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Hill over Hatch-Waxman...)



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Introduction

As the modern generic and biosimilar drug industry reaches its 40th anniversary, the industry faces unprecedented challenges that call into question the viability of sustainable competition from low-cost medicines.

The Drug Price Competition and Patent Restoration Act of 1984 stands out as a monument of federal legislation that produced lasting benefits for America's patients and taxpayers. Commonly known as the "Hatch-Waxman Act", the law created a pathway for the introduction of lower-cost generic drugs. The results have been wildly successful. In the last ten years alone, the use of generic drugs has saved patients and the U.S. healthcare system almost \$3 trillion dollars.¹

Seeking to build on this success, in 2011, Congress established a pathway for the approval of biosimilars – lower-cost versions of the high-cost brand biologic and specialty medicines, which represent only two percent of volume but drive more than half of all prescription drug spending.² Despite barriers to adoption, biosimilars are already expanding access and reducing spending for patients. To date, biosimilar medicines have allowed for more than 344 million incremental days of therapy – care that patients would not have received otherwise.³

The benefits are tangible: generics and biosimilars make it easier for patients to afford their medicines, for employers to pay for healthcare, and for health plans and pharmacy benefit managers (PBMs) to contain spending. Generics drive biomedical innovation as brand manufacturers respond to lower-cost competition. And generic competition creates "headroom" for spending on new, high-cost innovative medicines. Everyone wins when a generic drug is dispensed. As a result, the United States leads the world in both pharmaceutical innovation and adoption of lower-cost generic drugs.⁴

But this track record of success—and the resulting increase in patient access to care—is currently at risk. Low-cost generic competition appears fragile, evidenced most recently by increasing numbers of drug shortages; and generics face new challenges, many the result of federal and state legislation. Without legislative and regulatory action by policymakers in Congress, the White House and state governments, it is very possible that the shortages of today point to future supply chain strains and challenges to patient access.

The Challenges

Unchecked Price Deflation

Low prices delivered by generic competition are critical to patient access and affordability of care in the United States. And generics are delivering. Studies have shown that generic prices in the U.S. average 16 percent less than other countries, and between 30 to 50 percent less than nations such as the U.K., Mexico, France and Japan.⁵ This difference is the result of a hyper-competitive U.S. generic drug market in which prices can rapidly fall by 40 percent on average, and as much as 95 percent upon generic entry.⁶ Biosimilars are demonstrating similar impacts on prices, with rapidly falling biosimilar and brand biologic prices.⁷

1 Association for Accessible Medicines. (Sep 2023). "2023 U.S. Generic and Biosimilar Medicines Savings Report". Available at: <https://accessiblemeds.org/resources/reports/2023-savings-report>

2 IQVIA Institute. (Jan. 2023). "Biosimilars in the United States 2023-2027". Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027>

3 Association for Accessible Medicines. (Sep 2023). "2023 U.S. Generic and Biosimilar Medicines Savings Report". Available at: <https://accessiblemeds.org/resources/reports/2023-savings-report>

4 Mulcahy, A; Whaley, C; Tebeka, M. (2021). "International Prescription Drug Price Comparisons." Available at: <https://aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbebf28b/international-prescription-drug-price-comparisons.pdf>

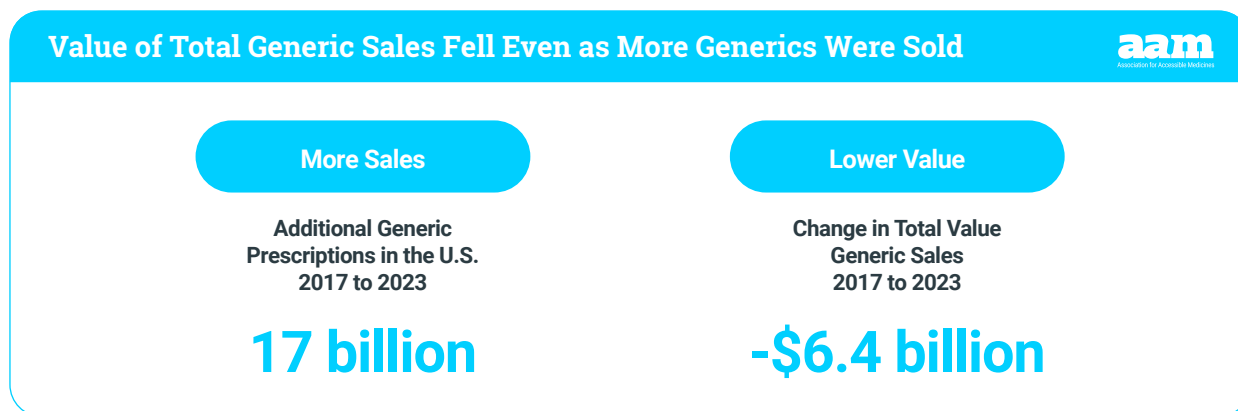
5 Mulcahy, A; Whaley, C; Tebeka, M. (2021). "International Prescription Drug Price Comparisons." Available at: <https://aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbebf28b/international-prescription-drug-price-comparisons.pdf>

6 Conrad, R; Lutter, R. (Dec 2019). FDA. "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>

7 IQVIA Institute. (Jan. 2023). "Biosimilars in the United States 2023-2027". Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027>

But while price competition is a long-standing feature of the U.S. generic drug market, generics are suffering extended and high, unchecked price deflation. In 2013, generics accounted for 86.1 percent of prescriptions and 28.7 percent of spending. In 2022, they were 90.3 percent of prescriptions and 17.5 percent of spending.⁸

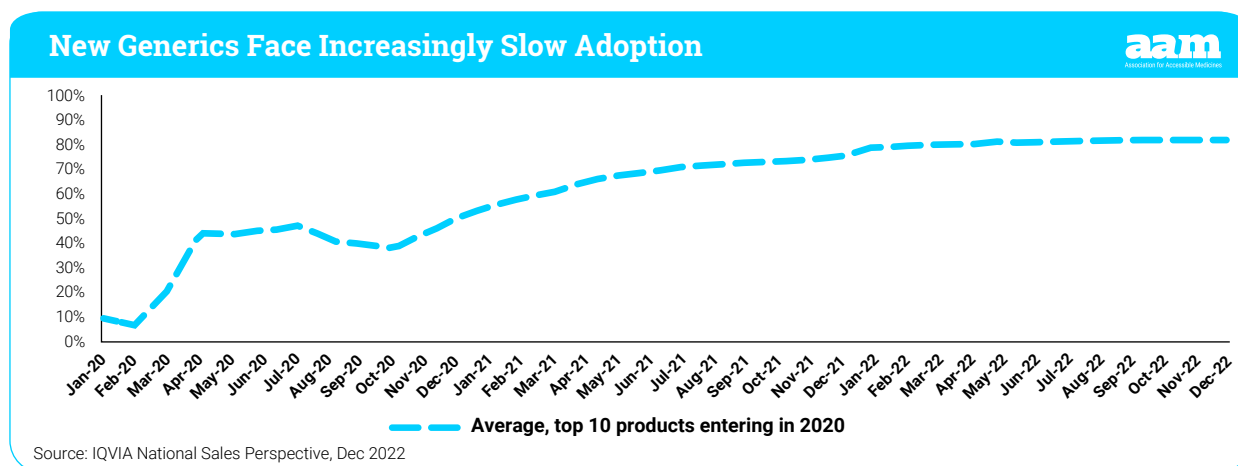
This represents a loss of \$6.4 billion in the value of generic sales since 2017, even when taking into account new generic launches and increased generic prescription market share, and it is the result of a multi-year period of sustained generic price deflation.⁹



There is increasing recognition that generic prices may actually be too low. As U.S. Food and Drug Administration (FDA) Commissioner Dr. Robert Califf recently noted, “We have got to fix the core economics if we’re going to get this situation fixed.”¹⁰

Fewer New Generics & Slower Market Penetration for New Generics

Unchecked deflation is compounded by challenges for new generic launches. This is witnessed in fewer large-scale new generic opportunities¹¹ and in slower market penetration for new generics. For instance, although generics would historically be expected to achieve 90 percent or more of total prescriptions within six months of launch, generics launched in 2020 remained stuck below 70 percent market share until mid-2021, and even by the end of 2022, only reached 84 percent market share.



8 Association for Accessible Medicines. (Sep 2023). “2023 U.S. Generic and Biosimilar Medicines Savings Report”. Available at: <https://accessiblemeds.org/resources/reports/2023-savings-report>

9 IQVIA Institute for Human Data Science. (April 2023). “The Use of Medicines in the U.S. 2023 Usage and Spending Trends and Outlook to 2027”. Available at: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2023/the-use-of-medicines-in-the-us-2023.pdf>

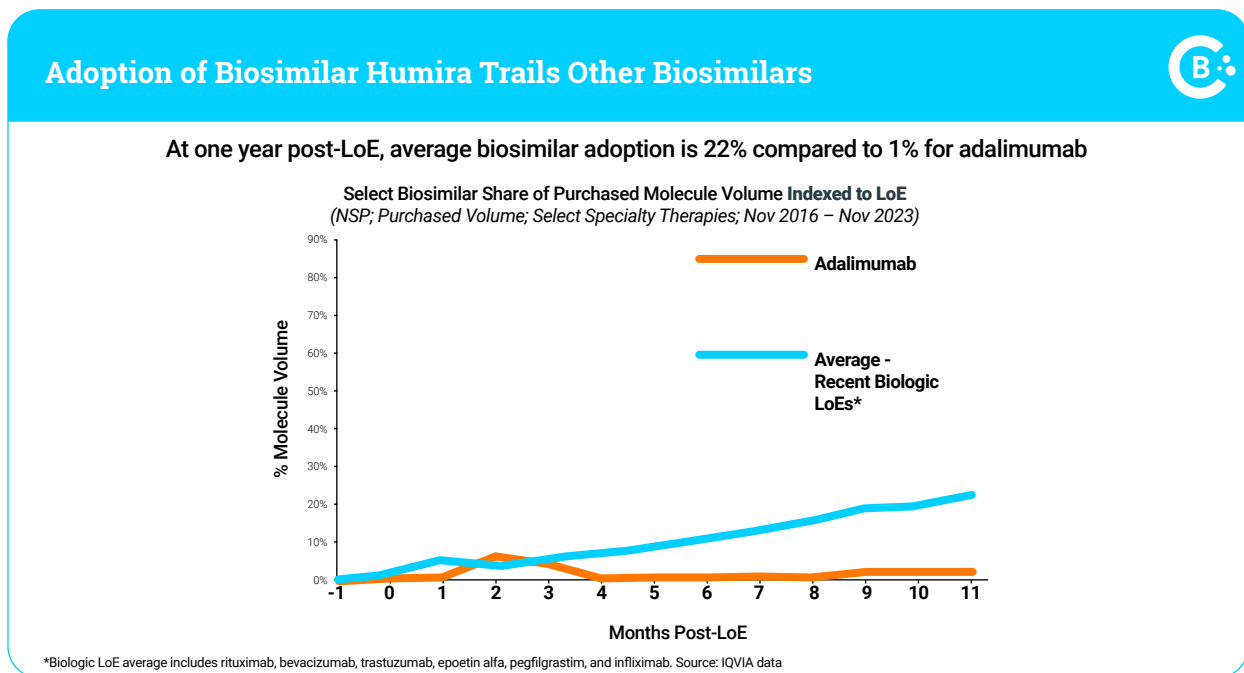
10 Jewett, C. “Drug Shortages Near an All-Time High, Leading to Rationing”. (May 17, 2023). New York Times, Available at: <https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html>

11 IQVIA Institute for Human Data Science. (April 2023). “The Use of Medicines in the U.S. 2023 Usage and Spending Trends and Outlook to 2027”. Available at: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2023/the-use-of-medicines-in-the-us-2023.pdf>

Slower Than Expected Biosimilar Adoption

Similar challenges have bedeviled new biosimilar competition. Although biosimilars are delivering on their promise of lower prices, adoption has been slower than anticipated.¹² And even in markets with relatively high biosimilar adoption, it is not clear that these lower prices are sustainable for multiple competitors.¹³

The story is even more concerning among pharmacy-benefit biosimilars such as insulin and adalimumab (brand name: Humira®). For instance, although more than half of new patient prescriptions are written for biosimilar insulin, these comprise less than a third of filled prescriptions.¹⁴



Drug Shortages are a Symptom of Increasing Market Fragility

Generic and biosimilar manufacturers are experiencing profound challenges. Older, more commoditized medicines are experiencing price deflation, while newer, more valuable commercial launches face slower adoption. The cumulative result is an underlying fragility of which the recent increase in drug shortages is a symptom.

A recent IQVIA Institute report highlights this:

- Shortages are overwhelmingly found in generic drugs, particularly sterile injectables;
- Shortages are increasingly in multi-source generic markets; and
- Shortages are centered in low-cost products below \$1 and \$5.¹⁵

In short, unsustainable pricing can cause market exits and create conditions in which the market is vulnerable to a shortage, whether caused by a natural disaster¹⁶, an FDA inspection¹⁷, corporate bankruptcy¹⁸, or other unforeseen events.

12 IQVIA Institute. (Jan. 2023). "Biosimilars in the United States 2023-2027". Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027>

13 IQVIA Institute. (Jan. 2023). "Biosimilars in the United States 2023-2027". Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027>

14 Biosimilars Council. (July 2023). "Pharmacy Benefit Managers Are Blocking Patient Access to Biosimilar Insulin". Available at: <https://biosimilarscouncil.org/resource/pharmacy-benefit-managers-are-blocking-patient-access-to-biosimilar-insulin/>

15 IQVIA Institute. (Nov 2023). "Drug Shortages in the U.S. 2023". Available at: <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023>

16 Lupkin, S. (July 2023). NPR "Tornado damage to Pfizer factory highlights vulnerabilities of drug supply". Available at: <https://www.npr.org/sections/health-shots/2023/07/27/1190507719/tornado-pfizer-factory-drug-shortages>

17 Gilbert, D. (June 2023). The Washington Post. "How troubles at a factory in India led to a U.S. cancer-drug shortage".

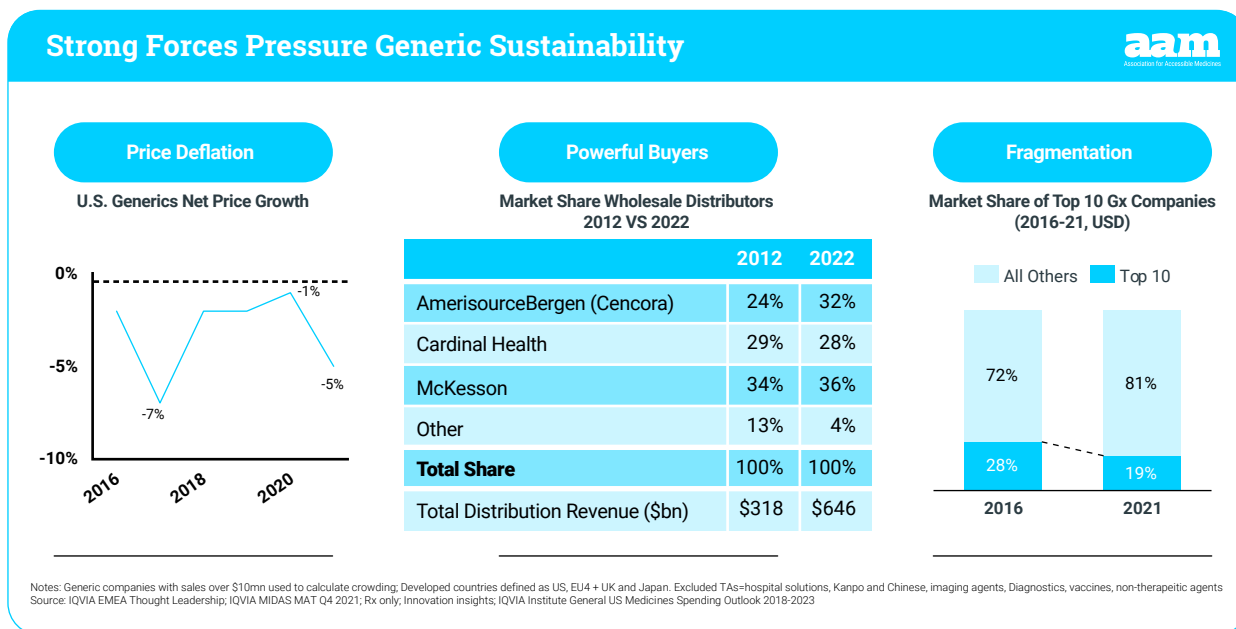
18 Hunter, E. (July 2023). Pharmacy Times. "Akorn Bankruptcy, Shortages Are Disrupting Patient Access to Generic Medications"

The Causes

The above challenges are caused by a combination of market abuses and legislative/regulatory mistakes.

Market Consolidation

Three hospital/clinic group purchasing organizations (GPOs) control roughly 80 percent of all generic medicine purchasing for hospitals/clinics¹⁹. In the retail market, three purchasing consortiums (wholesaler/retail chain combinations) collectively control 90 percent of the retail prescription market²⁰. Fewer buyers means fewer markets for the more than 200 generic drug manufacturers in the U.S.



This consolidation allows these entities to extract below-competitive prices and onerous contract terms that make continued production of low-margin products increasingly challenging

Delayed Entry / Patent Thickets

Ongoing patent litigation and large patent estates on brand drugs frequently delay generic and biosimilar medicines from coming to market. The patent estates on biologics such as Humira®, for example, have been extensively documented. Although the original compound patent on Humira® expired in 2016, AbbVie obtained over 160 patents on the product, many of those acquired years after its original FDA approval, which do not expire until 2037. The recent entry of biosimilar versions of Humira® was possible only through pro-competitive settlement agreements. While biosimilars can still obtain FDA approval, the threat of patent infringement damages represents a major deterrent from promptly entering the market.

Similarly, under Hatch-Waxman, a generic can obtain final approval as soon as the thirty-month stay of regulatory approval expires. But that does not end patent disputes. As a general matter, only a district court proceeding would likely be concluded at the termination of the thirty-month stay, and many key districts specifically time their decision off the thirty-month stay. At that point, the case will still likely be appealed to the Federal Circuit, which has as much as a 50 percent reversal rate on district court proceedings. The threat of substantial damages for an at-risk launch (meaning a launch before the conclusion of Federal Circuit proceedings) discourages early generic market entry.

These timing challenges are compounded by the sheer number of patents that brands hold for brand-

19 Seeley, E. (July 20, 2022). "The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending". Available at: <https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending>
20 Fein, A. (October 2022). "The 2022-23 Economic Report On Pharmaceutical Wholesalers And Specialty Distributors". Available at: https://drugchannelsinstitute.com/products/industry_report/wholesale/

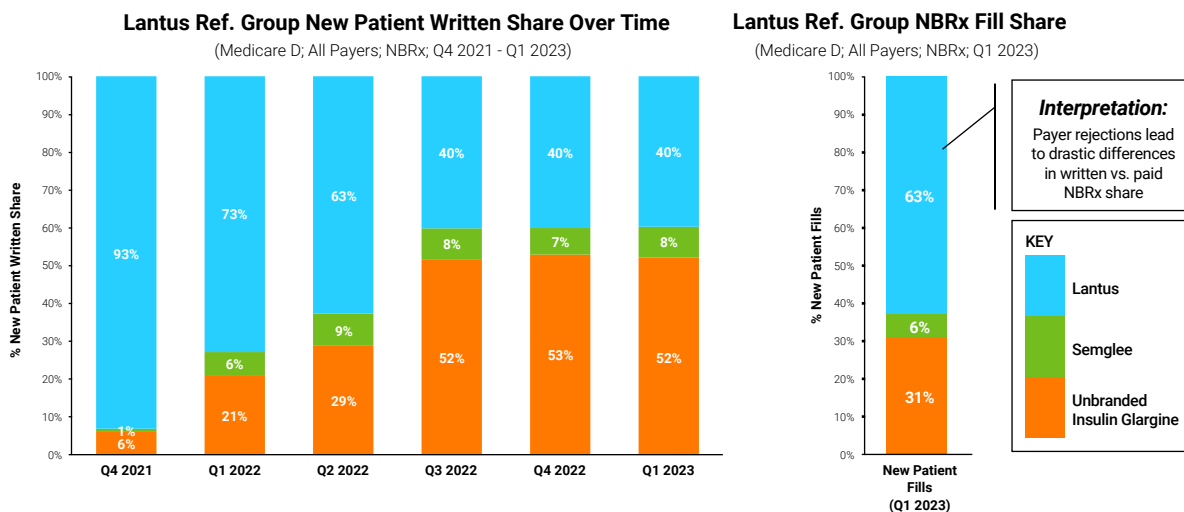
name drugs. To prevail in patent infringement litigation, a generic or biosimilar manufacturer must invalidate or show that each claim in each asserted patent is infringed. In other words, a generic or biosimilar manufacturer challenging 50 asserted patents with 10 asserted claims each would need to go 500-for-500 to prevail in litigation and be able to bring its lower-cost medicine to market. This can make litigation economically infeasible and delay patient access to generic or biosimilar medicines.

Slower Adoption / Rebate Traps

Slower adoption and lower efficiency rates for new generics is driven in part by coverage decisions by Medicare and commercial health plans and PBMs. These highly-consolidated entities profit from rebates on high-priced brand drugs, even though patients would save through lower-cost generics or biosimilars. For the 2021 Medicare Part D plan year, on average, only 21 percent of first generics that launched in 2020 were covered by plan formularies. It appears to take nearly three years before first generics are covered on more than half of Medicare Part D formularies. These delays and lack of coverage restrict patient access to lower-cost generics, denying patients savings in favor of unnecessarily high cost-sharing for brand medications, even though lower-cost alternatives are available.

And although some formularies have begun to cover biosimilars such as adalimumab (Humira®) or insulin, they often do so only by placing the biosimilar on parity with the brand, which provides patients no reason to switch to a lower-cost biosimilar and effectively serves to maintain brand market share.

Unbranded biosimilar insulin glargine accounts for more than half of new patient written share in Medicare plans, but access restrictions limit filled NBRx share



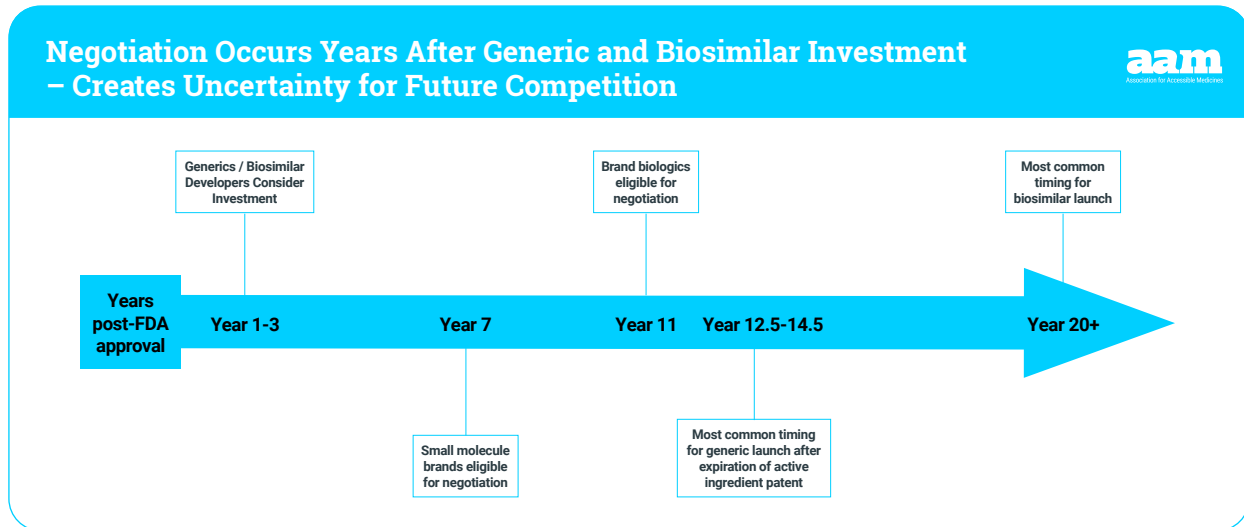
*Note Durable indicates a 30-day look-forward period following a claims initial adjudication to track any changes in status. Analysis performed by IQVIA on behalf of the Biosimilars Council using public and proprietary pharmacy claims information. Data used includes IQVIA Longitudinal Access and Adjudication Data (LAAD) from Jan. 2021-March 2023; analysis conducted by IQVIA, US Market Access Strategy Consulting and Analytics, June 2023. All conclusions represent the view of the Biosimilars Council.

IRA Creates New Uncertainty for Future Generic & Biosimilar Investments

Compounding the above challenges, future investments in new generics or biosimilars are clouded by uncertainty created by the price negotiation provisions of the Inflation Reduction Act (IRA). Under the IRA, the Department of Health and Human Services (HHS) is required to set prices for between 10 and 20 drugs per year. But the IRA provided no clarity on what the negotiated price should be, and set the timing of this process for years after a generic or biosimilar manufacturer faces the decision to commit as much as several hundred million dollars to develop a generic or biosimilar.

The IRA creates significant uncertainty for generic manufacturers unable to accurately forecast which products they should develop because the brand drugs subject to negotiation, and the price at which they might be set, is unclear.

Generic and biosimilar companies undertake extensive market analysis, engage in extremely costly patent litigation, and participate in a complex FDA approval process, making key decisions years in advance of launch. The IRA framework significantly increases the risks and uncertainty of those decisions.²¹



The Solution

As is often the case, no single action created this crisis, and no single solution will resolve it. Rather, policymakers must redouble efforts to encourage generic and biosimilar competition through approval, coverage and reimbursement policies.

Address Prices

Despite growing awareness of the need to “pay more” for generics, solutions have been few. Rather than a complete redesign of the nation’s system for reimbursement of generic drugs, it would be more efficient and effective to target three areas of government policy that harm low-priced generics.

1. Medicaid Generic Drug Inflation Program

In the Medicaid program, generics are subject to an inflation penalty under the Medicaid Drug Rebate Program (MDRP) even when they do not increase their price, as their average manufacturer’s price (AMP) can fluctuate due to factors outside a manufacturer’s control. Generic manufacturers operate in highly competitive markets; and, unlike brands, generic average prices can vary significantly from quarter to quarter as a result of changes in customer mix or seasonal purchasing patterns. This means that these penalties, in addition to being financially onerous, are highly unpredictable. Thus many generic manufacturers are paying rebates for changes in average price even when they did not take a price increase. These are rebates that manufacturers can neither control nor plan for, but they make continued production of low-cost products financially challenging.

²¹ Further, by rewarding a brand drug with a “maximum” price of 40 percent of its original average manufacturer’s price (AMP), IRA could create an incentive for patent abuse by brand manufacturers. Put simply, any brand manufacturer would jump at the chance to have 100 percent of the market at a 60 percent discount instead of competition from generics—competition that reduces their market share by more than 90 percent. All a brand drug maker needs to do is keep seeking new patents, stacking them into a fortress against competition—a practice that has already been long deployed to delay generic entry.

In 2022, the IRA created a separate inflation-based rebate for both brand drugs and generics, but tailored the language to address several unique aspects of the generic market. **Congress should amend the Medicaid inflation penalty consistent with the approach included in the IRA.** This modification would limit such rebates to single-source generics with average annual costs exceeding \$100 per patient. It would hold manufacturers accountable for price increases within their control, while granting the Centers for Medicare and Medicaid Services (CMS) discretion to waive inflation penalties for drugs that are in shortage or at risk of shortage.

2. 340B

The 340B Drug Pricing Program allows certain covered entities (CEs) to purchase covered outpatient drugs at a discount. The discounted “ceiling price” at which the drug may be sold to a CE is the AMP minus the MDRP Unit Rebate Amount (URA). If the calculation results in a price less than \$0.01, the ceiling price is set at \$0.01, known as “penny pricing.” The program obligates the manufacturer to sell products to CEs—which accounted for almost \$44 billion in drug purchases in 2021—for \$0.01²². The net result of these policies further compounds price erosion in the generics markets²³. These discounts also create a payment distortion in which generic manufacturers—operating on razor-thin margins and comprising the least expensive piece of a patient’s care—are asked to subsidize other healthcare services.

Policymakers should amend the 340B program to provide that generics be available to CEs at the AMP. This would ensure that providers continue to have access to generics at a low price while increasing the payment rate for generic manufacturers.

3. State Drug Pricing Initiatives

In recent years, multiple states have responded to news of drug price increases by enacting new restrictions on manufacturers. Ironically, the burden of many of these efforts has fallen on generics. This could be through the creation of new price reporting mandates, upper payment limits, or even the creation of new state-sponsored manufacturing. But because these restrictions are often based on percentage increases, the laws ignore the brand drugs that are driving drug spending and instead focus on generics (given that a \$0.01 increase on a \$0.10 pill far exceeds inflation). These laws create, at best, costly new reporting burdens for generic manufacturers, ignore the causes of high drug prices, and singularly (and severely) penalize generic manufacturers²⁴. **State policymakers should focus on proposals that encourage utilization of lower-cost generic and biosimilar medicines as a critical and effective tool in managing spending.**

Ensure Timely Access to Generic & Biosimilar Medicines

As noted above, large patent estates substantially impede patient access to lower-cost generic and biosimilar medicines. **Congress should ensure that generic and biosimilar companies can continue to enter into pro-competitive, pro-patient patent settlement agreements that expedite generic and biosimilar entry.** These patent settlements have led to generic drugs being introduced, on average, 81 months (6.75 years) prior to patent expiry²⁵. Proposals that would limit or severely restrict patent settlements would result in fewer generic and biosimilar application filings, fewer patent challenges, and higher drug prices.

22 Health Resources and Services Administration. “2021 340B Covered Entity Purchases | HRSA” (August 2022). Available at: <https://www.hrsa.gov/opa/updates/2021-340b-covered-entity-purchases>

23 Association for Accessible Medicines. “The U.S. Generic & Biosimilar Medicines Savings Report: September 2022.” (2022). Available at: [AAM-2022-Generics-Biosimilar-Medicines-Savings-Report.pdf](https://www.aam-2022-generic-biosimilar-medicines-savings-report.pdf)

24 AAM v. Ellison, Case No. 23-cv-2024, Dkt No. 42 at 19 (D. Minn. 2023) (“[I]t is far from clear how much of this harm the Act would prevent, given that it does not regulate price increases by anyone in the supply chain but manufacturers, and given that it does not regulate the price charged to Minnesota consumers.”).

25 See IMS Institute for Healthcare Informatics, (June 2013), Impact of Patent Settlements on Drug Costs: Estimation of Savings.

Address IRA Uncertainty

Even as the Biden Administration continues its work to implement the price negotiation provisions of IRA, there are important changes that could protect generic and biosimilar competition and position negotiation as a fallback to be used in the absence of generics or biosimilars. **Congress should account for the reality of timing for generic and biosimilar entry, which would: 1) prevent brand gamesmanship that delays generic/biosimilar entry; and 2) provide greater clarity for the price-setting process.**

Ensure Rapid Adoption

Finally, while IRA made some changes to Medicare to encourage plan adoption of lower-cost medicines, Medicare's design nonetheless continues to reward PBMs for preferring high-cost brand drugs with rebates over generics or biosimilars. **Congress should ensure rapid coverage of lower-cost generics and biosimilars and remove PBM incentives for use of higher list-price brand drugs.** Such policies should also be applied to the commercial market to prevent continued PBM preferences for products with high rebates and fees.

Policy Recommendations

Address Prices

Medicaid Generic Drug Inflation Program

Congress should amend the Medicaid inflation penalty consistent with the approach included in the IRA

340B

Policymakers should amend the 340B program to provide that generics be available to CEs at the AMP.

State Drug Pricing Initiatives

State policymakers should focus on proposals that encourage utilization of lower-cost generic and biosimilar medicines as a critical and effective tool in managing spending.

Ensure Timely Access to Generic & Biosimilar Medicines

Congress should ensure that generic and biosimilar companies can continue to enter into pro-competitive, pro-patient patent settlement agreements that expedite generic and biosimilar entry.

Address IRA Uncertainty

Congress should account for the reality of timing for generic and biosimilar entry, which would: 1) prevent brand gamesmanship that delays generic/biosimilar entry; and 2) provide greater clarity for the price-setting process.

Ensure Rapid Adoption

Congress should ensure rapid coverage of lower-cost generics and biosimilars and remove PBM incentives for use of higher list-price brand drugs.

Conclusion

Generic and biosimilar medicines are the backbone of accessible care for America's patients. Policymakers have a unique opportunity to preserve and enhance generic and biosimilar competition and sustainability, safeguarding and stabilizing not only future savings, but future care.



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