

**AAM REPORT**

Roadmaps for Ensuring  
Patient Access to Generic  
and Biosimilar Medicines

# Securing Sustainable Markets



**SecureOurMeds**

FEBRUARY 2021



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This paper examines the challenges to market sustainability for generic and biosimilar medicines that have cleared the regulatory and patent hurdles to obtain FDA approval and launch into the U.S. market. It is the first in a series of AAM papers that will highlight challenges to the overall sustainability of the generics and biosimilars industry. Future papers will examine threats to the balance between innovation and competition that drives generic and biosimilar development, including maintaining incentives to challenge brand-name drug patents and eliminating abuses of the patent system, as well as regulatory challenges relating to generics and biosimilars approval.

# Executive Summary

The COVID-19 global pandemic has tested and confirmed the resilience of the generic drug supply chain that continues to provide a bridge to vaccines. At the same time, generic and biosimilar markets face significant challenges that threaten sustainable patient access to more affordable treatments and billions in annual savings for the U.S. health care system.

Policymakers can address these challenges and ensure the sustainability of the generic and the emerging biosimilar medicines markets. The following are key steps policymakers should take to ensure all Americans continue to benefit from a competitive and robust generics and biosimilars industry.

## **COVID-19 / Emergency Preparedness**

- Support the expansion of the Strategic National Stockpile to include essential medicines manufactured in the United States that are necessary for use in a public health emergency.
- Support domestic manufacturers of essential medicines by ensuring the economic conditions exist to justify the use of currently existing domestic manufacturing capacity.

## **Medicare Modernization**

- Ensure generic drugs in Part D are placed on generic formulary tiers with lower cost-sharing than higher-priced brand drugs.
- Ensure new generics are covered and available to seniors in Part D.
- Update the Part D program to include a dedicated generic/biosimilar specialty tier.
- Comprehensively modernize the Part D program to lower cost-sharing for patients by rewarding health plans for encouraging use of lower-cost generics or biosimilars and eliminating barriers to access to biosimilars and generics.
- Implement the final rule that puts an end to brand rebate traps in Part D.
- Increase the add-on payment in Part B for providers who use biosimilars.
- Encourage biosimilars adoption through a shared savings program in Part B.

## **Medicaid Reform**

- Repeal or amend the Medicaid Generics Penalty to reduce its harmful impact on low-cost generics, especially when those products have not increased their list price.

Altogether, these proposals could save patients and taxpayers as much as \$20 billion over the next 10 years through lower out-of-pocket costs and taxpayer spending.

## Introduction

The COVID-19 global pandemic has highlighted the importance of and concerns about a continued stable supply of medicines and other health care items, particularly in the context of national security. But while generic pharmaceuticals faced unprecedented challenges – global export bans and skyrocketing transportation costs, to name two – data suggest the generic drug industry has been resilient during the pandemic. Put simply, patients who need generic medicines, including for the treatment of COVID-19, have generally been able to receive these drugs with minimal interruption.

Yet, the pandemic revealed the potential for shortages and supply chain disruptions caused by government decisions in a range of countries. Proven, reliable generic medicines approved by the Food and Drug Administration (FDA) are playing a critical role in the treatment of patients with COVID-19 and throughout a patient's recovery period. Access to these treatments will continue to serve as a bridge until FDA-authorized vaccines are more broadly distributed and administered to the general public.



This supply chain resilience may mask underlying fragility caused by downward reimbursement pressure that threatens the sustainability of the domestic solid oral dose and injectable generic drug market. Because generic medicines comprise 90% of all prescriptions dispensed in the United States, it may seem counterintuitive that patient access to these medicines is at risk. Yet, generic medicines face new challenges as a result of unprecedented price deflation. And new specialty generics and biosimilars face sub-optimal patient adoption stemming from government and payer policies that perversely reward the use of high-cost brands over lower-priced generic or biosimilar competitors. Left unchecked, these challenges threaten the long-term viability of generic and biosimilar competition.

# Generic and Biosimilar Medicines Deliver Access and Savings

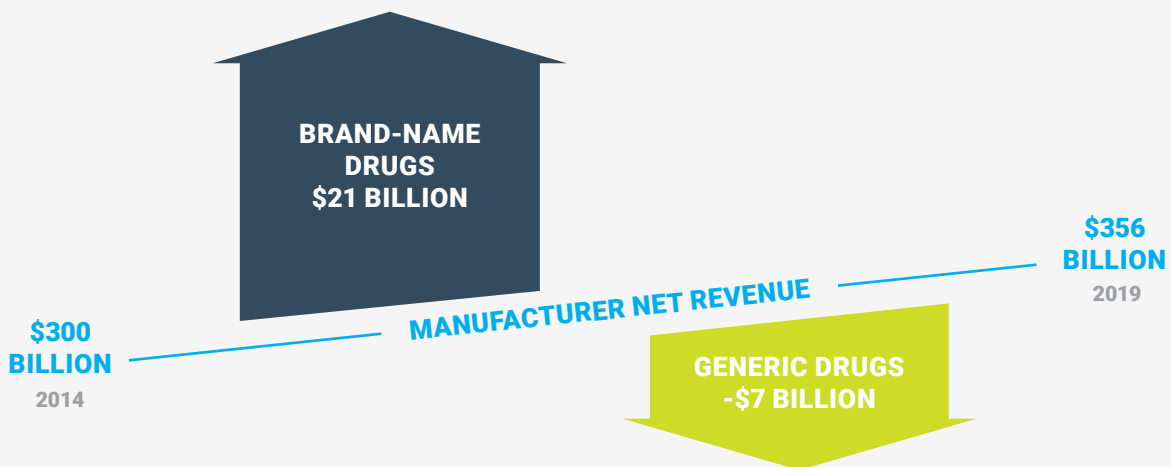
Enacted more than 35 years ago, the Hatch-Waxman Act established the foundation for stunning advances in medical innovation as well as at-the-time unimaginable savings from generic competition. In 2019 alone, the use of generic medicines saved America's patients and taxpayers \$313 billion – nearly \$2.2 trillion over the past 10 years.<sup>1</sup> These savings came from use of generic competitors to well-known brand medicines, but also included a range of therapies in which generic medicines are the only available option for patients.

In fact, the generics and biosimilars industry is the only actor in the health care system that consistently saves money for patients, employers and taxpayers. Health care data firm IQVIA reports that over the past five years, changes in prices on brand drugs have generated an estimated additional \$21 billion in manufacturer net revenue while generic drug price changes have resulted in a reduction of \$7 billion over the same time period.<sup>2</sup>

Even as the share of prescriptions filled by generic medicines continues to grow – to 90% in 2019 – the total spending on these prescriptions continues to fall, to only 20% in 2019.<sup>3</sup>

## GENERIC DRUGS ARE THE ONLY PART OF HEALTH CARE THAT CONSISTENTLY DECLINE IN PRICE

FROM 2014 TO 2019, CHANGES IN PRICE LED TO \$21 BILLION MORE REVENUE FOR BRANDS WHILE GENERIC MANUFACTURERS LOST \$7B.



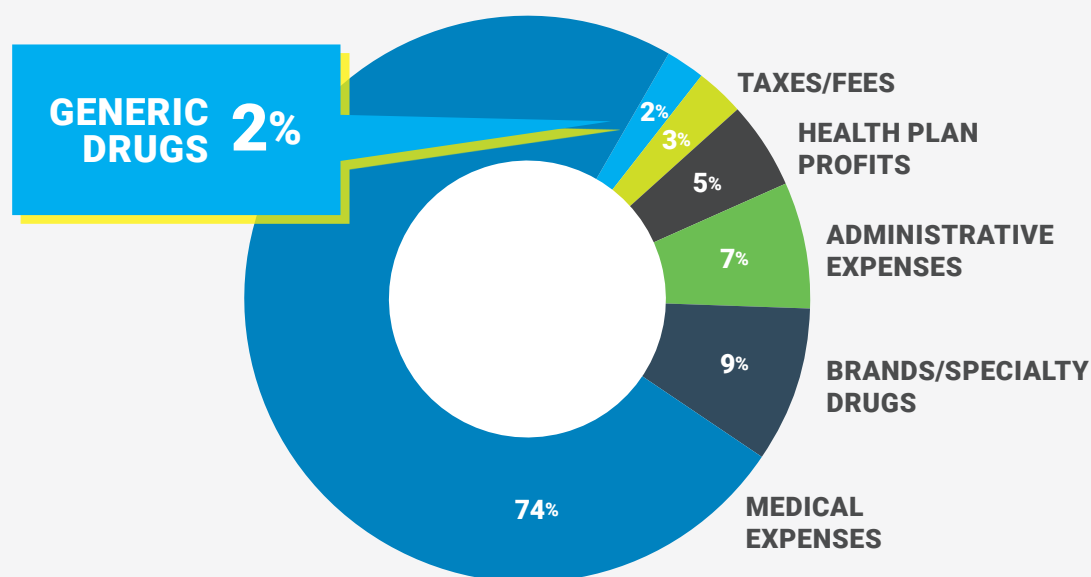
Source: IQVIA 2020.

- 1 AAM. Securing Our Access and Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report. Available at <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf>.
- 2 IQVIA Institute for Human Data Science. (August 2020). Medicine Spending and Affordability in the United States. Available at [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf?\\_=1611863416480](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf?_=1611863416480).
- 3 AAM. Securing Our Access and Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report. Available at <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf>.

Recent data on the cost drivers of health insurance premiums places this in context. Among total health plan costs, generics accounted for only 2% of premiums – compared to 9% driven by brand and specialty prescription drugs and 74% by medical expenses. In fact, the generics share of health plan premiums was less than health plan profits (5%) and taxes/fees (3%).<sup>4</sup>

## IN MOST POPULOUS STATE, GENERICS ARE LOWEST COST DRIVER

DATA FOR COST DRIVERS OF HEALTH INSURANCE PREMIUMS IN CALIFORNIA SHOW GENERIC DRUGS ARE A VERY SMALL SLICE OF COSTS.



Source: California Department of Managed Health Care. CA Prescription Drug Cost Transparency Report. Measurement Year 2019. <https://www.dmhc.ca.gov/Portals/0/Docs/DO/2019SB17PrescriptionDrugTransparencyReport.pdf>

In short, patients, health care providers and payers rely on a strong generic market for affordable access to life-saving and life-sustaining medications.

And unrelenting public concern about high brand drug prices makes clear there has never been a greater need for generic and biosimilar competition.<sup>5</sup> Brand specialty and biologic medicines account for roughly 2% of all prescriptions, but nearly 50% of all spending in the U.S.<sup>6</sup> Competition from specialty generic and biosimilar medicines is critical to the long-term affordability of these medicines. In 2019, the use of biosimilars and specialty generics saved patients and taxpayers more than \$67 billion.<sup>7</sup> And despite slower-than-expected adoption, biosimilars are projected to save \$100 billion between 2021 and 2025.<sup>8</sup>

4 California Department of Managed Health Care. Prescription Drug Cost Transparency Report. Measurement Year 2019. Available at <https://www.dmhc.ca.gov/Portals/0/Docs/DO/2019SB17PrescriptionDrugTransparencyReport.pdf>.

5 KFF Health Tracking Poll. (Jan. 2020). Available at <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>.

6 Express Scripts (2019). 2019 Drug Trend Report. Available at <https://www.express-scripts.com/corporate/drug-trend-report#2019-by-the-numbers>.

7 IQVIA National Sales Perspective, Dec 2019.

8 IQVIA Institute for Human Data Science. Biosimilars in the United States 2020-2024: Competition, Savings, and Sustainability. Available at <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.



# COVID-19 Has Revealed Challenges and Resilience of the Generics Industry

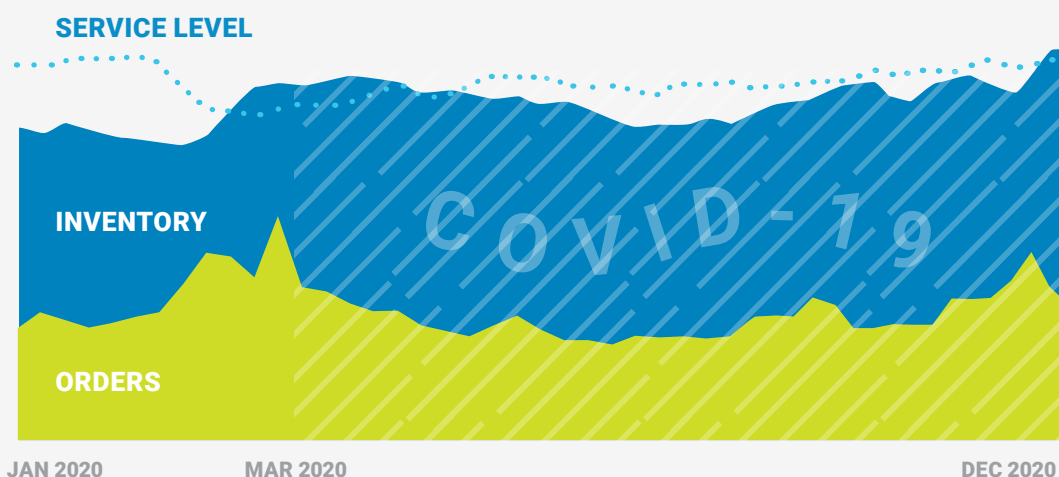
The onset of the COVID-19 global pandemic imposed new and unprecedented challenges for global industries, scientists and politicians. Few business sectors were immune from its impact. COVID-19 has caused supply disruptions from core consumer goods like toilet paper and groceries to needed protective equipment and medical supplies.

The pandemic has revealed significant challenges to the pharmaceutical sector, including skyrocketing costs of transportation<sup>9</sup> and targeted export bans in certain countries.<sup>10</sup> Observers have suggested the pandemic reveals the fragility of the generic drug industry, but the issue merits closer examination.<sup>11</sup> A review of the supply chain during the height of the March COVID-19 crisis in New York is illustrative of supply chain resilience.

At the request of AAM, IQVIA reviewed the availability of brand and generic medicines during the March COVID-19 crisis.<sup>12</sup> The data reveal a consistent story – wholesaler sales (service level) and inventory levels were relatively steady prior to the crisis, but demand for medicines (orders) spiked following the March 13 national emergency declaration. During the ensuing weeks, dispensing locations attempted to place orders with their wholesalers to ensure they did not run out of product. Although short-term service levels dropped as wholesalers allocated product to their customers, they consistently increased as inventory increased.

## DURING THE COVID PANDEMIC, THE GENERIC SUPPLY CHAIN WAS RESILIENT

AFTER THE INITIAL DEMAND FOR MEDICINES SPIKED IN MARCH, CONSISTENCY AND INVENTORY OF PRODUCT INCREASED.



Source: IQVIA Analysis for AAM.

9 AAM. (April 2020). Pharmaceutical Shipping Costs Spike in Response to Global COVID-19 Pandemic. Available at <https://accessiblemeds.org/resources/press-releases/pharmaceutical-shipping-costs-spike-response-global-covid-19-pandemic>.

10 <https://www.macmap.org/covid19>

11 <https://www.arnoldventures.org/stories/covid-19-reveals-fissures-in-the-nations-prescription-drug-supply-chain/>

12 Release pending.

This demonstrates the value of a diverse global supply chain that proved nimble and able to adapt to unprecedented spikes in demand. As a result, the generic supply chain was able to maintain America's patients' and health care providers' access to medicine.

As part of the ongoing response to the current pandemic as well as in preparation for the next pandemic, more can be done to support a diverse global supply chain, including encouraging the utilization of existing and creation of new domestic drug manufacturing capacity. In its [Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain](#), AAM has proposed a series of steps to ensure a reliable supply of life-saving medicines.<sup>13</sup>

## Looking Beyond the Pandemic – Resiliency Requires Sustainability

There are threats to the resilience of the generic drug industry and its long-term market sustainability that could impede patient access to affordable treatments even in the absence of pandemic circumstances.

### **These challenges include:**

- rapid price deflation;
- ill-advised government policies that contribute to drug shortages for older commoditized generics;
- anticompetitive brand practices; and
- adverse government policies that create barriers to adoption by rewarding use of high-priced brand drugs over generic or biosimilar competitors.

Then-HHS Secretary Azar captured the challenge in 2018 when he testified before Congress that policymakers should examine whether the U.S. is “underpaying for and under-reimbursing for generics. We need a strong, robust generic market. We may be driving those prices so low that we’re creating manufacturing anomalies that lead to sole-source products with others exiting.”<sup>14</sup>

Unlike brand drugs, generics consistently decline in price as a result of robust competition by generic manufacturers. Declining prices are embedded in the balance between innovation and competition struck by the Hatch-Waxman Act. They are the foundation of a highly competitive market that typically rewards generic entry and aggressive price competition with market share that changes rapidly as manufacturers compete to offer the lowest price.

But Azar also noted the perverse incentive undermining new generics whereby “a drug with a higher list price is often a more attractive choice to cover than a cheaper competitor.”<sup>15</sup>

Ultimately, the generic drug commercial model is sustainable only when government policies do not punish low-cost generics and no longer reward use of high-cost brands over generics or biosimilars. The current uncertain environment for generic and biosimilar medicines imperils manufacturers' continued ability to deliver value.

13 AAM. A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain. Available at <https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf>.

14 Azar, A. (June 26, 2018). Testimony before the U.S. Senate Finance Committee.

15 <https://www.statnews.com/2019/01/29/lowering-drug-prices-trump-alex-azar/>

# Symptoms of Market Failure – Shortages and Lack of Entry

Early symptoms of potential market failure may be found in the persistence of drug shortages and an emerging trend of manufacturer business decisions not to launch newly approved generic drugs because of negative market dynamics.

## CONTINUED CHALLENGES OF DRUG SHORTAGES

Evidence suggests that generic drugs are particularly susceptible to drug shortages, in part due to price reductions and loss of profitability due to low reimbursement.<sup>16</sup> This is directly related to the economic forces at play in generic markets, where market pressures may force generic manufacturers to reconsider production of lower-margin, often older, medicines to ensure continued business sustainability.

This results in a dynamic landscape where manufacturers regularly enter and exit markets as conditions change. These market exits can strain the supply chain and may leave providers with limited supply to meet patient needs. For instance, sterile injectable drugs, which have significant manufacturing complexities and therefore have limited suppliers with these capabilities, have in the past and continue today to experience shortages.

In 2011, future-FDA Commissioner Scott Gottlieb testified before Congress that many shortages were a direct result of low reimbursement for older, low-margin products.<sup>17</sup> These findings were reinforced by the 2019 report produced by the FDA-led interagency Drug Shortage Task Force that identified the lack of incentives for less-profitable drugs as a root cause of drug shortages.<sup>18</sup>

A contributing factor to unsustainable reimbursement is market consolidation among purchasers of generic drugs. Today, three large wholesaler-based entities control roughly 90% of all non-injectable generic purchases, while three large group purchasing organizations are responsible for 90% of injectable generic purchases.<sup>19</sup>

In response to these challenges, many older generics may be sourced outside of the U.S., with resulting longer supply chains that may be less able to respond quickly in the face of rapidly fluctuating demand. As noted above, AAM supports encouraging more U.S. manufacturing of generics, including injectable drugs, beginning with effective use of unused domestic capacity.

The likelihood of such shortages will only increase as generic companies discontinue unprofitable medicines – and as fewer generic companies manufacture certain products – in response to purchaser consolidation and increasing government-imposed burdens.

16 Stromberg, Chris, Drug Shortages, Pricing, and Regulatory Activity, National Bureau of Economics Working Paper (2014). Available at <http://www.nber.org/chapters/c13102.pdf>.

17 Gottlieb, Scott, M.D. Statement before the Senate Finance Committee on December 7, 2011. “Drug shortages: Why they happen and what they mean.” Washington, DC.

18 Drug Shortages: Root Causes and Potential Solutions

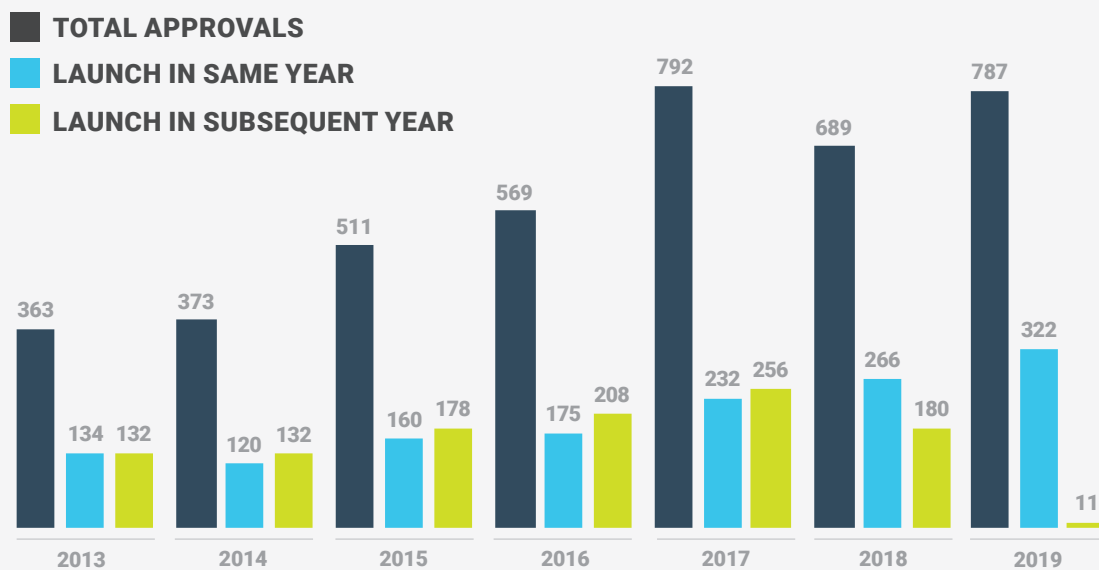
19 Fein, Adam. (October 2020). The 2020-21 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors.

## INCREASING NUMBERS OF APPROVED GENERICS ARE NOT AVAILABLE TO PATIENTS

Recent analyses have demonstrated that some generic drugs approved by FDA do not proceed with commercial market entry or do so only after a significant delay. This trend is found among generics for older medicines for which there are already many approved competitors and for which the average price has already been driven very low. Surprisingly, it is also observed among generics approved by the FDA as the first generic competitor to a brand where a greater market opportunity may exist.

### THERE IS A SIGNIFICANT DELAY IN GETTING NEW GENERIC MEDICINES TO PATIENTS

GREATER THAN 30% OF ANDAS ARE LAUNCHED IN SUBSEQUENT TIME PERIODS.



Source: FDA Orange Book, Dec 2019; IQVIA National Sales Perspectives, IQVIA institute, Feb 2020.

While one may expect this trend among older generics, particularly as FDA has worked to resolve its backlog of overdue generic drug applications, it is nonetheless a concerning trend that raises questions about the sustainability of the market. The decision to delay launch of first generics is an even more troubling signal, as patient access is negatively affected and savings are unrealized for payers.

There are many reasons a manufacturer might not market or might delay marketing of a product, but a major reason reported by AAM members is the commercial landscape. As noted, this might include the inability to reach a contract with one of the three purchasers that control 90% of the respective generic market or changes in the market opportunity in the time that a company has been awaiting FDA approval.<sup>20</sup>

The continued sustainability of generics also faces challenges resulting from government policies.

<sup>20</sup> Other reasons reported by AAM members include challenges sourcing API, manufacturing obstacles or capacity constraints.

# Policy Challenges – Older, Commoditized Generic Medicines

## MEDICAID GENERICS PENALTY

Older commoditized generics face significant challenges as a result of rapid and sustained price deflation. These trends have been compounded by policy decisions that have tightened the financial pressure on these medicines.

In particular, in 2015 Congress imposed an “inflation penalty” on generics in the Medicaid program. Modeled after a long-standing penalty on costly brand drugs, the penalty is paid when a product’s average price rises faster than the rate of inflation. Brand-name drugs generally experience consistent, sustained price growth. Generics do not, and application of the penalty to generics has generated significant negative unintended consequences.

The competitive generic market functions differently than the monopoly brand market, and low-cost generic medicines may have price variability directly related to fluctuations in purchasing patterns. And these variations may nonetheless be seen in percentage changes that exceed inflation, even if the actual change in price amounts to a few cents per dose. As a result, generic manufacturers face millions of dollars in additional rebates for products even when the list price of the product is unchanged. These fluctuations may not reflect a new higher price, but rather new purchasing patterns.

Experts predicted the Medicaid Generics Penalty could exacerbate the challenge of drug shortages.<sup>21</sup> They concluded it would “increase uncertainty, reduce revenues, encourage manufacturers to exit the market and discourage the entry of new manufacturers. The predictable effect of discouraging entry into competitive markets is that product availability will be hampered: shortages will be more likely, and the market forces that lead prices to fall will be dampened.” Ironically, the analysis also concluded that the penalty “will not only have little effect on generic prices, but it will also have the unanticipated and unintended consequence of increasing the likelihood of shortages for potentially life-saving generic medicines.” This prediction appears prescient.

AAM recently surveyed its manufacturer members to understand the real-world impact of the Medicaid Generics Penalty. For the fourth quarter of 2019, the most recent time period for which data was available, the survey found:

- **Changes in Customer Mix, Not Price Increases, Trigger the Medicaid Generic Penalty.**

Companies that paid the inflation penalty on generics reported a range of 40% to 100% of total penalties paid were attributable to a change in customer mix. The majority of instances in which companies incurred the penalty were not associated with an increase in the list price of the drug.

- **The Medicaid Generic Penalty Exacerbates Shortages for Patients.**

Half of responding companies reported they incurred the inflation penalty on products that are presently or have recently been on the FDA shortage list. This means the inflation penalty constructs one more barrier to creating a sustainable market for products vulnerable to drug shortages.

- **Portfolio Impacts Are Significant.**

Among those that paid the penalty, the penalty affected between 24% and 100% of their products.

21 Bates-White. Penalyzing Generic Drugs with the CPI Rebate Will Reduce Competition and Increase the Likelihood of Drug Shortages. May 2, 2017. Available at [https://www.bateswhite.com/media/publication/142\\_CPI%20Rebate.Manning\\_Selck.pdf](https://www.bateswhite.com/media/publication/142_CPI%20Rebate.Manning_Selck.pdf).

These unpredictable, onerous penalties create significant risk for manufacturers and make it more challenging for them to continue producing some low-margin or low-volume medicines. And for manufacturers attempting to sustainably produce products that are in shortage, the policy may present a further barrier, or even an incentive to exit the market entirely.

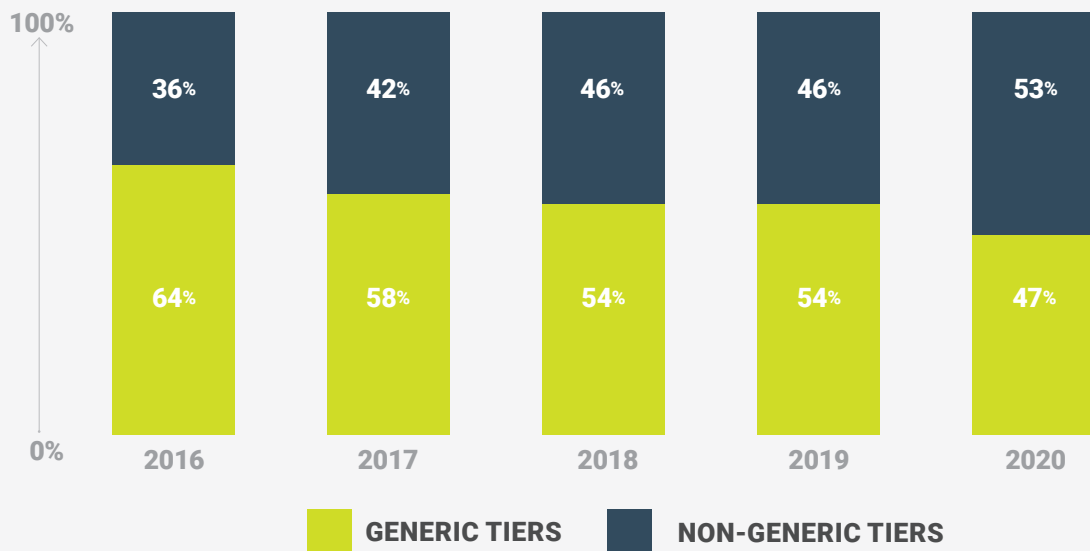
### MEDICARE PART D FORMULARY PLACEMENT

Even as generic prices continue to fall, patients may be forced to pay more at the pharmacy counter because Medicare plan formularies now place more generics on brand formulary tiers with higher cost-sharing requirements.<sup>22</sup>

Avalere Health evaluated the Medicare formulary placement and patient out-of-pocket costs for the same drugs in 2011 and 2015. The study found cost-sharing had increased by 93%, even though the drugs studied had increased in price by only 1%. Since then, this trend has only intensified, and in 2020 for the first time there were more generics on brand and specialty cost-sharing tiers than on generic tiers in Medicare.

#### IN 2020, FOR THE FIRST TIME MORE GENERICS WERE PUT ON NON-GENERIC TIERS

FROM 2016-2020 HEALTH PLAN FORMULARIES PLACED GENERICS ON BRAND FORMULARY TIERS WITH HIGHER COST-SHARING REQUIREMENTS.



As a result, America’s seniors pay more for low-cost generics — sometimes even paying the full cost of the drug with no help from their own health plan to which they pay premiums. This is one further discouragement to generic adoption and sustainability.

<sup>22</sup> Avalere. For the First Time, a Majority of Generic Drugs Are on Non-Generic Tiers in Part D. February 13, 2020. Available at <https://avalere.com/insights/for-the-first-time-a-majority-of-generic-drugs-are-on-non-generic-tiers-in-part-d>.

## Policy Challenges – New Generic and Biosimilar Competitors

New generic and biosimilar launches represent affordable access for patients and are the lifeblood for continued manufacturer sustainability. However, a combination of policy miscues and anti-competitive brand practices have created significant barriers to adoption of new lower-cost generic and biosimilar competitors.

### MEDICARE ADVANTAGE AND PART D FORMULARIES THAT PREFER BRAND DRUGS

Historically, plan formularies automatically preferred a new generic medicine over a brand given the significant price discount provided by the generic. However, this is no longer a given.

An AAM examination of launches and formulary coverage for newly approved first generics from 2016-2018 found that only about half were included on formularies of Medicare Part D plans. Once they are added to formularies, first generics are routinely placed on expensive brand drug tiers with higher patient copays, rather than on generic tiers with lower cost-sharing. It takes nearly three years before first generics are covered on 50% of Medicare Part D formularies. This restricts patient access to lower-cost generics, denying patients savings in favor of unnecessarily high cost-sharing for brand-name drugs. As a result, seniors do not benefit from lower prices and lower out-of-pocket costs, and taxpayers continue to pay for high-priced brand drugs.<sup>23</sup>

These findings are consistent with a recent analysis published in Health Affairs.<sup>24</sup> The study found the majority of generics receive preferred or equal coverage as their respective brand drug. However, the study also suggested as many as 10% of all generics are either not covered or have less preferred coverage than their reference brand drug.

Commercial plan formularies also delay coverage of first generics.<sup>25</sup> Although first generics face delays in coverage by commercial health plan formularies, commercial formularies were nonetheless meaningfully faster than Medicare drug plans, suggesting there are unique aspects of the Medicare drug program that advantage brand drugs over generic competitors.

It is important to note these poor coverage rates are not explained by generic prices. Formulary coverage did not appear to meaningfully increase as generic prices fell. Not only did the first generics reviewed in this analysis launch at a significant discount to the brand, but their prices declined by 44% on average by the second year after launch – yet plan coverage improved only by 9-15%.

FDA recently released a report examining launch prices of new generic competitors showing median first generic launch prices were 40% less than brand on net and 49% less than brands using list price.

23 AAM. (Sep. 2019). White Paper: Access Denied: Why New Generics Are Not Reaching America's Seniors. Available at [https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web\\_0.pdf](https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf). AAM. (Jan. 2020). Sideline: How Seniors Miss Out on Savings Available Through Generic Substitution. Available at <https://accessiblemeds.org/sites/default/files/2020-01/AAM-White-Paper-Substitution-January2020.pdf>.

24 Dusetzina, S., Cubanski, J., True, S., Hoadley, J., Roberts, D., Neuman, T. (Aug. 2020). Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available. Health Affairs, 39(8). Available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2019.01694>.

25 AAM. (Feb 2020). White Paper: Medicare and Commercial Plans Fail to Get New Generics to Patients. Available at <https://accessiblemeds.org/sites/default/files/2020-02/AAM-White-Paper-Medicare-Part-D-New-Generics-to-Seniors-web.pdf>.

This report reinforces new generic competitors have much lower prices than their brand counterparts.<sup>26</sup> It is clear their prices are not the reason Part D plans are not covering low-cost first generics.

Rather, there are structural incentives for both poor coverage of generics at launch and improper tier placement. For both commercial plans and Medicare plans, there are significant incentives, such as manufacturer rebates, for plans to place brand medicines on preferred or similar tiers. Additionally, the significantly worse coverage rates for first generics in Medicare are a direct result of Medicare design features that include the brand drug Coverage Gap Discount Program (CGDP), the availability of brand drug rebates and the lack of a dedicated specialty tier for lower-priced generics and biosimilars.<sup>27 28</sup>

## **MEDICARE PART B POLICIES ENCOURAGE USE OF HIGHER-PRICED BRAND DRUGS**

Likewise, new biosimilars face significant adoption barriers in Medicare Part B. These stem largely from reimbursement policies that do not encourage biosimilar adoption or even actively reward use of higher-priced brand drugs.

Although biosimilars are on average 30% less expensive<sup>29</sup> than reference brand-name biologics, biosimilars have yet to realize the full potential of savings through broad adoption. Patient out-of-pocket cost is often based on a percentage of the list price of a drug, meaning biosimilars provide patients with a significantly lower cost burden than brand-name biologics, leading to increased adherence and better patient outcomes. Further, payers that have preferred biosimilars over the brand-name biologic have been able to realize significant savings for their members and patients.

Not only do biosimilars provide a more affordable option for patients and the health care system, they also lower the price of the brand-name biologic as a result of competition. And biosimilars are directly responsible for increasing patient access to therapy by as much as 5%.<sup>30</sup>

Nonetheless, despite significant price discounts, few of the biosimilars available to patients have been able to garner significant market share. The result has been billions in lost savings for America's patients, employers and taxpayers.

This is a result of rebate traps previously mentioned, but also a result of other Medicare payment policies. Medicare Part B policies do not encourage providers to prescribe and administer lower-cost treatments. Rather, the Part B program pays providers the same administration fee whether they administer a lower-priced biosimilar or higher-cost brand-name biologic.<sup>31</sup> While this ensures providers are not penalized for using a lower-cost biosimilar, it also means providers have no incentive to use the lower-cost option.

26 Conrad, R., Lutter, R. (Dec 2019). FDA Report: Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices. Available at <https://www.fda.gov/media/133509/download>.

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31 Centers for Medicare & Medicaid Services, HHS, 42 C.F.R. § 405, 410, 411, 414, 425, 495. Available at <https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>.



# Call to Action – Policy Solutions to Ensure Generic and Biosimilar Sustainability During and After the Pandemic

Because many of these challenges are the result of imprudent or out-of-date government policies, there are actions policymakers can take to ensure the sustainability of the generic and biosimilar medicines market. These actions would maximize the value of current generic and biosimilar competition, support the ability of manufacturers to produce older, commoditized generics and ensure a strong foundation for future generic and biosimilar savings. In fact, IQVIA has projected that over the next four years, the value of brand drugs on track to lose patent protection exceeds \$100 billion in annual sales, thereby opening new avenues for patients to save through generic competition.<sup>32</sup>

It is essential to maximize the price competition generics bring to the marketplace for patients. The following are key actions policymakers should take to secure the stability of generic and biosimilar drug competition.

## COVID-19 / Emergency Preparedness

- Support the expansion of the Strategic National Stockpile to include essential medicines manufactured in the United States that are necessary for use in a public health emergency.
- Support local manufacturers of essential medicines by ensuring the economic conditions exist to justify the use of currently existing local manufacturing capacity.

## Medicare Modernization

- Ensure that generic drugs are placed on generic formulary tiers with lower cost-sharing than higher-priced brand drugs.
- Ensure that new generics are covered and available to seniors in Medicare.
- Update the Medicare program to include a dedicated generic/biosimilar specialty tier.
- Comprehensively modernize the Medicare program to lower cost-sharing for patients by rewarding health plans for encouraging use of lower-cost generics or biosimilars and eliminating barriers to access to biosimilars and generics.
- Implement the final rule that puts an end to brand rebate traps.
- Increase the add-on payment for providers who use biosimilars.
- Encourage biosimilar adoption through a shared savings program.

## Medicaid Reform

- Repeal or amend the Medicaid Generics Penalty to reduce its harmful impact on low-cost generics, especially when those products have not increased their list price.

Altogether, these proposals could save patients and taxpayers as much as \$20 billion over the next 10 years through lower out-of-pocket costs and taxpayer spending.

32 IQVIA Institute for Human Data Science. Biosimilars in the United States 2020-2024: Competition, Savings, and Sustainability. Available at <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.

## Conclusion

Savings from generic and biosimilar competition are vital to the ability of America's patients to continue to receive affordable access to life-saving and life-sustaining medicines. The COVID-19 global pandemic serves to highlight the need to continue efforts to protect patients' access to medicines by ensuring that public policy supports and rewards generic and biosimilar competition.





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