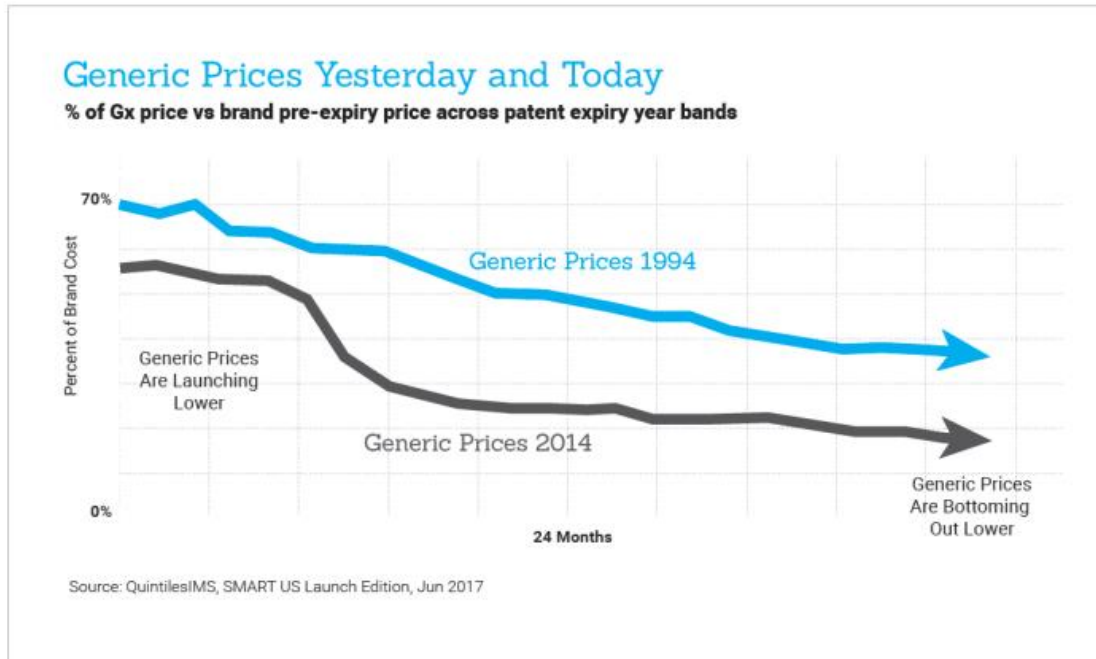
### Percent Distribution of All Generic Drugs on Part D Formulary Tiers, 2016–2019



**The fact that *any* generics are on branded drug tiers should be surprising; that generics are now placed on such tiers fully 43% of the time is especially alarming, particularly given the fact that the very high-cost non-preferred brand/non-preferred drug tier now accounts for 25% of generics.** These formulary trends are occurring despite the overall deflation of generic drug prices (app. 15% price decline per year for generics on average according to IQVIA) and also despite the fact that new generic launches are launching at lower prices overall as noted in the chart below by the Association for Accessible Medicine (“AAM”).

2017. Additionally, GAO’s report (GAO-16-706) on “Generic Drugs Under Medicare” from August 2016, also indicated that generic drug prices fell 59% from Q1 2010 through Q2 2015.

<sup>9</sup> Avalere “Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs,” February 28, 2019, available at <https://avalere.com/wp-content/uploads/2019/02/20190228-White-Paper-Part-D-Generic-Tiering.pdf> (hereinafter, Avalere 2019 Study”).



As AAM notes, “today generic drugs are launching at a greater discount off the price of their branded counterparts, lowering prices at a faster rate and ultimately reaching a lower price point than at any time in the last 20 years.”<sup>10</sup>

It is also worth noting that in 2016, CMS announced a change to the formulary structure of the Part D program, which included a ‘non-preferred drug’ tier that explicitly includes both brand and generic drugs.<sup>11</sup> This shift runs counter to the intended design of generic tiers to encourage generic utilization and reduce patient out-of-pocket costs. As Avalere’s May 2018 study found, plans started moving generics from generic tiers onto brand tiers gradually after 2011 until 2015 when nearly 53% of generics had been moved onto higher brand drug tiers.<sup>12</sup> However, after CMS’ May 2016 comments, this change emboldened the practice further as plans began placing generics onto higher brand tiers at generic launch, or worse, not offering patients lower cost generics at all on formulary.

The growing practice of mixing generics and brands on formulary tiers impact Medicare patients directly. **Avalere’s reports estimated that the increased placement of generics on brand tiers resulted in a \$6.2 billion increase in patient cost-sharing for these drugs over 2011-2015, and that Medicare beneficiaries spent or will spend approximately \$15.7 billion during 2016-2019 alone in increased cost sharing due to generics being placed on brand drug tiers—a total of nearly \$22 billion.**<sup>13</sup>

<sup>10</sup> AAM White Paper: Ensuring the Future of Accessible Medicines in the U.S. Avoiding Shortages & Ensuring Competition for America’s Patients, February 2018.

<sup>11</sup> Avalere “Generic Drugs in Medicare Part D, Trends in Tier Structure and Placement Study,” May 22, 2018.

<sup>12</sup> Avalere “Generic Drugs in Medicare Part D, Trends in Tier Structure and Placement Study,” May 22, 2018.

<sup>13</sup> Avalere 2018 Study at 1 and Avalere 2019 Study at 6-7. Notably, these numbers do not account for the full added cost-sharing borne by Part D beneficiaries due to placement of generics on brand tiers, since the \$6.2 billion number in the 2018 Avalere Study includes only the costs due to the increase in branded tier placement as compared to 2011, and neither study

### **3. Creation of a dedicated specialty tier for specialty generics and biosimilars with meaningfully more-favorable cost-sharing than the specialty tier for branded specialty drugs**

Specialty drugs are the highest spend and fastest growing medicines category in the U.S. representing at least 40% of spending for less than 2% of prescriptions.<sup>14</sup> Currently, there is no structural way to incentivize generic or biosimilar usage for specialty medicines as unlike non-specialty drugs, only one formulary tier exists for all specialty drugs, whether brand or generic or biosimilar. The lack of a more favorable specialty tier for lower cost specialty generics and biosimilars has resulted in significantly higher costs for seniors to date in Part D.

Under current Part D rules, sponsors may designate one tier as their specialty tier since this tier is exempt from tier cost-sharing exceptions. Only Part D drugs with sponsor-negotiated prices that exceed the dollar-per-month amount established annually by CMS (currently \$670 per month) may be placed in the specialty tier. The specialty drug marketplace has changed significantly since the specialty tier was first created in 2006. Whereas specialty generics or biosimilars were not yet on the market in 2006, an increasing number of these products that meet the \$670 cost threshold given their complex nature have now gained FDA approval.

However, unlike generics or biosimilars on non-specialty tiers which have lower cost-sharing for generics and brands through different tiers, *all* specialty drugs and biological products – whether original brand, generic or biosimilar – have one single formulary tier and associated cost-sharing in Part D (up to 33% cost-sharing). By placing generics or biosimilars on the same specialty tier as brands, with the same cost-sharing, plan sponsors disincentivize the use of lower cost specialty products in Part D and cause higher cost sharing for seniors.

As a result, the overall generic utilization rate for specialty generics is astonishingly low, particularly in the first few years after launch. Of the Top 30 specialty medicines by spend in 2018, only two Part D drugs have generic competition to date.<sup>15</sup> In both cases, the generic market share has not exceeded 37%.

An example of this phenomenon is generic competition to Copaxone, a brand specialty drug treating Multiple Sclerosis. CMS alone spent \$1.4 billion in 2016 on Copaxone for Part D according to the publicly released CMS Dashboard data. Nearly a year after generic launch in 2017, eight of the top 10 Medicare Part D plans did not cover generic Copaxone on their formularies. This stunning practice reflects a complete reversal of the longstanding approach of incentivizing generic utilization. In those Part D plans that do cover generics to Copaxone, generics are in the same formulary tier as the brand specialty tier meaning that patients are required to pay the same cost-sharing for both the brand and generic.

Generic alternatives to specialty medicines like Copaxone should already have saved the overall U.S. healthcare system billions of dollars. To date, however, not all Part D patients have access to these more affordable therapeutic equivalents because of formulary and coverage decisions.

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estimates the increased utilization of generics which would have resulted if they had been placed on generic tiers, instead of higher-cost branded drug tiers.

<sup>14</sup> IQVIA report: “Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022” April 2018

<sup>15</sup> IQVIA data and specialty list for CY2018 sales and 2015-2018.

To incentivize the robust usage of lower cost generics and biosimilars, we strongly urge Congress to modernize Part D benefit design to create a separate specialty tier designed for *only* generic and biosimilar products that meet the specialty-tier cost threshold. This generic and biosimilar specialty tier should have meaningfully lower cost-sharing than the specialty brand tier of the same plan to ensure seniors get the benefit of these lower cost medicines. Based on preliminary scoring analysis, we believe this change would provide significant savings to patients as well as the government.

## **II. Feedback on draft legislation to cap out-of-pocket costs and lower the government's share during the catastrophic phase**

### **A. We support the Committees goal to lower patient cost**

We appreciate the Committees' efforts to lower patient out-of-pocket costs and increase access to life-saving medicine through the proposed legislation aimed at capping out-of-pocket costs and lowering the government's share during the catastrophic phase. Patients who pay lower amounts out-of-pocket are more likely to pick up their prescriptions and take them as directed, decreasing medical costs overall and improving the quality of life for America's seniors.<sup>16,17</sup> We applaud the Committees for the proposed bill's objective of addressing high out-of-pocket costs for Medicare patients.

While much Part D program has been a huge success in reaching nearly 45 million enrollees in 2019 at an average monthly premium of \$29.20, according to the Kaiser Family Foundation,<sup>18</sup> the alarming trends described in Section 1 above as well and several studies confirm that seniors are no longer getting the full benefits of lower cost generics and biosimilars in Part D as Part D plans are no longer encouraging the use of these lower cost alternatives. For example, HHS found in 2018 that Medicare Part D plans were dispensing brand name drugs when therapeutically equivalent generics were available, costing almost \$3 billion in unnecessary costs in 2016.<sup>19</sup> This finding was supported by Avalere, which found that formulary placement practices in Part D plans resulted in \$22 billion in unnecessary out-of-pocket costs for seniors between 2015 and 2019 as noted above.<sup>20</sup> These data points underscore the importance of making sure all Part D policy proposals do not have the unintended effect of discouraging lower cost generics and biosimilars in favor of higher cost brand medicine.

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<sup>16</sup> Stuart, B., Davidoff, A., Lopert, R., Shaffer, T., Shoemaker, J. S., & Lloyd, J. (2011). Does Medication Adherence Lower Medicare Spending among Beneficiaries with Diabetes? *Health Services Research*, 46(4), 1180-1199. doi:10.1111/j.1475-6773.2011.01250.x

<sup>17</sup> Generic Drug Access & Savings in the U.S. Association for Accessible Medicines. (2017).

<https://www.accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>

<sup>18</sup> Cubanksi, J., Damico, A., & Neuman, T. (2019, June 04). 10 Things to Know About Medicare Part D Coverage and Costs in 2019. Retrieved from <https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/>

<sup>19</sup> U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. (2018, July 23). Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D. Retrieved from <https://aspe.hhs.gov/system/files/pdf/259326/DP-Multisource-Brands-in-Part-D.pdf>

<sup>20</sup> Avalere. February 2019). Medicare Part D Generic Drug Tiering Request for Comment: Implications for Patient Out-of-Pocket Spending and Part D Plan Costs. Retrieved from <https://avalere.com/wp-content/uploads/2019/02/20190228-White-Paper-Part-D-Generic-Tiering.pdf>; Avalere "Generic Drugs in Medicare Part D, Trends in Tier Structure and Placement Study," May 22, 2018.

## **B. Consideration of Unintentional Consequences**

As a result of current Part D practices and structural favoring of brands over generics, particularly during the coverage gap period, we believe the draft bill could have unintended consequences, particularly for seniors who take expensive specialty medications. A Kaiser Family Foundation issue brief helps explain the issue. KFF recently found that due to the Part D benefit design structure, patients pay more for the multiple sclerosis (MS) drug generic glatiramer acetate than they do for brand Copaxone, even though the generic is much lower-priced.<sup>21</sup> Specifically, the generic equivalent of Copaxone confers an annual savings of nearly \$30,000 over the brand. Because patients move through the donut hole more slowly for generics, the high costs that seniors bear are disproportionately below the catastrophic threshold. The issue brief notes,

“Expected annual out-of-pocket costs for glatiramer acetate are actually higher than costs for the brand Copaxone in 2019—and higher than out-of-pocket costs for the other branded MS drugs—while the share of out-of-pocket costs above the catastrophic threshold is lower. This is because enrollees who take the brand Copaxone would reach the catastrophic phase sooner than those who take the generic equivalent, because they receive a 70 percent manufacturer discount on the brand, which counts towards the annual out-of-pocket spending amount that triggers catastrophic coverage.”

Kaiser found that Part D patients currently pay \$737 more for generic glatiramer acetate than for Copaxone. Under the proposal, that difference would grow to \$2,277 – out-of-pocket costs for the generic product would be nearly two times that of the brand. That is due to the fact that, under the Part D catastrophic benefit currently, patients pay 5% coinsurance; consequently, they pay less out-of-pocket for the lower-cost generic than they do for the brand, in that phase of the benefit. Eliminating cost-sharing in the catastrophic portion of the benefit will eliminate any economic incentive for patients to switch to the lower-cost generic in that phase of the benefit, without affecting the strong economic incentive to use the higher-cost brand instead of the generic during the coverage gap.

Clearly, unless this issue is addressed in the draft bill, this phenomenon would exacerbate current trends that discourage generic uptake and steer patients toward drugs that cost more overall. In line with these estimates, Oliver-Wyman Consultants found that the proposed legislation would cost the government \$85 billion over 10 years and cost patients – not only those who use specialty medications, but all Part D seniors – \$20 billion in increased premiums.<sup>22</sup>

## **C. Straightforward solution to avoid this unintended outcome**

Fortunately, we believe there is a straightforward solution to avoid this unintended outcome. Specifically, the proposed bill should adopt the three formulary recommendations identified in Section I above and add a provision to eliminate the economic incentive for patients to use the higher-cost brand in the coverage gap, and thereby reach the catastrophic benefit sooner.

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<sup>21</sup> Cubanski, J., Koma, W., & Neuman, T. (2019, February). The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019. Retrieved from <http://files.kff.org/attachment/Issue-Brief-the-Out-of-Pocket-Cost-Burden-for-Specialty-Drugs-in-Medicare-Part-D-in-2019>

<sup>22</sup> Giese, G., Conway, B., & Sober, J. (2019, May 28). PART D CATASTROPHIC COVERAGE - FINANCIAL IMPLICATIONS OF RESTRUCTURING LIABILITY.

While one option for doing that would be to no longer count the brand manufacturer coverage gap discount towards the patient's true out-of-pocket spending (TrOOP), we recognize that would have the effect of increasing patient cost-sharing, at cross-purposes to the objective of the bill. **Instead, we recommend that patients who use generic drugs in the coverage gap be credited with the same TrOOP spending as they would receive if they used the branded drug equivalent. This change would eliminate the perverse economic incentive for patients to use the higher-cost brand, due to the 70% coverage gap discount being credited towards TrOOP.**

Analytically, this change would be similar to the policy Congress has adopted with respect to Medicare Part B reimbursement of biosimilars versus their branded reference biologics. There, Congress faced a similar problem of physicians having an economic incentive to administer the more expensive branded product, since reimbursement was 106% of average sales price (ASP), and the 6% "profit" component for the physician is greater for the product with the higher ASP—i.e., the more-expensive brand. Congress acted to eliminate this economic disincentive for physicians to administer the lower-priced biosimilar by providing that reimbursement for the biosimilar be 100% of the biosimilar ASP plus 6% of the brand ASP—i.e., the physician receives the same "profit" amount regardless of which product is used.

While this change would result in patients who take generics reaching the coverage gap sooner than they do under existing law, the related costs would be reduced or potentially exceeded by savings—particularly during the catastrophic portion of the benefit—from use of generics having a lower cost than the equivalent brand. Notably, this specific policy change would only affect patients' TrOOP balances, not their cost-sharing during the coverage gap.

While we believe generic utilization should be further incentivized by requiring a generic/biosimilar specialty tier as described earlier in our comments in Section I, even under existing law cost-sharing during the coverage gap would be less for the generic, so long as the generic has a meaningfully-lower negotiated price and both products are on the specialty tier (for which there would be 25% coinsurance beginning in 2020). Such an incentive to switch to the generic before entering the catastrophic benefit is particularly important since the new policy would eliminate any economic incentive for patients to switch to the generic after they enter the catastrophic benefit.

Moreover, this policy change could be administered using existing Part D systems and processes. For every pharmacy on any given day, there will be a given negotiated price applicable to both the brand and the generic. If the patient uses the brand, the Part D plan currently credits the patient's TrOOP balance, including the 70% coverage gap discount—that happens automatically, as the drug is dispensed and the claim paid. All that would be required is to provide that the TrOOP which would otherwise be credited to the patient's TrOOP balance for using the generic would be increased to the TrOOP that they would receive from using the brand, when the brand TrOOP is greater. Mylan shares your goal of reducing patient out-of-pocket costs and increasing access to affordable medicine for Part D seniors and we look forward to working with you to ensure this policy achieves these objectives.