



**Association for Accessible Medicines  
Biosimilars Council  
Statement of Craig Burton  
House Committee on Oversight and Accountability  
The Role of Pharmacy Benefit Managers in Prescription Drug Markets  
September 14, 2023**

Good morning, Chairman Comer, Ranking Member Raskin, and other members of the Committee. My name is Craig Burton, and I am the Executive Director of the Biosimilars Council and Senior Vice President of Policy and Strategic Alliances at the Association for Accessible Medicines (AAM).

AAM and its Biosimilars Council represent the manufacturers of finished generic and biosimilar pharmaceutical products, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM and the Council work to expand patient access to safe, quality, and effective generic and biosimilar medicines by promoting a positive regulatory, reimbursement, and policy environment, and advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

It's important that I begin my testimony by emphasizing two main points:

1. Generic medicines are the backbone of the U.S. prescription drug market, supplying more than 9 out of every 10 prescriptions.
2. Medicare policy incentives are delaying patient access to and savings from new generics and biosimilars, undermining the long-term sustainability of generic and biosimilar competition.

**The Value of Generic and Biosimilar Medicines**

It is not an overstatement to say that patients and the U.S. health care system as a whole depend on generic and biosimilar medicines. Generics and biosimilars represent 90 percent of all prescriptions filled in the U.S., but only account for 17.5 percent of prescription drug spending. The use of generics and biosimilars generated \$408 billion in savings in 2022, totaling \$2.9 trillion in savings over the past ten years. The Medicare program alone saved more than \$130 billion through generics and biosimilars in 2022. To drive home the value, consider that generics and biosimilars account for less than 2 percent of all U.S. health care spending.<sup>1</sup>

Biosimilars are a key part of future savings. Biosimilars and complex generics represent new competition and savings for the high-priced specialty medicines that drive more than half of all

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<sup>1</sup> Association for Accessible Medicines. "The 2023 Generic and Biosimilars Savings Report" (September 2023)  
Accessible at: <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>

drug spending. To date, the U.S. Food and Drug Administration (FDA) has approved 42 biosimilars, 36 of which are on the market. Biosimilars bring lower prices: today they cost less than half the price of the brand product at the time of biosimilar launch. Biosimilar competition is also causing brand biologic prices to decline by an average of 25 percent.<sup>1</sup>

But most importantly, generics and biosimilars result in greater patient access to therapy. Patients are more likely to fill and use a low-cost generic prescription rather than a high-cost brand. And biosimilar introduction has resulted in more than 344 million *additional* days of patient therapy that would not have occurred otherwise. Put simply, biosimilars are making it possible for more patients to receive treatment.<sup>1</sup>

But these savings are increasingly at risk. Before I address the challenges preventing patients from receiving the full benefit of lower-priced generics and biosimilars, I will briefly describe how these markets function, and some notable differences from brand drug markets.

### **Overview of the Generic and Biosimilar Drug Supply Chain**

When a new drug product is developed and initially marketed, it may be protected by a patent, which prevents other companies from marketing a similar product. These drugs are typically referred to as “brand” or “reference” drugs. “Generic” or “biosimilar” drugs are drugs that are approved by FDA under the 505(j) or 351(k) pathways. Generic and biosimilar companies can challenge patents ahead of patent expiration to bring more affordable medicines to patients as early as possible. Congress has created incentives to take on these legal and regulatory challenges, by providing eligibility for 180 days of market exclusivity to the first generic to submit a substantially complete application with a patent challenge. Congress also created an incentive for manufacturers to develop interchangeable biosimilars by providing exclusivity for the first approved interchangeable.

The brand drug market is notably different than the generic and biosimilars markets (Figure 1 and 2).<sup>2</sup> Brand manufacturers are responsible for bringing new products to market and take on substantial financial risk to do so. Because of the current reimbursement model, brand manufacturers are incentivized to set high list prices and compete for formulary placement through opaque back-end rebates and fees.

### **CONSOLIDATION AMONG PHARMACEUTICAL SUPPLY CHAIN ACTORS**

In contrast, generic manufacturers compete against one another to offer the most competitive acquisition cost to wholesalers and pharmacies. Generic and biosimilar manufacturers are not immune from financial and legal risk, however. They must invest to demonstrate bioequivalence and biosimilarity. They may also take on significant legal risk by challenging weak brand patents. Development of a new product may cost as little as \$5 to \$10 million for a simple generic, to several hundred million for a complex generic or a biosimilar.<sup>3</sup>

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<sup>2</sup> Association for Accessible Medicines. “Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers” (October 2017) Accessible at: <https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf>

<sup>3</sup> Chin. Y. “An Inflection Point For Biosimilars” (June 2021) McKinsey & Company. Accessible at: <https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars> ;

This, in turn, leads to important differences in how products are priced by manufacturers, and how they are covered by PBMs and health plans. One of the most important differences is that generic manufacturers rarely, if ever, negotiate rebates with PBMs and health plans. In the brand drug market, where there is a sole manufacturer, PBMs and health plans will negotiate utilization discounts with manufacturers. Generally, payers will negotiate more favorable coverage in exchange for larger rebates or fees based on list price.

Further, unlike brand manufacturers who often operate in single source market, generics are competing against multiple manufacturers of the same product. This means that generic drug competition is based solely on cost and ability to supply, giving middlemen – such as pharmacies, wholesalers and group purchasing organizations (GPOs) – the ability to negotiate lower acquisition costs and maximize their margins. Compared with the generic industry, where the top 10 manufacturers collectively account for only 19 percent of the market, middlemen in the supply chain continue to consolidate and achieve greater purchasing power. For instance, three group purchasing organizations control roughly 90 percent of all generic medicine purchasing for hospitals/clinics.<sup>4</sup> In the retail pharmacy market, three purchasing consortiums (wholesaler/retail chain combinations) collectively control 90 percent of purchasing.<sup>5</sup> Fewer buyers means fewer markets for the more than 200 generic drug manufacturers in the U.S., and the constant downward contractual pressure created by the ‘most favored nations’ contract terms used by supply chain purchasers can result in unsustainably low prices. This unchecked consolidation has resulted in a ‘take it or leave it’ market for many of the lowest-cost generic medicines, which face one-sided terms and conditions. Further, vertical integration maximizes downward pricing pressure, but with no certainty on price or volume in return. As a result, the total value of all generic drug sales has decreased by more than \$6.4 billion over the past five years, even accounting for new generic launches and more prescriptions filled.<sup>1</sup>

#### REIMBURSEMENT MODELS IMPACT BRAND AND GENERIC MARKETS DIFFERENTLY

Another major difference between the branded and generic supply chains is the way that pharmacy reimbursement rates are set by payers. While both brand and generic drug manufacturers set unique prices for their products, the approach health plans and PBMs use to reimburse pharmacies for dispensing these products is substantially different. Reimbursement for brand prescription drugs is usually a percentage of a published list price for the drug itself. As the cost of the drug increases, so does the contracted reimbursement to the pharmacy.

Conversely, for generic drugs, payers typically establish one single reimbursement rate for a specific dosage and form of a particular drug (for example, a 10 mg tablet of atorvastatin) and cap reimbursement at that rate (maximum allowable cost, or MAC). Plans and PBMs may also use reimbursement methods such as generic effective rate (GER) guarantees to set an average

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<sup>4</sup> Seeley, E. “The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending” (July 20, 2022) The Commonwealth Fund. Available at: <https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending>

<sup>5</sup> Fein, Aj. “The 2022-23 Economic Report On Pharmaceutical Wholesalers And Specialty Distributors” (October 2022) Drug Channels Institute. Available at: [https://drugchannelsinstitute.com/products/industry\\_report/wholesale/](https://drugchannelsinstitute.com/products/industry_report/wholesale/)

rate of reimbursement for generic drugs sold over a period of time, where aggregate reimbursement can be adjusted retroactively. This results in a reimbursement rate that is not necessarily tied to the generic list price. While in theory both MAC and GER programs provide an incentive for pharmacies to purchase the most economically reasonable product, studies have noted that these incentives may be different when a pharmacy (for instance, specialty pharmacy) is owned by the PBM.<sup>6</sup> The methodologies that plans and PBMs use to calculate MAC prices are proprietary and may vary from plan to plan.<sup>7</sup> Additionally, MAC and GER programs for generic drug reimbursement may be less transparent or predictable to network pharmacies, thereby reducing some incentives to dispense generic medications.

#### PRICING EXPECTATIONS FOR BIOSIMILARS ARE STILL EVOLVING

The biosimilar market is still evolving and the decisions made by Congress will have a significant impact on the biosimilar pricing model. This is best seen in the biosimilar insulin and adalimumab (Humira) markets. As biosimilar manufacturers seek to learn the best way to achieve formulary coverage and patient adoption, some biosimilars are pricing based on a lowest list price strategy, while others are using a rebate-based strategy.

#### **Key Challenges**

Unfortunately, patients are increasingly facing barriers to access to new generics and biosimilars as a result of formulary decisions to delay or block coverage. And when generics and biosimilars are covered on formulary, patients are often forced to pay too much, sometimes even more than the cost of the medicine.

#### CHALLENGES TO COVERAGE OF NEW GENERICS

Despite significantly lower prices, many new generic drugs are facing delays to formulary coverage. A review of the past six years of Medicare and commercial formularies highlights the extent of the problem.

The FDA considers “first generics” – “the first approval which permits a manufacturer to market a generic drug in the United States”<sup>8</sup> – to be a public health priority.<sup>9</sup> In 2021, the FDA approved 93 first generic drugs, introducing more affordable therapeutic options for a variety of conditions. And the use of new generics saves money for patients, as generic prices can rapidly fall by more than 95 percent when compared to brand prices.<sup>10, 11</sup>

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<sup>6</sup> Lieberman, S. “Would Price Transparency For Generic Drugs Lower Costs For Payers And Patients?” (June 2017) Brookings Institution. Accessible at: <https://www.brookings.edu/articles/would-price-transparency-for-generic-drugs-lower-costs-for-payers-and-patients/>

<sup>7</sup> Association for Accessible Medicines. “Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers” (October 2017) Accessible at: <https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf>

<sup>8</sup> U.S. Food and Drug Administration. First Generic Drug Approvals. (July 2022). Accessible at: <https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals>

<sup>9</sup> Association for Accessible Medicines. (May 2022). AAM Comment Letter on the FDA Safety and Landmark Advancements Act (FDASLA)

<sup>10</sup> U.S. Food and Drug Administration. (December 2019). “Generic Competition and Drug Prices”. Accessible at: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>

<sup>11</sup> IQVIA. (December 2022). National Sales Perspective

Nonetheless, first generics are experiencing slower than expected adoption. Generics have historically achieved rapid adoption of 80 percent or more within only a few months. But this is no longer the case.<sup>12</sup> In 2021, the average prescription market share for the top ten new generics narrowly achieved 70 percent, reflecting a palpable shift in market dynamics.<sup>13</sup> These delays are driven by perverse incentives leading PBM to prefer high-priced drugs with high rebates over drugs with lower list prices.

A review of first generics approved in 2016 highlights the challenge. Medicare and commercial formulary data were used to assess formulary coverage of the first generics approved in 2016. The study found that Medicare drug plans, including both Medicare Advantage and Part D Plans, covered these lower-cost options only 22 percent of the time. The data demonstrated that it takes nearly three years before first generics are covered on more than half of Medicare drug formularies. Even today, six years later, these new generics are covered by fewer than two-thirds of all Medicare drug formularies.

This is not an outlier. As reflected in the appendix, subsequent years tell a consistent story: first generics launched in 2021 were covered on only 23 percent of Medicare formularies in 2021, and only 46 percent in 2022 (Figure 3).

But these challenges are not limited to the Medicare prescription drug program. Although Commercial drug formularies also fall short of ensuring patient access to lower cost medicines. For instance, first generics that launched in 2016 were covered only 46 percent of the time. Coverage of these generics eventually reached 90 percent in 2022 – six years after the generics first came to market.<sup>14</sup>

When PBMs pursue varying rebate agreements with plan sponsors, coverage of generics is delayed and patients suffer as a result. In fact, at the beginning of the month, a report from the Government Accountability Office notes an explicit condition found in rebate agreements of the top plan sponsors “*All [had] rebate agreements where manufacturer rebates were based on the absence of competing generic drugs. Specifically, some agreements stated that the rebate agreements would cease when an applicable generic entered the market while others stated rebate agreements would cease when an applicable generic was placed on the same or a more preferred tier on the formulary.*”<sup>15</sup> These delays in coverage restrict patient access to lower-cost generics and expose patients to unnecessarily high cost-sharing, even though lower-cost alternatives are available. The U.S. Department of Health and Human Services notes, “*large*

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<sup>12</sup> Avalere. “Variation in Generic Substitution Rates Among Part D Plans”. (January 2020). Accessible at: <https://avalere.com/insights/avalere-analysis-finds-variation-in-generic-substitution-rates-among-part-d-plans>

<sup>13</sup> Association for Accessible Medicines. (July 2021). “New Generics Are Less Available in Medicare Than Commercial Plans”. Accessible at: <https://accessiblemeds.org/resources/reports/new-evidence-shows-medicare-part-d-plans-continue-fail-get-new-generics-seniors>

<sup>14</sup> Although coverage rates improved from 2021 to 2022, a longitudinal assessment has not yet determined that this trend is enduring.

<sup>15</sup> United States Government Accountability Office. “MEDICARE PART D: CMS Should Monitor Effects Of Rebates On Plan Formularies And Beneficiary Spending” (September 2023) Accessible at: <https://www.gao.gov/assets/gao-23-105270.pdf>

*rebates offered by manufacturers for higher cost [drugs] benefit plan sponsors but provide little relief to beneficiaries who received the drugs or the Medicare program.”<sup>16 17</sup>*

Recent reporting from STAT News highlights why and how PBMs might prefer a brand drug over a lower-priced generic. The report highlights a lawsuit alleging that a vertically integrated Part D plan sponsor, its PBM, and its pharmacy network coordinated to limit consumer access to first generics.<sup>18</sup> According to the allegations, the PBM informed its plan sponsors that the program could help protect their revenue generated by brand drug rebates from new lower-price generics. Although the company claimed the generics would be incorporated if they would result in an equal or lower cost to patients, the report alleges that these generics were blocked well past their initial launch phase. For example, the lawsuit contends the company’s PBM continued to prefer and limit the inventory of the brand version of Renvela. Despite the availability of eight generic competitors, even patients willing to pay cash were restricted within its retail pharmacy locations from accessing the lower-priced options.

This practice increased costs for Medicare beneficiaries, taxpayers, and its retail pharmacy customers. Generics for widely used drugs such as Renvela and Advair Diskus were not only denied to Medicare patients but also for *any* customers filling a prescription at this national retail pharmacy chain.<sup>19</sup>

#### CHALLENGES TO COVERAGE OF BIOSIMILARS

Biosimilars also face well-documented challenges to achieving preferred formulary coverage. There has been significant attention to the launches this year of eight biosimilar versions of adalimumab given that the brand biologic Humira has been the top-selling brand drug in the U.S.

And while biosimilars are launching at discounts of up to 85 percent less than the brand, formulary coverage has been less than it should be for the lower-cost product, although the data is limited.

But the impact of PBM preferences for products with higher list prices and rebates – and the potential impact on future biosimilars – can be seen by examining the biosimilar insulin market.

In late 2021, Semglee and unbranded insulin glargine launched as the first pharmacy-distributed, fully interchangeable biosimilars. These drugs reference blockbuster insulin, Lantus. As detailed by IQVIA, Semglee has two different prices, one with a slight decrease in price and a high

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<sup>16</sup> U.S. Department of Health and Human Services Office of Inspector General. (August 2022). “Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending”. Accessible at: <https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf>

<sup>17</sup> Formulary coverage challenges for lower priced medicines are not unique to generics. Note formulary coverage of insulin products, specifically the limited coverage of the lower-priced unbranded version of the interchangeable insulin Semglee. IQVIA. (November 2022). “Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars”. Accessible at: <https://www.iqvia.com/locations/united-states/library/white-papers/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars>

<sup>18</sup> Silverman, Ed. (June 2022). “A ‘veritable playground’: CVS whistleblower details how patients were charged higher drug prices”. STAT News. Accessible at: <https://www.statnews.com/wp-content/uploads/2022/06/CVS-Miller-whistleblower-lawsuit.pdf>

<sup>19</sup> Used to treat chronic kidney disease and Chronic Obstructive Pulmonary Disease respectively.



rebate, and another with a major (65 percent) decrease in price. With two price points, payers can select the product with a high price but a high rebate, or the lowest list price. Although the lower list price would have translated into lower costs to patients, many PBMs opted to stick with the brand version rather than encouraging use of the lowest list price. And because many patients pay cost-sharing based on the list price of the product, the decisions made by payers have significant impacts on patients and their wallets.

In fact, although the lowest-cost biosimilar insulin accounted for more than half of all new written prescriptions, it accounted for less than one-third of filled prescriptions in the first quarter of 2023. This is because of formulary controls that blocked patient access to the biosimilar. If PBMs had simply placed the biosimilar on parity with the brand, more patients would have accessed the lower-cost insulin – 60 percent of new insulin prescriptions, in fact. Once again, this challenge is most prominent in the Medicare market.<sup>18</sup>

#### FORMULARY PLACEMENT INCREASES PATIENT COSTS FOR GENERICS

But even when formularies finally cover generic medicines, are often placed on brand and/or non-generic formulary tiers, causing confusion and unnecessarily high costs to patients. For instance, a recent Avalere analysis of Medicare drug plans showed that in 2022, just 43 percent of generic drugs were placed on a “generic tier.”<sup>20</sup>

And while generics receive somewhat more favorable placement in exchange plans, there is significant room for improvement. Just two-thirds of generics are currently on generic tiers in the exchanges in 2022.<sup>21</sup>

The movement of generics to tiers with higher copayments has occurred despite consistently declining generic prices.<sup>22</sup> Avalere tracked the formulary placement and patient costs for generics covered in Medicare in 2011 and 2019. The analysis found that patient spending per year on these medicines increased by 135 percent between 2011 and 2019.<sup>23</sup> However, over that same period, the average sales price for those medicines fell by 38 percent.<sup>24</sup>

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<sup>20</sup> Avalere (January 24, 2022). “57% of Generic Drugs are Not on 2022 Part D Generic Tiers.” Accessible at: <https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers>.

<sup>21</sup> Prepared by Avalere Health. (January 2023). Analysis of Exchange Plans from Clarivate Drug Related Group (DRG) Formulary data for Plan Year 2022 [Unpublished Analysis].

<sup>22</sup> Medicare Payment Advisory Commission (MedPAC) (January 15, 2021). “The Medicare Prescription Drug Program (Part D): Status Report.” Accessible at: [https://www.medpac.gov/wp-content/uploads/import\\_data/scrape\\_files/docs/default-source/meeting-materials/part-d-status-report-medpac-jan-2021.pdf](https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/meeting-materials/part-d-status-report-medpac-jan-2021.pdf); A 2019 Medicare Payment Advisory Commission (MedPAC) analysis found that the average cost of prescription generic drugs decreased 13.7 percent between 2006 and 2018 and an additional 11 percent between 2018 to 2019

<sup>23</sup> Avalere (September 14, 2022). “New Analysis of Trends in Part D Generic Tiering, Pricing, and Patient Spending.” Accessible at: <https://avalere.com/insights/new-analysis-of-trends-in-part-d-generic-tiering-pricing-and-patient-spending>

<sup>24</sup> Association for Accessible Medicines (October 2022) Patients Pay More When Generic Drugs Are Placed On Non-Generic Tiers, Even Though Prices For Generics Are Going Down. Accessible at: <https://accessiblemeds.org/resources/blog/patients-pay-more-when-generic-drugs-are-placed-non-generic-tiers-even-though-0>

This is echoed by a recent IQVIA analysis which found that over half of patients covered by commercial health insurance or Medicare, and who had abandoned their prescription, could reduce their out-of-pocket costs by 20 percent or more by using a discount card.<sup>25</sup> This indicates that patients can frequently find substantial financial relief by paying outside of their coverage, utilizing cash prices rather than their insurance benefit, for which they pay monthly premiums.

### IMPLICATIONS FOR PATIENTS

These challenges cause patients to wait longer to receive a lower-cost generic or biosimilar and pay more when they finally receive one. But there also obstacles in the way of long-term sustainability of generic and biosimilar competition.

As we have all seen, the risk of drug shortages is increasing.. Generic prices are decreasing, drug purchasers are becoming more concentrated, new generics are not adopted as quickly, some generics are never launched due to limited commercial opportunities, and registered manufacturing sites are declining.<sup>26 27</sup> Collectively, these changes force generic manufacturers to reconsider production of lower-margin, often older, medicines to ensure continued financial sustainability of the overall pipeline.<sup>28</sup> More specifically, generic product discontinuations have numbered over 3,000 since 2010 and appear to be on the rise.<sup>29</sup>

Even though new product launches are the lifeblood of the cost saving generic industry, Medicare policies reward the continued use of higher-cost brands. When the ability for generics to recoup their investment in new products is blocked, it becomes more difficult to justify the continued production of revenue-negative products, thereby decreasing patient access to lower-cost medicines.

### **Policymakers Can Ensure Patient Access to New Generics**

Congress and the Centers for Medicare and Medicaid Services (CMS) have a range of tools to reduce patient spending by increasing utilization of generic and biosimilar medicines. And while recent legislation eliminated the Medicare Coverage Gap Discount Program and shifted greater financial liability to drug manufacturers, it has not fully removed the perverse incentives of high rebates on expensive brand drugs that prevent patients from receiving lower-cost generics.

We encourage Congress to increase patient access to new, lower-price generics or biosimilars. This includes ensuring that Medicare Advantage and Part D plans cover all generic products at

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<sup>25</sup> IQVIA (September 6, 2022). "Pharmacy Discount Card Utilization and Impact." Accessible at: <https://www.iqvia.com/locations/united-states/library/white-papers/pharmacy-discount-card-utilization-and-impact>.

<sup>26</sup> Association for Accessible Medicines. "AAM Comments in Response to Administration's Blueprint on Drug Pricing" (July 26, 2018) Available at: <https://accessiblemeds.org/sites/default/files/2018-07/AAM-HHS-Blueprint-to-Lower-Drug-Prices-RFI-71-16-18.pdf>

<sup>27</sup> Long, D. "US Pharmaceutical Trends, Issues and Outlook" (February 2023) Presentation at Access!2023.

<sup>28</sup> For example: 1) Swetlitz, I. "Teva Plans to Cut Back Generic Drug Production Even As Shortages Intensify," (May 18, 2023) Bloomberg. Available at: <https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg> and 2) PR Newswire "Lannett Company, Inc. Enters Into Restructuring Support Agreement" (May 1, 2023). Available at: <https://www.prnewswire.com/news-releases/lannett-company-inc-enters-into-restructuring-support-agreement-301811795.html>

<sup>29</sup> Raffat, U. Evercore ISI Research. (July 16, 2018)



launch, particularly first generics, or requiring Part D plans to review first generics and biosimilars within a specified time frame and provide written justifications to CMS if they are not placed on formulary. Legislation introduced by Senators Lankford (R-OK) and Menendez (D-NJ) and Representatives Kuster (D-NH) and Miller-Meeks (R-IA) would ensure that patients have access to new generics and biosimilars and that patients do not spend more than necessary for low-cost generics. Further, the legislation would encourage head-to-head price competition and lower list prices that would benefit patients, taxpayers and employers alike.

### **Conclusion**

America's patients and health care system rely on generic and biosimilar medicines. Generics reduce costs, expand access to care, and result in greater patient adherence – ultimately keeping patients healthy and productive. This track record of success is jeopardized by policy incentives that delay patient access to new generics and biosimilars. To realize the full value of new generic competition, as well as savings from new biosimilar medicines, Congress must ensure rapid plan coverage of new generics and biosimilars to help improve the sustainability of generic drug markets and a stable supply of lifesaving generic medicines.

## Appendix

Figure 1. Financial Distribution Across Generic Supply Chain

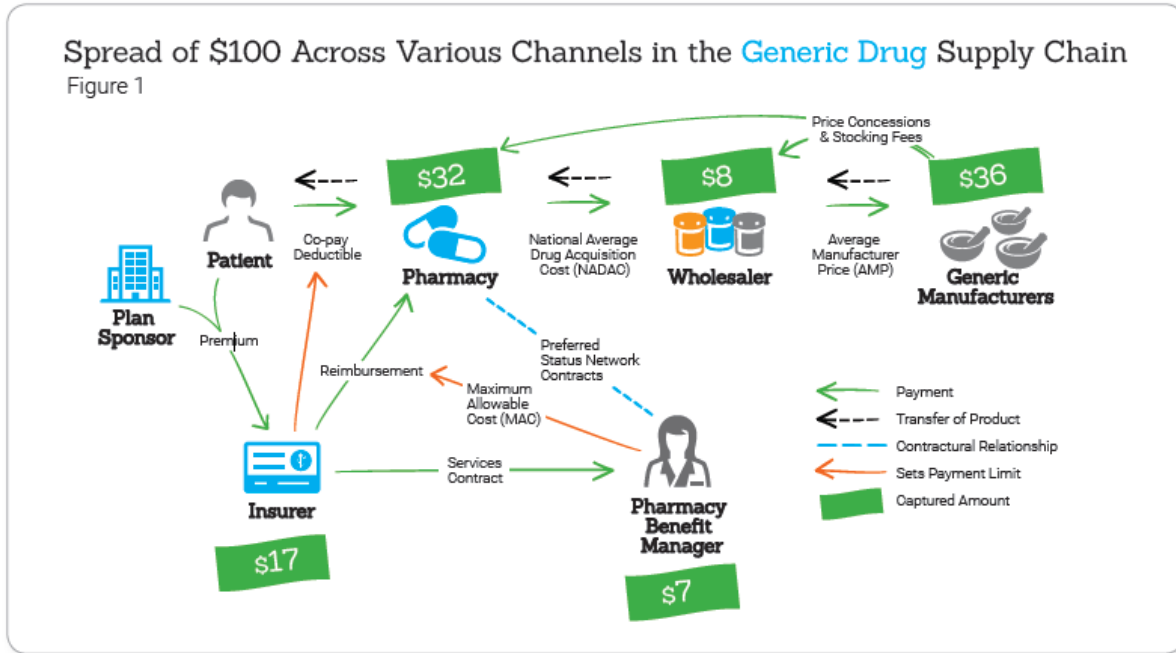


Figure 2. Financial Distribution Across Brand Drug Supply Chain

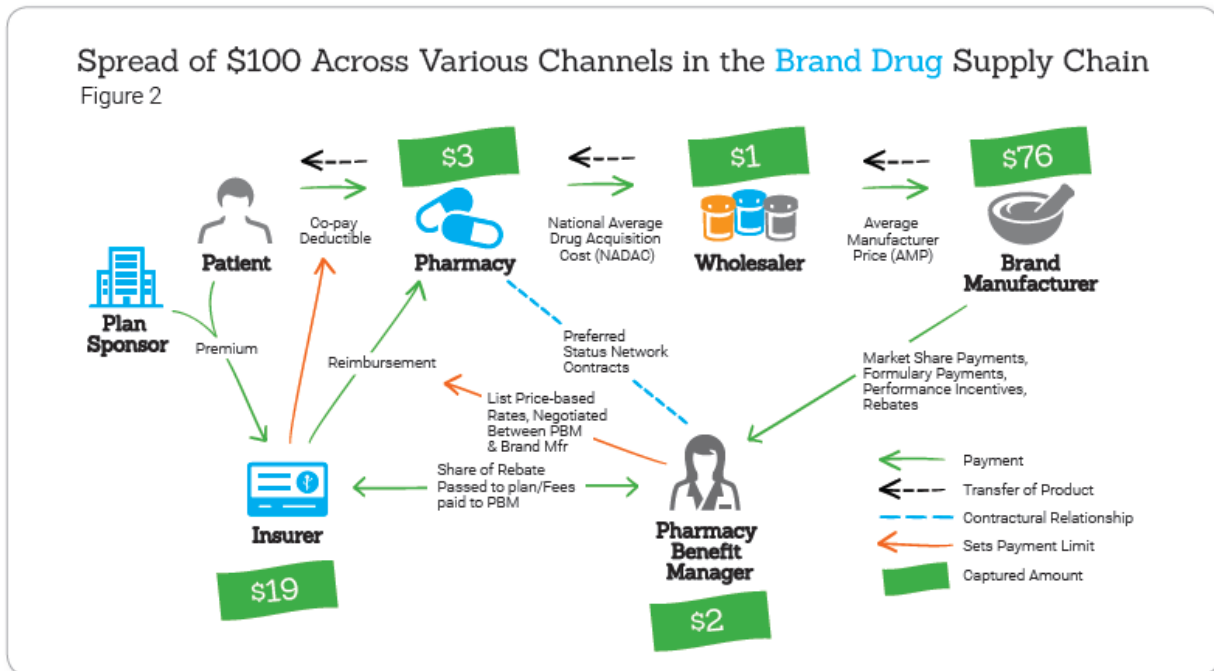


Figure 3. Coverage of New Generics in Medicare and Commercial Plans

**Percent of New Generics Covered by Medicare Part D and Commercial Plans by Formulary Year**

Launch Year	2016		2017		2018		2019		2020		2021		2022	
	M	C	M	C	M	C	M	C	M	C	M	C	M	C
2016	22%	46%	31%	68%	63%	72%	58%	72%	60%	76%	62%	78%	61%	90%
2017			12%	58%	25%	73%	58%	73%	65%	76%	65%	76%	64%	89%
2018					17%	39%	27%	49%	51%	59%	54%	60%	54%	84%
2019							31%	44%	59%	60%	72%	61%	72%	88%
2020									21%	55%	41%	66%	60%	90%
2021											23%	86%	46%	89%

● MEDICARE PART D (M) ● COMMERCIAL (C)

Source: Analysis of Medicare Part D formulary data from CMS and commercial market formulary data from Managed Markets Insight & Technology, LLC.